WEARABLE WIRELESS CONTINUOUS VITAL SIGNS MONITORING ON THE GENERAL WARD

A TECHNOLOGICAL INNOVATION IN NURSING

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Wearable wireless continuous vital signs monitoring on the general ward

A technological innovation in nursing

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(met een samenvatting in het Nederlands)

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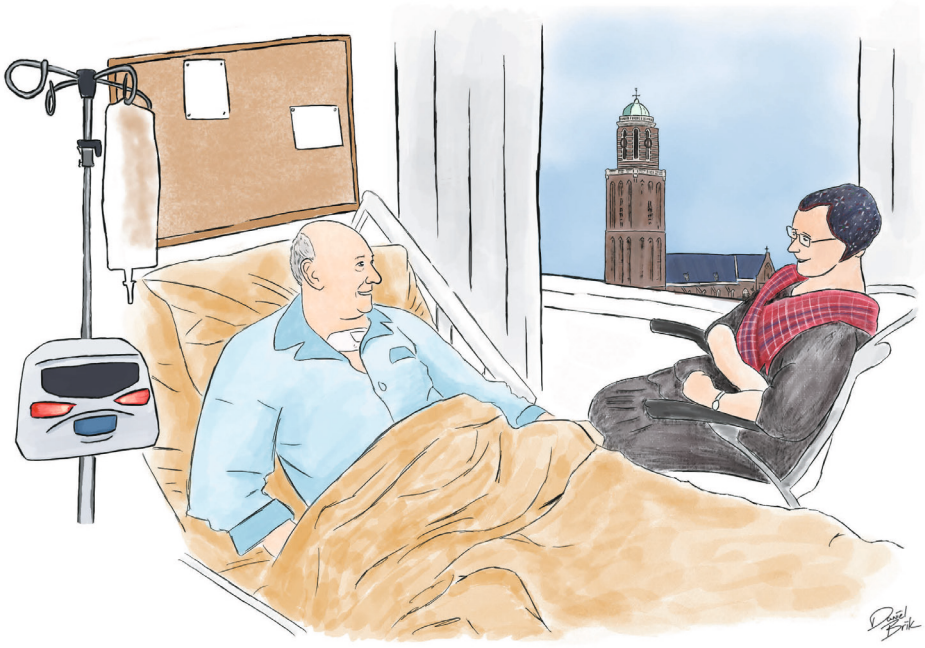
‘Not everything that counts can be counted,
and not everything that can be counted counts.’

William Bruce Cameron



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1

GENERAL INTRODUCTION

Hospitalised patients are at risk of complications and adverse events during their stay. Most patients who experience adverse events, such as in-hospital cardiac arrest, unplanned intensive care unit (ICU) admission and mortality, exhibit changes in physiological signs for hours preceding these events,[1–6] a situation referred to as clinical deterioration.[7,8] Therefore, monitoring, timely recognition of clinical deterioration and treatment is critical.[7,9,10] Late detection or missed deterioration, often referred to as failure to rescue (FTR), increases the risk of mortality, unplanned ICU admission and prolonged hospital stay.[8,11]

Following the Institute of Healthcare Improvement's '100,000 lives' campaign in the United States, setting a goal of saving 100,000 lives of patients in hospitals through safety improvements, the concept of Rapid Response Systems (RRSs) was introduced in 2005 to improve recognition and response to clinically deteriorating patients outside of ICUs.[12,13] This system comprises an 'afferent limb' and ' efferent limb'.[11,12] In the afferent limb, general ward nurses use 'track-and-trigger' systems to identify patients at risk of clinical deterioration and to alert the efferent limb promptly. Here, the attending physician or rapid response team (RRT), usually consisting of an ICU or emergency department physician and critical care nurse(s), responds to calls from the general ward when (specialised) help is needed.[13–15]

As track-and-trigger system, Early Warning Scores (EWS) are widely used in general wards to support nurses in detecting clinical deterioration and promote identifying patients at risk of clinical deterioration.[16,17] The EWS is an aggregated score that includes objective parameters, such as vital signs and level of consciousness, and a subjective parameter, 'nurses' worry'. The EWS should be calculated at predetermined intervals, typically once every 8 to 12 h. Based on current EWS values and recent changes, nurses can trigger responses to the afferent limb according to a local hospital protocol.[18,19]

The EWS can predict adverse patient outcomes, such as cardiopulmonary arrest, unplanned ICU admission or unexpected death.[17,20–23] In addition, EWS are user-friendly and provide a common language for healthcare providers across different specialities.[20] Despite the strengths of the EWS, local implementation varies and missed or late detection of clinical deterioration still occurs, leading to FTR events.[24–27]

Several limitations of EWS may account for this. First, EWS are generic tools, and disease and population differences may influence efficacy.[20,28] For example, the EWS detects the probability of cardiac arrest more accurately in younger patients than in elderly patients.[29] Second, poor compliance with EWS protocols has been mentioned as a limitation in several studies.[1,18,26,30–32] Finally, a major limitation of the EWS is its

intermittent nature.[20] Measurements are performed manually and intermittently, and the predefined intervals make it possible to miss the patient's deterioration between those intermittent measurements.[33] The intervals of these measurements are typically only once every 8-h shift or even longer, which can result in missing the early signs of deterioration and FTR events, especially at night.[33–35]

Although increasing the frequency of patient observation and vital sign measurements by nurses seems a logical step to improve safety, several challenges facing healthcare today make this infeasible. The main reason is the ongoing growing nursing shortage, estimated to reach a demand of 12.9 million nurses in 2035 globally.[36,37] This shortage is caused by multiple factors, such as the retirement of current nurses, the decrease in the number of new nurses, and the failure of retaining existing nurses, which results in a disproportionate number of existing and new nurses to the number of nurses needed to meet patient needs.[37–45] This is all the more important given the ever-growing demand for care due to the increasing population of elderly who are also live longer, the so called 'double ageing'.[46]

In 2017, around 962 million people worldwide were 60 or over, which is 13% of the total population, but this will continue to grow to nearly 25% in 2050.[47] In the Netherlands, in 2040, more than a quarter of the Dutch population will comprise people 65 years or over, and the oldest group is increasing.[48] Due to the ageing population, chronic illness and multimorbidity will rise, and most of these older people will require care sooner or later. Thus, healthcare costs will rise as care consumption increases.[48] Already in 2016, almost half of the healthcare costs were attributed to caring for older people in the Netherlands.[49]

One possible solution to improve safety in hospital wards in the face of increasing nursing shortages is the implementation of promising, innovative technological solutions to enhance the timely detection of clinical deterioration.[48,50] Wearable continuous monitoring of vital signs (CVSM) could contribute to earlier recognition of the deteriorating patient, especially in 'low-care' environments, such as the general ward, and perhaps even after (early) discharge home.[51–55] Such systems may facilitate automated notification of clinical deterioration, trigger early therapeutic interventions and reduce the need for patient rescue events or unplanned ICU transfers.[56,57] In addition, better insight into patients' vital sign trends instead of spot-check measurements may allow the detection of abnormalities at an early stage.[58–60] However, ICU-grade monitors for patients at the general ward and home hinder mobilisation, resulting in potentially more functional decline. Thus, they are infeasible for patients in the general ward. Therefore, wireless and wearable devices intended for CVSM are more suitable and increasingly available.[54,60] These devices can accurately

record vital signs, such as the heart rate, respiratory rate and temperature and can detect clinical deterioration.

Provided that CVSM is well integrated into the nurses' clinical workflow, at least in theory, it might result in a better quality of care. Although the technical validity of the current technologies seems acceptable, successful full-scale implementation and rigorous evaluation of these devices in clinical practice are still lacking.[60] Initial studies with CVSM have demonstrated variable results, and it has proved challenging to implement them in nursing practice properly. The main reasons for poor implementation are incomplete integration into clinical workflows, lack of integration with hospital electronic health records (EHRs) and the low acceptability by nurses.[52] Nurses play a crucial role in the interpretation of vital signs, detection of abnormalities and adequate follow-up; thus, any benefits of the technology for patients are critically dependent on the acceptability by nurses and tight integration into the nursing workflow.[61,62] How wearable CVSM using can best be integrated into existing workflows and hospital IT systems is currently unknown. The main hypothesis underlying the research questions in this thesis is that wearable CVSM for early detection of clinical deterioration could enhance the quality of care and patient safety by improving patient outcomes and satisfaction, supports nursing work and reducing healthcare costs.

WEARABLE CONTINUOUS VITAL SIGN MONITORING AS A COMPLEX INTERVENTION

CVSM by wearable, wireless devices in general wards can be defined as a complex intervention because it is multifaceted, with many interacting components within the intervention, the difficulty of behaviours required by those delivering or receiving the intervention, and the number and variability of the outcomes.[63,64] Two key questions can be asked when evaluating a complex intervention: 'Is it effective in everyday practice?' and 'What are the active components, and how are they exerting their effect?'.[65] Therefore, the development and evaluation process of complex interventions includes the following four phases that do not necessarily follow a linear sequence: development, feasibility, evaluation and implementation (Figure 1).

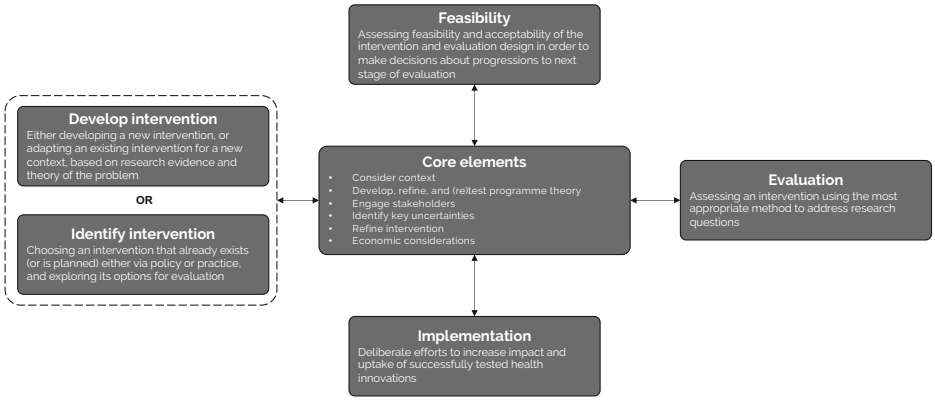
In the development phase, a theoretical understanding of the likely change process is developed by drawing on existing evidence and theory. Existing evidence is identified regarding what is already known about similar interventions, including the methods used to evaluate them. Moreover, modelling processes and outcomes can provide vital information about the design for the intervention and evaluation.

In the feasibility phase, the key uncertainties identified during the intervention development are examined, and the processes and clinical outcomes related to the evaluation design are assessed. This approach is important because evaluations are often undermined by problems of acceptability, compliance, intervention delivery, recruitment and retention, and smaller-than-expected effect sizes that could have been predicted by thorough piloting.[66]

The evaluation phase exceeds an exclusive focus on obtaining unbiased estimates of the effectiveness on clinical outcomes[67] to a broader range of answerable research questions about what other impact it has, theorising how it works, considering how it interacts with the context in which it is implemented, how it contributes to system change, and how the evidence can support decision-making in the real world.[68] Therefore, expanding standard designs of randomised controlled trials is crucial to improve the adequate evaluation of complex intervention research. Adaptive designs include sequential multiple-assignment randomised trials, *n*-of-1 trials, and hybrid effectiveness-implementation designs.[69–72] Thus, a purely quantitative approach using an experimental design without additional elements, such as process evaluation, is rarely appropriate for complex intervention research, where qualitative and mixed methods may be needed to answer questions beyond those on effectiveness.[64]

In the implementation phase, questions about implementation-specific outcomes (e.g. the reach or uptake of the intervention), the implementation strategy and contextual factors that support or hinder the implementation are critical. These questions can be asked throughout the phases of intervention development, feasibility testing and process and outcome evaluation.

Figure 1: The Medical Research Council Framework for developing and evaluating complex interventions[63]



AIM AND OUTLINE OF THIS THESIS

The general aim of this thesis is to gain a better understanding of the following:

1. core elements of CVSM;
2. critical aspects of the implementation process; and
3. potential beneficial effects of CVSM on patient care in general wards in the prelude to further development and future implementations

Therefore, the research objectives of this thesis are as follows:

- develop a CVSM system (consisting of CVSM technology and corresponding work processes) for the general ward;
- determine the feasibility of this CVSM system in general wards;
- gain insight into the perspectives of healthcare professionals about CVSM systems in general wards;
- develop and evaluate a scaled implementation process for CVSM systems in general wards; and
- assess the potential impact of a CVSM system on patient care.

For all of the above, we have focused specifically on the nurses' perspective and role, as they are the primary healthcare professionals at the bedside observing clinical deterioration.

This thesis is divided into chapters to achieve these objectives. **Chapter 2** provides an overview of the current evidence for CVSM using wearable sensors in a hospital using a systematic literature review. In total, 27 studies were included, and the evaluated outcomes were validation, feasibility, clinical outcomes and costs. **Chapter 3** presents a qualitative study to explore nurses' and surgeons' expectations of the potential effectiveness and impact of wearable CVSM in patients admitted to the general ward after an esophagectomy. In total, 12 semi-structured interviews were conducted at three oesophageal cancer centres in the Netherlands. **Chapter 4** details an observational cohort study to determine feasibility regarding the acceptability and fidelity of a CVSM system in a general surgical ward over a three-month period. System fidelity was measured by analysing the monitoring data. Acceptability by patients and nurses was assessed using questionnaires. **Chapter 5** explores nurses' experiences with the CVSM system during the feasibility study using 12 semi-structured interviews to provide insight into the capability, opportunity and motivation of nurses. In **Chapter 6**, insights were integrated and evaluated in an explanatory sequential mixed-method

study of a general surgical ward to determine the feasibility of a CVSM system without using alarms, exclusively relying on interval trend monitoring for three months. **Chapter 7** describes the results of a mixed-method study to 1) systematically evaluate the process of implementation of CVSM system in an internal medicine and surgical nursing ward and 2) determine any differences between wards. **Chapter 8** presents the results of a before-after study to explore 1) the effect of a CVSM system in the general ward on the length of the hospital stay in major abdominal surgery patients and 2) the effects of a CVSM system on a broad range of patient outcomes and within subgroups for colorectal and hepatobiliary surgery. Last, **Chapter 9** provides a general discussion and reflection on the key findings, methodology, future directions and implications for clinical practice for CVSM systems in the general ward.

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2

CURRENT EVIDENCE FOR CONTINUOUS VITAL SIGNS MONITORING BY WEARABLE WIRELESS DEVICES IN HOSPITALIZED ADULTS: SYSTEMATIC REVIEW

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ABSTRACT

Background

Continuous monitoring of vital signs by using wearable wireless devices may allow for timely detection of clinical deterioration in patients in general wards in comparison to detection by standard intermittent vital signs measurements. A large number of studies on many different wearable devices have been reported in recent years, but a systematic review is not yet available to date.

Objective

The aim of this study was to provide a systematic review for health care professionals regarding the current evidence about the validation, feasibility, clinical outcomes, and costs of wearable wireless devices for continuous monitoring of vital signs.

Methods

A systematic and comprehensive search was performed using PubMed/MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials from January 2009 to September 2019 for studies that evaluated wearable wireless devices for continuous monitoring of vital signs in adults. Outcomes were structured by validation, feasibility, clinical outcomes, and costs. Risk of bias was determined by using the Mixed Methods Appraisal Tool, quality assessment of diagnostic accuracy studies 2nd edition, or quality of health economic studies tool.

Results

In this review, 27 studies evaluating 13 different wearable wireless devices were included. These studies predominantly evaluated the validation or the feasibility outcomes of these devices. Only a few studies reported the clinical outcomes with these devices and they did not report a significantly better clinical outcome than the standard tools used for measuring vital signs. Cost outcomes were not reported in any study. The quality of the included studies was predominantly rated as low or moderate.

Conclusions

Wearable wireless continuous monitoring devices are mostly still in the clinical validation and feasibility testing phases. To date, there are no high quality large well-controlled studies of wearable wireless devices available that show a significant clinical benefit or cost-effectiveness. Such studies are needed to help health care professionals and administrators in their decision making regarding implementation of these devices on a large scale in clinical practice or in-home monitoring.

INTRODUCTION

Continuous monitoring of vital signs of inpatients is a common practice in intensive care, medium care, operation theatre, and recovery ward settings.[1] The goal of continuous vital signs monitoring in these settings is early detection of the clinical deterioration, thereby allowing timely intervention.[2,3] However, once patients are discharged to the general ward, vital signs are only monitored intermittently, often just once or twice daily. Early warning scores have been implemented to guide clinical interpretation, but this value is limited by the intermittent nature of the measurements.[4-6] Serious unexpected adverse events do occur regularly in general wards, especially in high-risk postsurgical or elderly frail patients.[7-13] This incidence of adverse events is expected to increase owing to the aging population, increasing complexity of in-hospital care, increasing pressure to limit health care costs, and increasing shortage of nursing staff. These adverse events may be prevented or mitigated if continuous monitoring of vital signs would be available to facilitate early detection of the deteriorating trends in vital signs, thereby allowing timely interventions.[14-16] An important advantage of continuous monitoring may be the insight in the trends, which can be much more informative and predictive than single deviating values.[17-19]

Recent studies have shown that continuous monitoring in combination with automated alerts in case of deterioration improves patient outcomes.[17,20-23] However, for continuous monitoring to be applicable in general wards, it should not lead to decreased mobility of the patient. Therefore, continuous monitoring devices should preferably be portable, wireless, and wearable on an easily accessible body part.[18,24] Such wearable devices also have the potential to be used for continuous monitoring of the vital signs of the patients at home or in rehabilitation centers, thereby possibly leading to reduced length of hospital stay and preventing unplanned readmissions.[25]

The technology of wearable wireless sensors for vital signs monitoring is advancing rapidly.[26] Many manufacturers are now developing wearable sensors with different capabilities and different underlying technical specifications and algorithms.[27] The reliability and the accuracy of these devices have often only been demonstrated in healthy volunteers instead of in patients with deviating values.[17] In addition, the scientific evidence regarding the feasibility, effectiveness, and costs of these wearable sensors in clinical practice is still very limited.[17,28,29] Previous reviews on continuous monitoring of vital signs did not focus on wearable wireless devices but rather on conventional nonambulant monitoring.[14] The aim of this study was to systematically review the current evidence on wearable wireless devices for continuous vital signs monitoring by providing a thorough overview of the currently available studies.

METHODS

Design

We conducted a systematic review of the literature by following the guidelines as outlined in the Cochrane Handbook for Systematic Reviews of Interventions version 6.0 and reported according the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[30,31]

Eligibility Criteria

Studies were considered eligible for inclusion when they met the following criteria: consisted of participants older than 18 years; evaluated a continuous monitoring device that measured vital signs such as heart rate (HR), respiratory rate (RR), blood pressure (BP), temperature, and blood oxygen saturation (SpO2)[16]; used a device that measured ≥2 vital signs; used a device that was wireless and wearable; and published after 2009. This timeframe was chosen to prevent the inclusion of papers on outdated technology. Studies were excluded when the device was not wearable by the patient and the device had no formal approval as a medical device through the Conformité Européenne (CE) mark or Food and Drug Administration (FDA) clearance or both. Furthermore, conference abstracts, review articles, letters, editorials, articles without full texts, and non-English or non-Dutch articles were excluded.

The outcomes of interest were as follows: validation (eg, sensitivity, specificity, limits of agreement [LoA]), feasibility (eg, acceptability, user experiences, system fidelity), clinical outcomes (eg, mortality, length of stay, fail-to-rescue [FTR], intensive care unit [ICU] admission), and costs (eg, cost-minimization, cost-benefit, cost-effectiveness, or cost-utility outcomes).[25,32-35]

For validation studies, the prespecified clinically relevant mean difference and LoA were 10±10 beats per minute for HR, 3±3 breaths per minute for RR, 0.5°C±1.0°C for temperature, 10±20 mmHg for systolic BP, and 3%±5% for SpO2. The guidelines for the acceptable mean differences and LoA for continuous monitoring of vital signs are unfortunately lacking.

Search Strategy

A systematic literature search of PubMed/MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials was performed with the last search run on September 6, 2019. In addition, the references of the retrieved studies were manually screened to obtain additional relevant studies. The following keywords were used: vital signs, clinical deterioration, and wireless continuous monitoring. Keywords on

outcomes were based on terms about validation, feasibility, clinical outcomes, and cost outcomes. The full search strategy is available in Appendix 1. The search string was audited by a clinical librarian and adapted for the individual databases and interfaces as needed. The information about the specifications of the wearable devices was obtained from the manuals and fact sheets of the manufacturers.

Study Selection

All identified references were checked for duplicates and consolidated in the reference manager software (*Mendeley 1.19.5*). Titles and abstracts of references were independently screened by 2 researchers against the inclusion and exclusion criteria. Full-text articles of references that matched the inclusion criteria were read independently to determine eligibility. Disagreements were resolved by discussion between the 2 review authors; if no agreement could be reached, the third author was consulted.

Data Collection Process

A data extraction sheet was developed based on the Cochrane Consumers and Communication review group's data extraction template and was pilot tested using 5 randomly selected included studies and refined accordingly.[31] One review author extracted the data from the included studies and the second author checked the extracted data. Disagreements were resolved by discussion between the 2 review authors; if no agreement could be reached, the third author was consulted.

Data Extraction and Synthesis

The following data were extracted for each study: (1) first author, country, year of publishing, aim, design, setting, patient population, sample size, and conflicts of interest; (2) manufacturer and name of the device and type of vital signs measured by the device; and (3) outcomes of the studies divided in previously defined categories: validation, feasibility, clinical, and cost outcomes. The study outcomes were presented for each device.

Risk of Bias of Individual Studies

For assessing the risk of bias of individual studies, 2 authors independently appraised each study critically. Disagreements in the quality assessment between the authors were solved by discussion until consensus was reached. Owing to the large diversity of the included study designs, 3 different instruments were used. The 2018 version of the Mixed Methods Appraisal Tool (MMAT) was utilized for 5 study designs: qualitative, quantitative randomized controlled, quantitative nonrandomized, quantitative descriptive, and mixed methods.[36] Each category contained 5 criteria with

the score range from 0 to 5 of the criteria met. For mixed methods studies, scores were calculated as the lowest score from among the 3 relevant designs (quantitative, qualitative, and mixed methods). A score of 0 to 2 was considered as low, a score of 3 and 4 was considered as moderate, and a score of 5 was considered as high. For diagnostic accuracy study designs, the quality assessment of diagnostic accuracy studies 2nd edition (QUADAS-2) was utilized to assess the risk of bias.[37] QUADAS-2 consists of 4 domains: patient selection, index test, reference standard, and flow and timing. All domains were assessed for the potential for risk of bias and the first 3 domains, that is, patient selection, index test, and reference standard were assessed for concerns regarding applicability. For economic evaluation studies, the quality of health economic studies (QHES) tool was utilized to assess the quality.[38] The QHES instrument is a validated method for assessing the quality of health economic analyses. It consists of 16 items, each with specific weight values ranging from 1 to 9. Each score is multiplied by the weight to produce a total score, with a maximum score of 100.

RESULTS

Study Selection

We identified 5403 potentially relevant studies in our literature search after duplicate removal, of which 5 studies were accessed from the reference list of the potentially relevant studies. Screening of titles and abstracts resulted in 198 studies, which were read full text. Eventually, 27 studies that met the eligibility criteria were included.[39-65] A PRISMA flowchart of the search is presented in Figure 1.

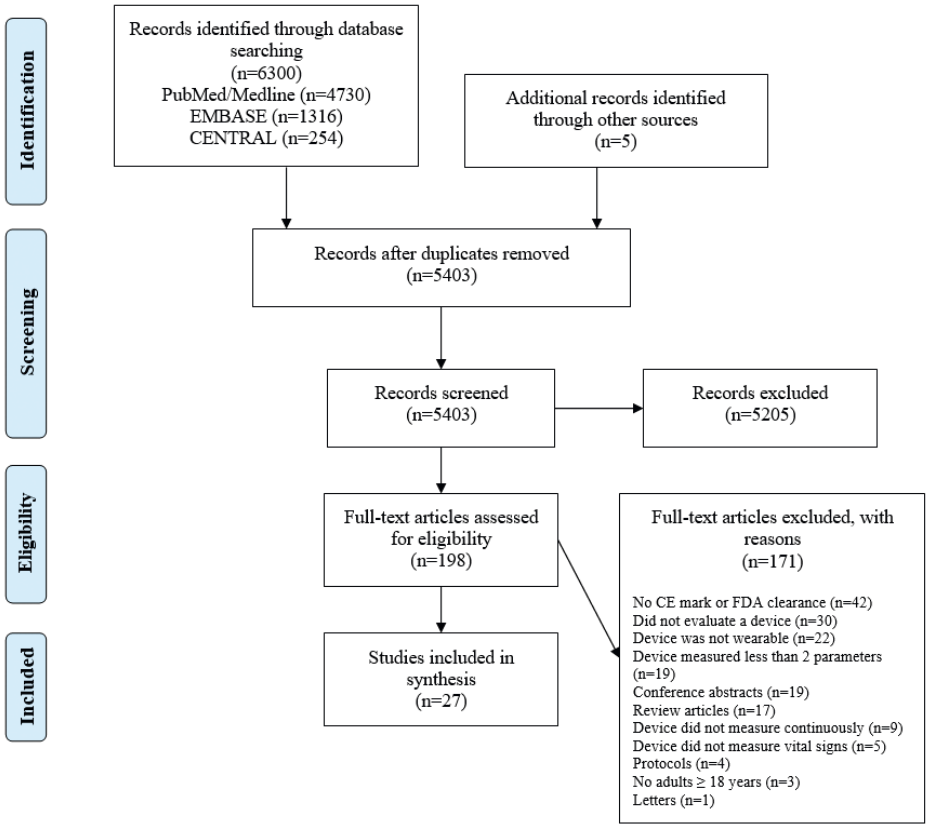
Study Characteristics

In this study, 13 different devices of 10 manufacturers were studied in 2717 subjects (median 43, range 6-736). Subjects were healthy patients, trauma patients, surgical patients, or neurological/neurosurgical patients (Table 1). The 13 devices were as follows: ViSi Mobile, SensiumVitals, HealthPatch MD, VitalPatch, Wireless Vital Signs Monitor (WVSM) device, MiniMedic, Zephyr BioPatch, Biosensor, IntelliVue Cableless Measurement Solution, Wavelet Wristband, Proteus patch, Alarm Management System, and EQ02 Lifemonitor (Table 2).

Of the 27 included studies, 15 were from the United States and the remaining were from the United Kingdom (N=6), the Netherlands (N=2), Canada (N=1), China (N=1), Australia (N=1), and Austria (N=1). Among these, 13 were validation studies, 6 were cohort studies, 2 were case-control studies, 3 were mixed methods studies, 1 was a qualitative study, and 2 were pilot randomized controlled trials. The reported outcomes

were validation (N=15), feasibility (N=15), and clinical outcomes (N=6; Table 3). Seventeen studies declared that they had no conflicts of interest. In 6 studies, one or more authors were employees of the manufacturing company of the studied device. The remaining 4 studies did not declare any possible conflicts of interest (Table 1).

Figure 1. PRISMA flowchart.



PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; CENTRAL: Cochrane Central Register of Controlled Trials; CE: Conformité Européenne; FDA: Food and Drug Administration.

Devices

ViSi Mobile

Five studies (N=1308) have been published about the ViSi Mobile (Sotera Wireless; Table 1).[39,40,51,59,60] This device is worn on the wrist, upper arm, or chest, and it measures HR, RR, BP, SpO2, and skin temperature (Table 2).[66]

Validation outcomes

This device was validated in 1 study, which reported an acceptable mean difference but wide LoA between the device and manual nurse measurements for HR, RR, and BP (Table 4).[59] SpO2 had an acceptable mean difference and LoA.

Feasibility outcomes

Patients reported the wristband as big or heavy. Four studies reported the perceptions of the health care professionals.[39,51,59,60] Nurses mentioned that this device had a short battery life and poor connection but it reported better insight into the vital signs.[59] Both nurses and physicians felt confident about their ability to identify patients at risk of deterioration but were concerned about the accuracy of the device.[39,59] Besides, physicians were positive about the potential of continuous monitoring, as this device provided reassurance to patients and supported interdisciplinary communication between nurses and physicians.[39] Another study stated that 67% of the nurses were positive about the deployment of continuous monitoring in the ward.[51] All nurses were positive that the monitor provided valuable patient data that increased patient safety.[60] However, they had certain reservations, including the potential decrease in the bedside nurse-patient contact, increase in inappropriate rapid response team (RRT) calls, and possible discomfort for patients wearing the device.[39] Two studies reported system fidelity. The system generated 2 to 10 alarms per patient in a day[40,60], of which one study[60] reported that 92% of the nurses indicated that the number of alarms were appropriate. One study showed that 70% of the artefacts, defined as the noncollected parameters, were caused by connection failure and 74% lasted less than 5 minutes.[59]

Clinical outcomes

RRT calls, FTR, unexpected deaths, and ICU transfers were not significantly reduced by continuous monitoring.[40,51] The complication rate was higher in the intermittent monitoring group than in the continuous monitoring group.[51] One study described only 4 alert-initiated interventions in 236 patients.[60] The quality of these studies ranged from low to moderate, as assessed by the MMAT tool, thereby indicating that these studies are subject to bias (Figure 2).

Cost outcomes

None of the studies reported this type of outcome.

SensiumVitals

Five studies (N=371) have been published about the SensiumVitals (Sensium Healthcare; Table 1).[56,61-64] This is a patch device attached to the chest for continuous monitoring of the HR, RR, and axillary temperature (Table 2).[67]

Validation outcomes

This device was validated in 3 studies. Two studies included surgical patients[63,64] and 1 included healthy volunteers.[61] The results were conflicting. The mean difference between the device and reference standard was acceptable for HR and RR (Table 4). For HR, LoA was acceptable in 2 studies and outside acceptable limits for 1 study. For RR, LoA was wide for all studies. One study[64] reported temperatures outside acceptable ranges. Furthermore, RR was frequently rejected by the algorithm owing to the inaccuracy of the measurement.[61,63] However, the results may be biased owing to the high risk of bias at the reference standards and patient selection (Figure 2). In addition, 2 of the 3 studies[61,63] were authored by the employees of the SensiumVitals manufacturing company and one study was also funded by the manufacturer.[61]

Feasibility outcomes

Two studies described the feasibility of this device. One qualitative study showed the patient perceptions.[56] Six themes emerged from the interviews: (1) patients emphasized the importance of nursing contact, (2) patients indicated that they hoped to be disturbed less for night-time observations with the new monitoring system, (3) patients reported high comfort, (4) patients experienced a high sense of security, (5) patients expressed that monitoring could be a solution for the busy nursing staff, and (6) patients expressed reservations about the reliability of the technology such as the data security and system failure. The second study reported that patients were comfortable with the patch and that it enhanced the feeling of safety although 16.4% discontinued the intervention owing to the discomfort before the end of the study.[62]

Clinical outcomes

Only one study reported the clinical outcome. In that study, no statistically significant better clinical outcomes for the patch group were seen, possibly owing to the sample size.[62] Notably, the authors reported that an unacceptable high number of alerts were sent to the nurses before adjusting the alarm thresholds. Since the quality of these studies was rated from low to high by the MMAT tool, possible bias is introduced (Figure 2).

Cost outcomes

None of the studies reported this type of outcome.

VitalPatch and HealthPatch MD

Five studies (N=133) have been published on the VitalPatch and its previous version HealthPatch MD, which is not available anymore (VitalConnect; Table 1).[41-43,65] Of them,

one mixed methods study compared the HealthPatch with the ViSi Mobile.[59] This patch device is applied to the chest and measures HR, RR, and ST (Table 2).[68]

Validation outcomes

This device was validated in 4 studies. For HR, the mean difference was acceptable for all studies and LoA was acceptable for 2 studies (Table 4). The mean difference for RR was acceptable; however, all studies reported LoA outside of the preset acceptable range. One study reported a mean absolute error of less than 3 for HR and 1 for RR.[65] All studies were subject to potential bias at patient selection and the reference standard (Table 4).

Feasibility outcomes

The acceptability of this device was reported as high by the majority of the nurses.[41] However, the exact numbers were not reported. Besides, the health care professionals recommended that it was necessary to gain experience with use of the device in clinical practice.[41] Patients reported that the HealthPatch did not restrict them in daily activities. The fidelity of the system was reported in 2 studies, of which one study reported a loss of data of 6%.[42] They compared several thresholds; 63% of the measurements were performed without data loss greater than 2 minutes. In addition, another study reported that more than 50% of all the artefacts lasted for less than 1 minute, and 43% of them lasted for less than 5 minutes.[59] The reasons for these artefacts were wireless signal connection problems or losing skin contact.

None of the studies reported the clinical and cost outcomes.

Table 1: Study characteristics

Author, year	Country	Study design	Setting	Study population	Sample size (N)	Device	Comparison	Conflicts of interest
Prgomet et al, 2016[39]	Australia	Mixed methods	Single-center hospital	Physicians and nurses of a respiratory and neurosurgery ward	106	ViSi Mobile	None	Not reported
Weller et al, 2017[40]	USA	Case-control	Single-center hospital	Neurological and neurosurgical patients	736	ViSi Mobile	Manual measurements	None declared
Verillo et al, 2018[51]	USA	Before-after	Single-center hospital	Orthopedic and trauma patients	422	ViSi Mobile	None	None declared
Weenk et al, 2017[59]	The Netherlands	Mixed methods	Single-center hospital	Internal and surgical patients	20	ViSi Mobile, HealthPatch	Manual measurements (HR[a], RR[b])	None declared
Watkins et al, 2015[60]	USA	Cohort	2 hospitals	Nurses	24	ViSi Mobile	None	None declared
Downey et al, 2018a[62]	UK	Pilot Randomized control trial	Single-center hospital	General surgical patients	226	SensiumVitals	Manual and intermittent measurements by nurses (HR, RR, temperature)	None declared
Downey et al, 2018b[56]	UK	Qualitative	Single-center hospital	Surgical patients	12	SensiumVitals	None	None declared
Hernandez-Silveira et al, 2015a[63]	UK	Validation study	Single-center hospital	Surgical and comorbid patients	61	SensiumVitals	Philips Intellivue MP30: 3-lead ECG[c] (HR); Microstream Oridion Capnography (RR)	5 authors were employees of the manufacturing company of the device

Table 1: (Continued)

Author, year	Country	Study design	Setting	Study population	Sample size (N)	Device	Comparison	Conflicts of interest
Hernandez-Silveira et al, 2015b[61]	UK	Validation study	Laboratory	Healthy subjects	21	SensiumVitals	Rigel 333 patient simulator (HR, RR), Simman (HR), Philips IntelliVue MP30: 2-lead ECG (HR), capnography (RR)	Study was funded by manufacturer, one author was an employee
Downey et al, 2019[64]	UK	Validation study	Single-center hospital	Major elective surgery patients	51	SensiumVitals	Pulse-oximeter (HR), manually (RR), tympanic thermometer (ST)	None declared
Chan et al, 2013[65]	USA	Validation study	Laboratory	Healthy subjects	25	HealthPatch	Actiheart, Oridion Capnostream	Authors were employees of the manufacturer of the device
Izmailova et al, 2019[41]	USA	Validation study	Laboratory	Healthy subjects	6	HealthPatch	Dinamp device (HR), oral thermometer (ST), manual measurement (RR)	None declared
Breteler et al, 2018[42]	The Netherlands	Validation study	Single-center hospital	Surgical patients	25	HealthPatch	XPREZZON bedside monitor	None declared
Selvaraj et al, 2018[43]	USA	Validation study	Laboratory	Healthy subjects	57	VitalPatch	Bench testing, Capnostream20, (RR), Actiheart device (HR)	Not reported
Liu et al, 2014[69]	USA	Validation study	Prehospital	Trauma patients	305	WVSM[d]	LIFEPAK 12 defibrillator/ monitor	None declared

Table 1: (Continued)

Author, year	Country	Study design	Setting	Study population	Sample size (N)	Device	Comparison	Conflicts of interest
Liu et al, 2015[45]	USA	Cohort	Prehospital	Trauma patients	104	WVSM	None	One author is the CEO[e] of the manufacturing company
Razjouan et al, 2017[46]	USA	Cohort	Single-center hospital	Hematology and oncology patients	35	Zephyr BioPatch	None	None declared
Boatin et al, 2016[47]	USA	Mixed methods	Single-center hospital	Full-term pregnant women and nurses	38	Zephyr BioPatch	Pulse-oximeter (HR), manually (RR)	None declared
Kim et al, 2012[48]	USA	Validation study	Laboratory	Healthy subjects	12	Zephyr BioPatch	12-lead ECG (HR), Model K4 b2, (RR)	None declared
Van Haren et al, 2013[49]	USA	Cohort	Prehospital	Patients transported by the prehospital provider	113	MiniMedic	LIFEPAK, Propaq MD monitor	None declared
Meisozo et al, 2016[50]	USA	Validation study	Single-center hospital	Trauma patients in the intensive care unit	59	MiniMedic	GE Solar 8000M multichannel monitor	Not reported
Dur et al, 2019[52]	USA	Validation study	Laboratory	Healthy subjects	35	Wavelet Wristband	ECG (HR), spirometry sensor (RR), BIOPAC M36	One author was an employee of Wavelet Health
Li et al, 2019[57]	USA	Validition study	Single-center hospital	Emergency department	17	Biosensor	Capnography (RR)	Two authors were employees of Philips and study was funded by Philips
Ordonnel et al, 2019[53]	UK	Cohort	Home	Patients with heart failure	13	Proteus patch	None	None declared

Table 1: (Continued)

Author, year	Country	Study design	Setting	Study population	Sample size (N)	Device	Comparison	Conflicts of interest
Hubner et al, 2015[54]	Austria	Cohort	Single-center hospital	Patients at the emergency department and nurses who provided care	226	IntelliVue Cableless Measurement Solution	None	None declared
Liu et al, 2013[55]	China	Validation study	Laboratory	Healthy subjects	6	Equivital EQ02 Lifemonitor	Polar S810i HR Monitor (HR), Spirometer MLT1000L (RR), MLT422/D TSK probe (Temperature)	Not reported
Paul et al, 2019[58]	Canada	Pilot randomized control trial	Single-center hospital	Mixed surgical patients	250	Covidien Alarm Management System	None	None declared

[a]HR: heart rate. [b]RR: respiratory rate. [c]ECG: electrocardiogram. [d]WVSM: wireless vital signs monitor. [e]CEO: chief executive officer.

Table 2: Device characteristics

Device	Manufacturer	Vital signs	Other parameters	Location	BL[a]	CoTy[b]	CR[c] (meter)	EMR[d]	SoA[e]	D[f]	W[g]	S[h]
ViSi Mobile	Sotera Wireless	HR[i], BP[j], RR[k], SpO_2[l], ST[m]	Body posture, fall detection	Upper arm, chest, wrist	14-16 h	Wi-Fi 802.11 radio	180	✓	✓			Clinic
SensiumVitals	Sensium Healthcare	HR, RR, ST	None	Chest, armpit	5 days	Wi-Fi 802.11 b/g	180	✓	✓	✓	✓	Clinic
HealthPatch MD	VitalConnect	HR, RR, ST	HRV[n], fall detection, step count, body posture, R-R interval, stress level, energy expenditure	Chest	3 days	Bluetooth	max. 10		✓	✓	✓	Clinic, home
VitalPatch	VitalConnect	HR, RR, ST	HRV, steps, body posture, fall detection, activity	Chest	5 days	Bluetooth	max. 10	✓	✓	✓	✓	Clinic, home
Wireless Vital Signs Monitor Device	Athena GTX	HR, BP, RR, SpO_2	None	Upper arm, chest, fingertip	7+ h	Wi-Fi 802.11 b/g	180	N/A[o]	✓		✓	Clinic, home
MiniMedic	Athena GTX	HR, SpO_2, ST	PR[p], PWTT[q], Murphy Factor	Forehead, fingertip	12 h	Zigbee 802.15.4	100	N/A	✓		✓	Clinic, home
Zephyr BioPatch	Medtronic	HR, RR, estimated CT[r]	Activity, body posture	Chest	12-28 h	Zephyr ECHO gateway, Bluetooth 2.1+, 3G	N/A	N/A	N/A		N/A	Clinic

Table 2: (Continued)

Device	Manufacturer	Vital signs	Other parameters	Location	BL[a]	CoTy[b]	CR[c] (meter)	EMR[d]	SoA[e]	D[f]	W[g]	S[h]
Biosensor	Philips	HR, RR, ST	Body posture	Chest	4 days	Bluetooth	Max. 10	✓	✓	✓	✓	Clinic, home
IntelliVue Cableless Measurement Solution	Philips	HR, RR, BP, SpO_2	None	Upper arm, wrist, belly	12-24 h	Short range radio to IntelliVue Guardian Software	<100	✓	✓			Clinic
Wavelet Wristband	Wavelet Health	HR, RR	HRV	Wrist	5 days	Bluetooth	max. 10		N/A		✓	Home
Proteus patch	Proteus Digital Health	HR, RR, ST	None	Upper left chest	7 days	Bluetooth	max. 10	N/A		N/A	✓	Home
EQ02 Lifemonitor	Hidalgo Ltd	HR, RR, ST	ECG[s], accelerometer, body posture, fall detection	Chest with belt	12-48 h	Bluetooth 2.1, 3G, 4G, GPRS[t], CDMA[u]	100	N/A	✓		✓	Clinic, home
Alarm Management System	Covidien	HR, SpO_2	None	Fingertip	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Clinic

[a]BL: battery life. [b]CoTy: connection type. [c]CR: connection range.[d]EMR: electronic medical record. [e]SoA: system of alerts. [f]D: disposable. [g]W: waterproof. [h]S: setting. [i]HR: heart rate. [j]BP: blood pressure. [k]RR: respiratory rate. [l]SpO_2: blood oxygen saturation. [m]ST: skin temperature. [n]HRV: heart rate variability. [o]N/A: not applicable. [p]PR: pulse rate. [q]PWTT: pulse wave transit time. [r]CT: core temperature. [s]ECG: electrocardiogram. [t]GPRS: general packet radio service.[u]CDMA: code-division multiple access.

Table 3: Reported outcomes of included studies

Author, year	Validation outcomes	Feasibility outcomes	Clinical outcomes	Cost outcomes
Prgomet et al, 2016[39]	—[a]	Knowledge, confidence, perceptions and feedback about continuous monitoring device, interdisciplinary communication regarding deterioration	—	—
Weller et al, 2017[40]	—	Alarm rate	RRT[b] calls, ICU[c] transfers, unexpected deaths	—
Verillo et al, 2018[51]	—	Staff satisfaction	Complication rate, RRT calls, ICU transfers, FTR[d] events	—
Weenk et al, 2017[59]	Bland-Altman agreement	Artifacts, user experiences	—	—
Watkins et al, 2015[60]	—	Nursing experiences, number of alarms	Log of interventions based on alarms	—
Downey et al, 2018a[62]	—	Patient acceptability and compliance	Time to AB[e], mortality, length of stay, admission to level II or II, 30-day readmission	—
Downey et al, 2018b[56]	—	Patient perceptions	—	—
Hernandez-Silveira et al, 2015a[63]	Bland-Altman agreement	—	—	—
Hernandez-Silveira et al, 2015b[61]	Bland-Altman agreement	—	—	—
Downey et al, 2019[64]	Bland-Altman agreement	Completeness of continuous patch data	—	—
Chan et al, 2013[65]	Mean absolute error, root-mean-square error	—	—	—

Table 3: (Continued)

Author, year	Validation outcomes	Feasibility outcomes	Clinical outcomes	Cost outcomes
Izmailova et al, 2019[41]	Data collection rate, comparison with control, data limitations	Data collection rate, acceptability	—	—
Breteler et al, 2018[42]	Limits of agreement and bias	Data loss	—	—
Selvaraj et al, 2018[43]	Bland-Altman agreement	—	—	—
Liu et al, 2014[69]	—	—	Prediction of life-saving interventions	—
Liu et al, 2015[45]	—	Percentages of valid measurements and nonzero waveform samples	—	—
Razjouan et al, 2017[46]	—	Any potential adverse events or complaints as a result of the patch	—	—
Boatin et al, 2016[47]	Bland-Altman agreement	Acceptability, functionality	—	—
Kim et al, 2012[48]	Bland-Altman agreement	—	—	—
Van Haren et al, 2013[49]	Sensitivity, specificity, negative predictive value, positive predictive value, and area under the receiving operating characteristic curves	—	Prediction of life-saving interventions	—
Meisozo et al, 2016[50]	Paired student *t*-test, Fisher exact tests	—	—	—

Table 3: (Continued)

Author, year	Validation outcomes	Feasibility outcomes	Clinical outcomes	Cost outcomes
Dur et al, 2019[52]	Pearson correlation coefficients along with Bland-Altman plots and Bland-Altman limits of agreement	—	—	—
Li et al, 2019[57]	Correlation, mean difference	—	—	—
Ordonnel et al, 2019[53]	—	Wear-time detection	Sleep detection	—
Hubner et al, 2015[54]	—	Monitoring time, patient and user experiences	—	—
Liu et al, 2013[55]	Bland-Altman agreement, coefficient of variation, ICC[f], SEE[g], Pearson correlation coefficients, ANOVA[h]	—	—	—
Paul et al, 2019[58]	—	Recruitment rate, acceptance and tolerance, number of alarms per day including type and response, reliability of the system	Respiratory event rate, ICU transfer, RRT calls	—

[a]Not available. [b]RRT: rapid response time. [c]ICU: intensive care unit. [d]FTR: fail-to-rescue. [e]AB: antibiotic administration. [f]ICC: intraclass correlation. [g]SEE: standard error of the estimate. [h]ANOVA: analysis of variance.

Table 4: Bland-Altman agreement of validation studies

Device, study, subgroup	HR[a], mean difference (Limits of Agreement)	RR[b], mean difference (Limits of Agreement)	T[c], mean difference (Limits of Agreement)	SpO_2[d], mean difference (Limits of Agreement)	BP syst[e], mean difference (Limits of Agreement)	BP diast[f], mean difference (Limits of Agreement)
VitalPatch, Selvaraj et al, 2018[43]	0.4 (−8.7/9.5)	−1.8 (−10.1/6.5)	—[g]	—	—	—
HealthPatch, Chan et al, 2013[65]	—	—	—	—	—	—
HealthPatch, Breteler et al, 2018[42]	−1.1 (−8.8/6.5)	−2.3 (−15.8/11.2)	—	—	—	—
HealthPatch, Weenk et al, 2017[59]	−1.52 (−12.55/9.51)	−0.64 (10.32/9.04)	—	—	—	—
ViSi Mobile, Weenk et al, 2017[59]	−0.2 (−11.06/10.66)	1.19 (−5.53/7.91)	—	0.10 (−3.13/3.33)	0.44 (−23.06/23.94)	−8.00 (−27.46/11.46)
SensiumVitals, Hernandez-Silveira et al, 2015[63]						
Surgical patients	−0.5 (−3.97/2.97)	0.4 (−6.3/7.1)	—	—	—	—
Cardiovascular disorders (low voltage/variable QRS morphology)	0.97 (−3.73/5.67)	−1.4 (−10.8/8.0)	—	—	—	—
Cardiovascular disorders (atrial fibrillation)	−1.0 (−8.0/6.0)	−1.0 (−9.4/7.0)	—	—	—	—
Metabolic disorders	0.9 (−3.5/5.3)	−0.4 (−11.4/10.6)	—	—	—	—
Diabetes	−0.02 (−6.98/7.02)	0.1 (−7.7/7.9)	—	—	—	—
SensiumVitals, Hernandez-Silveira et al, 2015[61]	−0.23 (−0.61/0.15)	−0.43 (−6.10/5.20)	—	—	—	—
SensiumVitals, Downey et al, 2019[64]	1.85 (−23.92/20.22)	2.93 (−8.19/14.05)	0.82 (−1.13/2.78)	—	—	—
Zephyr BioPatch, Boatin et al, 2016[47 h]	1.6 (−11.6/14.8) - 4.2 (−4.4/22.8)	0.7 (−4.7/6.1) - 4.2 (−1.9/10.3)	0.02 (−1.48/1.52) - 0.5 (−1.3/2.3)	—	—	—
Zephyr BioPatch, Kim et al, 2012[48]	0.5 (−15.3/16.3)	−0.6 (−5.6/4.4)	—	—	—	—
Wavelet Wristband, Dur et al, 2019[52]	−0.3 (−2.6/1.9)	1.0 (−3.0/4.0)	—	—	—	—
Biosensor, Li et al, 2019[57]	—	3.5	—	—	—	—
Equivital EQ02, Liu et al, 2013[55 i]	1.2 (−5.4/7.8)	0.2 (−2.2/2.6)	0.59 (−0.29/1.47; skin) -0.1 (−0.32/0.12; core)	—	—	—

[a]HR: heart rate.[b]RR: respiratory rate. [c]T: temperature. [d]SpO_2: oxygen saturation. [e]BP syst: systolic blood pressure. [f]BP diast: diastolic blood pressure. [g]Not available.
[h]This study reported the 25th and 75th percentile. [i]This study reported the Bland-Altman agreement of two types of temperature: skin and core temperature.

Figure 2: Quality assessment of the included studies. Check marks: low risk of bias; Crosses: high risk of bias; Question marks: unclear risk of bias; Grey cells: Quality assessment tool not used for the study

Study	MMAT-tool	QUADAS-2						
		Risk of bias				Applicability concerns		
		Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
Progmet et al, 2016 [39]	2							
Weller et al, 2017 [40]	2							
Verillo et al, 2018 [51]	3							
Weenk et al, 2017 [59]	2							
Watkins et al, 2015 [60]	0							
Downey et al, 2018a [62]	2							
Downey et al, 2018b [56]	5							
Hernandez-Silveira et al, 2015a [63]		?	✓	✓	✓	✓	✓	✓
Hernandez-Silveira et al, 2015b [61]		?	?	✓	✓	×	✓	✓
Downey et al, 2019 [64]		✓	?	×	✓	✓	✓	×
Chan et al, 2013 [65]		×	?	×	✓	×	✓	?
Izmailova et al, 2019 [41]		×	✓	×	✓	×	✓	×
Breteler et al, 2018 [42]		?	✓	?	×	✓	✓	✓
Selvaraj et al, 2018 [43]		×	?	?	?	×	✓	✓
Liu, et al, 2015 [69]	4							
Liu et al, 2014 [45]		×	?	?	✓	✓	✓	✓
Razjouan et al, 2017 [46]	3							
Boatin et al, 2016 [47]	3							
Kim et al, 2012 [48]		×	✓	✓	✓	×	✓	✓
Van Haren et al, 2013 [49]	4							
Meizoso et al, 2016 [50]		×	✓	✓	✓	✓	✓	✓
Dur et al, 2019 [52]		?	?	?	×	×	?	?
Li et al, 2019 [57]		×	✓	✓	×	✓	✓	✓
Ordonnel et al, 2019 [53]	2							
Hubner et al, 2015 [54]	4							
Liu et al, 2013 [55]		?	?	×	✓	×	?	×
Paul et al, 2019 [58]	4							

✓ = low risk of bias, × = high risk of bias, ? = unclear of bias

WVSM Device

Two studies (N=305) evaluated the WVSM device (Athena GTX) in trauma patients (Table 1).[45,69] This device measures the HR, BP, RR, and SpO2 continuously and is worn on the chest, upper arm, and fingertips (Table 2).[70]

Feasibility outcomes

One study reported the feasibility outcomes.[45] This study was a posthoc analysis of the previous study of Liu et al.[69] They found at least 75% adequate data for BP, HR, and RR for predicting life-saving interventions (LSIs)[45] However, the results were subject to bias because of a high risk of bias in the following categories: patient selection and flow and timing (Figure 2).

Clinical outcomes

One study reported the clinical outcomes and showed that the data of this device were accurate in comparison with that shown in a conventional monitor for the determination of LSIs, without periodic loss of signals or other errors.[69] The authors learned during the study that new medical devices to be used for prehospital studies require integration into the local information technology infrastructure. The quality of this study was rated as high (Figure 2).

None of the studies reported the validation and cost outcomes.

MiniMedic

Two studies (N=155) evaluated the MiniMedic (Athena GTX) in trauma patients (Table 1).[49,50] This device measures the HR, SpO2, and ST both at the fingertip and in the forehead (Table 2). In addition, a Murphy factor, an injury acuity algorithm that generates a score, can be calculated for triaged patients in need of LSIs.[71]

Validation outcomes

One study compared the pulse-wave transit time, a derivate of BP, reported in the device with the BP reported in the conventional monitor and found correlations between them (R^2=0.036, P<.001; Table 3).[50] Temperature measurements were significantly different between the device and the reference standard and between the fingertip and the forehead sensor of the device. For HR, a mean difference of 3 beats per minute was found between the device and the reference standard (P<.001). For SpO2, the median difference between the conventional monitor and the fingertip sensor was 0% and that between the conventional monitor and the forehead sensor was 7% (P<.001). However, this study had a high possibility of bias at patient selection (Figure 2). The second study demonstrated that the MiniMedic was capable of computing a single numeric value, the Murphy factor, to summarize the overall patient status and to identify prehospital trauma patients who need LSIs.[49]

None of these studies reported the feasibility, clinical, and cost outcomes.

Zephyr BioPatch

Three studies (N=85) have been published about the Zephyr BioPatch (Medtronic Annapolis; Table 1).[46-48] This is a patch or a patch fixed by a harness on the chest and it measures the HR, RR, and the estimated core temperature (Table 2).[72]

Validation outcomes

Two studies reported the validation outcomes (Table 3). One study was conducted in healthy volunteers during graded exercise and in a hot environment and one was conducted in full-term pregnant women.[47,48] For HR, both studies reported acceptable mean differences but nonacceptable LoA. For RR, one study[47] reported acceptable mean differences but nonacceptable LoA for RR but the other study[48] that also reported acceptable mean differences but nonacceptable LoA for RR was subjected to a high risk of bias at patient selection (Figure 2). Therefore, Boatin et al[47] are the only researchers who have reported acceptable mean differences but nonacceptable LoA for RR.

Feasibility outcomes

Considering the feasibility outcomes, the participants found the patch comfortable (78%), likeable (81%), and useful (97%). Among nurses, 80% of the nurses found the monitor easy to use and 84% would recommend it to patients.[47] Another study reported a retention rate of 88.6% at the end of the 24-hour monitoring period after exclusion of 2 patients with poor electrocardiogram (ECG) signals.[46] Furthermore, the authors interviewed patients and nurses about any challenges wearing the sensors. Both groups did not report any challenges. The quality of the studies was rated as moderate and high (Figure 2).

None of the included studies reported the clinical and cost outcomes.

Biosensor

One study (N=17) reported about the Philips Biosensor, which is a rebrand of the VitalConnect's HealthPatch (Table 1).[57] This device is able to measure HR, RR, and ST (Table 2).[73]

Validation outcomes

This study only compared the RR of the device with a reference standard. This resulted in acceptable limits of mean difference of 3.5±5.2 breaths per minute and a statistically significant correlation of Spearman's ρ of 0.86. However, results may be biased due to the high risk of bias regarding patient selection and flow and timing (Figure 2). In addition, 2 authors were employees of Philips and the study was funded by the manufacturer.

This study did not report the feasibility, clinical, and cost outcomes.

Wavelet Wristband

One study (N=35) reported about the Wavelet Wristband (Wavelet Health), a watch that monitors HR and RR (Table 1 and Table 2).[52,74]

Validation outcomes

For HR, acceptable mean differences and LoA were found (Table 4). For RR, the LoA was outside of the acceptable limits. However, all aspects of risk of bias were either unclear or high and applicability was low (Figure 2). Besides, 4 authors were former or current employees of the manufacturing company.

This study did not report the feasibility, clinical, and cost outcomes.

Proteus Patch

We found 1 study (N=13) that reported about the Proteus patch (Proteus Digital Health; Table 1).[53] This device monitors HR, RR, and ST (Table 2).[75]

Feasibility outcomes

In the feasibility study, the patch was able to monitor for over 5 days at home. However, data of 2 patients was insufficient for performing the analysis and were excluded. The quality of the study was rated as low (Figure 2).

This study did not report the validation, clinical, or cost outcomes.

IntelliVue Cableless Measurement Solution

We found about the IntelliVue Cableless Measurement Solution (Philips) in 1 study on clinical patients (N=226; Table 1).[54] This is a device for monitoring the HR, RR, BP, and SpO2 (Table 2).[76]

Feasibility outcomes

There was an overall good acceptance by patients and health care professionals. No data was lost due to technical difficulties over a median monitoring period of 178 minutes per patient. The quality of the study was rated as high (Figure 2).

This study did not report the validation, clinical, or cost outcomes.

Equivital EQ02 Lifemonitor

We found 1 study (N=6) that reported about the Equivital EQ02 Lifemonitor (Hidalgo Ltd) for measuring the HR, RR, ST, and core temperature by using a chest-worn belt monitor (Table 1 and Table 2).[55] The core temperature was measured using an ingestible pill.[77]

Validation outcomes

Acceptable results were found for HR and RR (Figure 2). Skin temperature was outside of the acceptable limits for mean difference and LoA, but the core temperature measurement was considered as acceptable. However, these results were subjected to a high risk of bias at patient selection and reference standard (Figure 2).

This study did not report the feasibility, clinical, and cost outcomes.

Alarm Management System

We found 1 study (N=250) that reported about the Alarm Management System (Covidien; Table 1).[58] This device was worn at the fingertip and it measures HR and SpO2 (Table 2).

Feasibility outcomes

The authors reported that 86.6% of the patients completed the monitoring period in the study. Besides, a mean of 4 alarms per week was reported due to decreased SpO2 in about 75% of the alarms.

Clinical outcomes

The authors reported respiratory event rates, ICU transfer, and RRT calls. However, this occurred 0 times in the control and 1 time in the intervention group. Eventually, the quality of this study was rated as high (Figure 2).

This study did not report about the validation or cost outcomes.

DISCUSSION

Summary of Evidence

In this study, we aimed to provide a systematic review of the current evidence on wearable wireless continuous monitoring devices for vital signs monitoring. We included 27 studies, which evaluated 13 different wearable devices. Overall, the studies predominantly evaluated the validation of the recorded data (N=15) or the feasibility (N=15) of these devices. Clinical outcomes were only reported in 6 studies, and studies describing the cost outcomes are still lacking. Although 13 different devices were included in this review, these devices did not share the same indication in terms of monitoring. In general, 2 main target indications could be identified. First, the ViSi Mobile, WVSM Device, MiniMedic, and IntelliVue Cableless Measurement Solution were designed for more extensive prehospital (ambulance) or clinical physiological monitoring. This monitoring level may be comparable to standard ICU monitoring, and therefore, these devices are usually bulkier wearable devices. Second, patch, wristband, and harness devices such as the SensiumVitals, VitalPatch, Philips Biosensor, Zephyr BioPatch, EQ02 Lifemonitor, Alarm Management System, Wavelet Wristband, and the Proteus patch were designed for ambulant wireless clinical monitoring of only a few basic vital signs. These devices are possibly more suitable for patients in the general ward and for monitoring the vital signs at home.

Regarding the validation of the devices, a few considerations should be taken into account. Many of these studies were conducted in healthy volunteers, which may introduce a bias owing to the lack of deviating vital signs values when compared to the vital signs of the actual patients. Further, for technical reasons, vital signs cannot be measured continuously by wearable sensors with equal accuracy. In particular, the RR and temperatures still appear to be difficult to be measured reliably in several included studies. In fact, the optimal reference standard for measuring RR has still not been found, although it is considered to be the most important parameter for predicting clinical deterioration.[78-81] In addition, the optimal method for measuring temperature by using wearable wireless devices has yet to be found. Most devices measure the skin temperature, which is known to be unreliable as equivalent for core temperature.[82-84]

Feasibility outcomes were focused on acceptability by health care professionals and patients. In general, both groups were positive about the deployment of the devices. In addition, the operation of the system was evaluated, such as the completeness of the measurements and the number and appropriateness of the alarms. Both outcomes were assessed as feasible.

The impact of these devices on clinical outcomes is still unclear because most included studies were underpowered to demonstrate any significant effect. However, multiple studies described cases wherein a complication was recognized earlier by the device and acted upon in a timely manner.

Regarding costs, no outcomes were reported about the devices in the included studies. Such data may however be essential for preparing future business cases for large-scale implementation, considering the relatively high cost of such monitoring devices and platforms.[85]

Previously published reviews on continuous monitoring did not focus on wearable devices, except for one, but this was not a systematic review.[32] We found comparable but also contrasting results in that study.[32] The review of Joshi et al[32] reported the same devices as those reported by us as well as some other devices that we excluded since there were no published studies about those devices or they were published before 2009. In line with our results, they also concluded that the diagnostic accuracy of the devices was suboptimal, especially the alarm rates and the false alarms. In addition, they also indicated that there were no sufficiently powered studies to show beneficial clinical effects or cost-effectiveness.

In a review of nonwearable devices, Cardona-Morrell et al[14] found that early detection of deterioration was enhanced but there were no significant improvements in the clinical outcomes, which is in line with our findings regarding wearable devices. This could be explained by the heterogeneous and underpowered character of the included studies.[14] Downey et al[86] also came to this conclusion and further stated that continuous monitoring seems to be feasible in terms of the frequency of implementation in hospitals; they found that patient and nurse perceptions were positive and that continuous monitoring may be cost-efficient.

Limitations

This systematic review had several limitations. First, the quality varied across the included studies. Several accuracy studies contained high risk of bias regarding patient selection as well as the applicability. Further, the reference standard was often not free from potential bias. Considering the studies assessed with the MMAT tool, quality was predominantly rated 2 or 3 out of 5; therefore, bias is present. Moreover, assessing the quality of the studies and comparing these studies was difficult owing to the heterogeneity of the included studies. Therefore, performing a meta-analysis was not possible owing to the heterogeneity in the devices and the outcomes. Second, 5 of the included studies had possible conflicts of interest owing to funding by the

manufacturer or because employees of the manufacturing companies of the devices played a role in the conduct of the study. This highlights the possible risk of reporting and publication bias within this field of research. Third, there were some limitations about the search. We only focused on devices that measured at least two vital signs. However, this cut-off was based on previous studies about the predictive value for clinical deterioration. These studies found that the more vital signs are monitored, the more accurate the detection is.[87,88] Besides, we only focused on off-the-shelf devices with a clearance by the CE mark or FDA as a medical device for clinical use. We excluded 42 prototype studies that were considered to be less clinically relevant for health care professionals. However, this indicates that there may be many more monitoring devices that will be launched in the health care market in the future. Besides, the review was restricted to English and Dutch publications published from 2009 and after. Only a few studies were excluded based on language and the older studies were considered be less clinically relevant owing to outdated technology. Fourth, we prespecified the clinically relevant mean difference and LoA for vital signs. It may be clinically desirable to redefine acceptable accuracy limits depending on the value of the vital signs measured and the patient population. For example, a difference of 3 breaths per minute is more clinically relevant in a range of 5-8 breaths per minute than with 30-33 breaths per minute. However, reliable evidence or guidelines for continuous monitoring of vital signs are currently lacking.

Clinical Implications

This review outlines several important clinical implications before health systems may proceed to large-scale implementation of wearable wireless continuous monitoring devices for vital signs monitoring for patients in the hospital and at home. For both settings, vital signs data measurements should be accurate, reliable, and validated in clinical studies. This is especially important for the home setting, wherein a health care professional is not readily available to assess the clinical condition of the patient. For further optimization, the monitoring measurements should preferably be incorporated into an early warning score system supported by a validated decision support algorithm.[89] These analysis algorithms should be further enhanced to prevent too many alarms in order to avoid alarm fatigue.[90] Further, for optimal adoption into clinical workflows, the vital signs measurements should preferably be integrated into the electronic medical record. This will likely improve commitment and compliance from nurses and doctors and will also allow for the summarized monitoring data to be archived in the patient records.[32] When all such factors are optimized, it is anticipated that studies will be able to show a significant effect on clinical outcomes. For monitoring patients at home, the patient data need to be sent to health care professionals through a stable and secure wireless connection. Such a system will need to be embedded in

a validated care work flow, thereby providing alarm reviews by care professionals who will assess, make an initial phone call, and then escalate to a home visit by a nurse or direct the patient to the emergency department when needed.[91] Furthermore, for home monitoring, the devices should be small, flexible, and hypoallergenic and not bother patients during their daily activities.[18,24] Battery life, which currently ranges from 3 to 7 days in most devices, may be further extended especially for long-term monitoring of patients with chronic diseases such as heart failure.[18,19] Eventually, when all the conditions are optimized, larger studies may be able to demonstrate that continuous home monitoring safely allows for routine early discharge from the hospital. Further, such a system may potentially provide timely detection of complications, and thereby prevent readmissions, improve overall outcomes, and decrease health care costs.[21,92]

Conclusions

Continuous monitoring devices are mostly still in the validation and feasibility phases. Besides, studies reporting clinical outcomes are still sparse and cost outcome studies are still lacking. Such studies are needed to help health care professionals and administrators in their decision making regarding the implementation of these devices on a large scale in clinical practice or in home monitoring.

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APPENDICES

Appendix 1: search string of database PubMed/Medline

#1 vital OR vital sign* OR vital function* OR vital parameter* OR clinical deterioration OR deterioration OR Vital Signs [MeSH]

#2 Remote continuous monitoring OR Wireless continuous monitoring OR wireless device OR patch OR appliance OR wearable OR portable OR smart OR sensor OR Physiologic Monitoring [MeSH]

#3 clinical outcome OR mortality OR death OR length of stay OR LoS OR readmission OR intensive care unit admission OR ICU admission OR rapid response team OR RRT OR intervention* OR sepsis OR operation OR valid* OR reliab* OR feasibility* OR acceptability OR demand OR implementation OR practicality OR adaptation OR integration OR expansion OR limited-efficacy testing OR cost* OR cost-effectiveness OR cost-efficient

3

EXPECTATIONS OF CONTINUOUS VITAL SIGNS MONITORING FOR RECOGNIZING COMPLICATIONS AFTER ESOPHAGECTOMY: INTERVIEW STUDY AMONG NURSES AND SURGEONS

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ABSTRACT

Background

Patients undergoing esophagectomy are at serious risk of developing postoperative complications. To support early recognition of clinical deterioration, wireless sensor technologies that enable continuous vital signs monitoring in a ward setting are emerging. Objective: This study explored nurses' and surgeons' expectations of the potential effectiveness and impact of continuous wireless vital signs monitoring in patients admitted to the ward after esophagectomy.

Methods

Semistructured interviews were conducted at 3 esophageal cancer centers in the Netherlands. In each center, 2 nurses and 2 surgeons were interviewed regarding their expectations of continuous vital signs monitoring for early recognition of complications after esophagectomy. Historical data of patient characteristics and clinical outcomes were collected in each center and presented to the local participants to support estimations on clinical outcome.

Results

The majority of nurses and surgeons expected that continuous vital signs monitoring could contribute to the earlier recognition of deterioration and result in earlier treatment for postoperative complications, although the effective time gain would depend on patient and situational factors. Their expectations regarding the impact of potential earlier diagnosis on clinical outcomes varied. Nevertheless, most caregivers would consider implementing continuous monitoring in the surgical ward to support patient monitoring after esophagectomy.

Conclusions

Caregivers expected that wireless vital signs monitoring would provide opportunities for early detection of postoperative complications in patients undergoing esophagectomy admitted to the ward and prevent sequelae under certain circumstances. As the technology matures, clinical outcome studies will be necessary to objectify these expectations and further investigate overall effects on patient outcome.

INTRODUCTION

Surgical treatment of esophageal cancer is highly complex and associated with considerable postoperative morbidity. Although the centralization of care and introduction of minimally invasive surgery have improved clinical outcomes, complications still occur in approximately 60% of patients undergoing esophagectomy.[1,2] These postoperative complications contribute to mortality, prolonged hospitalization, and increased costs.[3-6]

To prevent severe sequelae of complications after esophagectomy, early recognition of clinical deterioration is essential.[7-9] As complications are often preceded by detectable signs, such as atrial fibrillation or hemodynamic instability [10,11], patients are usually admitted to high-care units in the first days after surgery for close monitoring of vital signs (eg, heart rate, respiratory rate, blood pressure, body temperature) and other clinical markers. However, with the introduction of enhanced recovery pathways, patients tend to be transferred to surgical wards earlier.[12,13] Consequently, clinical signs of complications after esophagectomy present more often at the ward. Since the level of patient monitoring is typically lower in a ward setting, where vital signs are only measured a few times per day, this poses a risk of missing important early signs of deterioration.

As the market for wearable medical technologies grows, unobtrusive tools for wireless vital signs monitoring are emerging. By allowing continuous vital signs monitoring even while mobilizing, these technologies may aid early recognition of clinical deterioration in ward patients[14-18] and could therefore be of interest for patients undergoing esophagectomy. However, despite the potential promises, the technology is still immature, and further developments are needed to facilitate optimal implementation.[19,20] Furthermore, it is as of yet unclear how continuous monitoring should be integrated in current routines to promote effective care escalation. Accordingly, acceptance of the new technology and adoption by caregivers is uncertain, while this is crucial for effective implementation. Lastly, to date, there is still only scant evidence of the clinical value in specific patient populations.[21] Therefore, the aim of this study was to gain insight into nurses' and surgeons' expectations of the potential effectiveness and clinical impact of continuous vital signs monitoring in patients admitted to the surgical ward after esophagectomy.

METHODS

Participants

We performed semistructured interviews with nurses and surgeons involved in the postoperative care of patients undergoing esophagectomy, which allowed thorough discussion of research topics from different perspectives. The study focused on surgical practice in the Netherlands, and interviewees were recruited from 3 Dutch high-volume centers for esophageal surgery (University Medical Center Utrecht, Catharina Hospital Eindhoven, ZGT Hospital Almelo). Purposive sampling[22] was applied to obtain a sample of care professionals with a high level of relevant expertise, aiming to promote in-depth discussion and informed judgements of the interview topics. Accordingly, in each participating center, the chair of the surgical (ward) team proposed candidates with the most knowledge and experience of postoperative monitoring of patients undergoing esophagectomy. Candidates were invited to participate in the study through email and gave written consent for the interview.

Interview Setup

The interview setup and scheme (Appendix 1) was developed by a group of 5 researchers and care professionals with expertise in the field of telemonitoring, clinical patient monitoring, esophageal surgery, and qualitative research. The interview included structured and open questions within 5 main themes. First, current approaches to patient monitoring after esophagectomy and factors influencing early recognition of postoperative complications were investigated. Subsequently, the participant's expectations regarding the effectiveness and clinical impact of continuous vital signs monitoring were discussed. Last, considerations regarding the implementation of continuous monitoring were explored. As anastomotic leak and pneumonia are the most prevalent complications that can seriously affect clinical outcome in patients undergoing esophagectomy[1,3,23], these complications were used as case examples to discuss the topics and elicit concrete predictions.

Two pilot interviews were conducted—one with an experienced nurse (working experience: 9 years) and one with a surgeon (working experience: 2 years)—within one of the participating centers to verify whether questions were interpreted correctly and whether the research goals were obtained. Based on these test interviews, visual aids described below were added to further improve clarification of questions and structuration of the interview. Furthermore, the test interview led to the removal of questions regarding potential effect size, since the test participants indicated that the validity of such expert-based judgments would be questionable given the many uncertainties involved.

A researcher from an independent institute with a background in technical medicine and wireless patient monitoring performed all interviews in private workplaces within the hospital. The interviewer was guided by the interview scheme but was allowed to change the sequence of questions within main topics or to add questions for emerging topics. Rephrasing of questions and probing was used to encourage detailed answering. The interviews were audiotaped, and no notes were taken.

Materials

The interviewer used visual aids for clarification of theoretical concepts and structured collection of information (Appendix 1). The concept of continuous vital signs monitoring was introduced as the ability to constantly track heart rate, respiratory rate, body temperature, and oxygen saturation by means of unobtrusive wearable sensors that allow patient mobilization within the hospital. In addition, it was stated that automatic threshold alarms or (variations of) early warning scores could be integrated to assist detection of abnormalities.

To support and anchor estimations of potential clinical effects and minimize the possible influence of differences in preknowledge between participants, descriptive data of the local patient population were collected for each center and presented as the prior situation to the corresponding participants during the final part of the interview. Data included population characteristics, complication rates, and clinical outcome measures for all patients that underwent elective esophagectomy for nonrecurrent esophageal cancer between January 2015 and December 2016. All data were registered according to definitions by the Dutch Upper Gastrointestinal Cancer Audit[6,24] and collected prior to the interviews. Appendix 2 summarizes the baseline characteristics of the pooled patient populations of the 3 participating centers.

Analysis

The interviewer transcribed the interview recordings. Next, all transcripts were coded using Atlas.ti software (*version 8.3.2; Atlas.ti Scientific Software Development*) for content analysis.[25] Coding was performed independently by the interviewer and a second researcher with expertise in nursing and wireless patient monitoring. In this process, content was categorized according to the predefined interview topics, after which the results of structured questions were summarized and emerging themes within categories were coded. Codes were refined as analysis progressed and added when new themes emerged. Any discrepancies in coding by the 2 researchers were mutually discussed to obtain consensus for all codes and themes. The transcripts were not returned to the participants for correction to avoid censoring, and study findings were member checked after completion of the analysis. To evaluate the level of data saturation that was obtained, we assessed the number of new themes that

were elicited across the inclusion of participants. In addition, we explored the number of themes mentioned exclusively by either nurses or surgeons or by participants of 1 center only. The results were reported following the Standards for Reporting Qualitative Research guidelines.[26]

RESULTS

Participants

All candidates that were invited for the interview participated in the study. The recruited nurses (n=6) had a median working experience of 7.5 years (range 2-25 years), of which they worked 4 years (range 1-25 years) with patients undergoing esophagectomy. The participating surgeons (n=6) had a median working experience of 11 years (range 6-21 years) in upper gastrointestinal surgery. Interviews had an average duration of 44 minutes (range 25-63 minutes).

Data Saturation

Content analysis resulted in identification of 40 themes (Appendix 3), of which 14 themes were described by participants in 2 centers and 25 themes were discussed in all included centers. In each center, at least 75% of all themes were described by at least one of the participants. In total, 85% of all themes were described by both nurses and surgeons. Analysis of the interviews from the last included participants did not result in elicitation of new themes (Appendix 3); hence, sufficient data saturation was assumed.

Current Monitoring Routine

Current protocols for patient monitoring during ward stay were similar among the 3 hospitals. Typically, a physician visited the patient during daily rounds and performed physical examination on indication. Chest radiography, blood tests of infection parameters, and drain amylase tests were performed daily in the first days after surgery. Each hospital used an early warning score system (similar to the Modified or National Early Warning Score[27,28]) to evaluate the patient's status 3 to 4 times per day. As part of these early warning scores, standard vital sign measurements of heart rate, respiratory rate, blood pressure, oxygen saturation, and temperature were performed. This set was complemented by routine measurements of urine output and evaluation of mental status. However, participants of one hospital described that urine output and mental status were not assessed routinely for each patient but specifically in patients with suspected instability.

In case deterioration was suspected based on routine measurements and subjective nurse observations, additional physical examination, vital signs measurements, blood

tests, or diagnostic imaging were performed to confirm findings and for further diagnosis. However, the approach of diagnostic confirmation seemed to vary between hospitals, as participants from one hospital promoted early activation of diagnostic imaging, while other participants advocated a wait-and-see policy to prevent overdiagnosis.

Early Recognition of Complications

All participants underlined that early recognition of complications is important for rapid recovery and minimization of adverse clinical outcomes. Furthermore, all participants were confident that the current monitoring routine supports early complication recognition but recognized that the time to identification and treatment of complications depends on various factors.

The majority of participants reported that signs of anastomotic leak and pneumonia typically present first in vital signs measurements and subjective nurse observations (Appendix 4). In a later phase, abnormalities often present in lab tests and physical examinations, followed by medical imaging. However, several participants pointed out that the presentation of clinical deterioration varies per patient and complication type. As one nurse explained:

> *The presentation of a complication differs between patients. Some patients are able to compensate for a long time, while other patients deteriorate immediately.* Participant 3

Participants noted that clinical deterioration is not always visible in an early stage or for a mild degree of complications, where physiology is still unaffected or impairment is too small to be captured by routine observations or diagnostic tests. Furthermore, compensatory mechanisms or medication may suppress signs of deterioration. As such, abnormalities may remain undetected.

Conversely, abnormal diagnostic test results or physical symptoms, for example, tachycardia, could relate to various complication types, which hampers differentiation in an early phase. Moreover, abnormalities can be caused by the surgical stress response, comorbidities, or normal variations. For these reasons, identification of deterioration relies on the combination of subjective observations and diagnostic tests. Accordingly, caregivers often wait to see whether the observed abnormalities persist or present in other diagnostic tests before acknowledging a (potential) complication. Last, half of the participating surgeons mentioned that routine test results are often assessed statically according to standard thresholds, while temporal changes are more indicative of deterioration.

Participants explained that late detection of clinical deterioration can be caused by incomplete or delayed routine examinations. Nurse observations and vital signs measurements may be skipped or postponed if the patient appears stable, in particular when workload is high. Additionally, vital signs are not always measured in patients who are asleep to avoid sleep deprivation. Lastly, the interval between the onset of deterioration and evaluation of test results depends on the timing of routine measurements and clinical rounds, which leads to variable response times.

A total of 6 participants mentioned that the level of expertise of the treating physician and nurse influences how fast deterioration is recognized and acted upon, as this impacts the ability to observe and interpret physical signs and identify abnormalities in diagnostic results. This mainly concerns weekend, evening, and night shifts, which are typically occupied by less experienced staff.

Effectiveness of Continuous Vital Signs Monitoring

The majority of participants expected that continuous vital signs monitoring could support early recognition of deterioration related to anastomotic leak and pneumonia (Figure 1). A total of 6 participants estimated a maximal time gain of 1 to 8 hours, deduced from the fact that continuous availability of data can facilitate direct notification of (acute) abnormalities and hence fill the gap between current intermittent measurements, which are typically obtained every 8 hours. Conversely, 5 participants argued that the time gain could be higher and might reach 12 to 48 hours, mainly supported by the increased ability to identify time trends or abnormal patterns. As one surgeon described:

> *With the availability of continuous data, we can better observe trends, which are more important than spot-checks…These patterns influence our judgement of the patient's status.*
> Participant 4

This can be of particular benefit for patients with slowly developing complications or in cases where deterioration is not suspected due to unspecific or absent physical signs. Lastly, 3 participants also described that it is likely that continuous monitoring promotes early identification by increasing the awareness of potential abnormalities. Next to pneumonia and anastomotic leak, participants mentioned that continuous monitoring could contribute to early detection of arrhythmias, such as atrial fibrillation, infections, and severe acute events, such as pulmonary embolism and myocardial infarction.

The participants who were more doubtful about the ability to recognize deterioration early mostly ascribed this to the limited sensitivity and specificity of vital signs measurements and the importance of full clinical assessment. A nurse stated:

> *These numbers don't tell the whole story.*
> Participant 2

Furthermore, it was argued that early warning does not just rely on vital signs, since first signs of complications could be observed in other measurements at the same time or even earlier depending on presentation (Appendix 4). Last, several participants stated that it is unlikely that deterioration can be identified earlier, as current routines are already effective and caregivers are constantly alert to potential complications.

Most participants expected that early notification of deterioration effected by continuous vital signs monitoring would lead to earlier treatment of the underlying complication in (a subset of) patients (Figure 1). Participants pointed out that continuous monitoring would also promote earlier activation of therapy by increasing the certainty that abnormalities persist or providing an objective description of the patient status that could be used to justify escalation of care. The overall effect on time to treatment might, however, be limited, as clinical progress or diagnostic confirmation is often awaited first. A nurse explained:

> *There are cases where we have to wait and follow-up the measurements. Then we can identify whether the patient is indeed deteriorating or stabilizes.*
> Participant 2

Six participants stated that the implementation of active alarms is crucial for effective monitoring, as these could raise the awareness of abnormal vital signs. One of the surgeons mentioned:

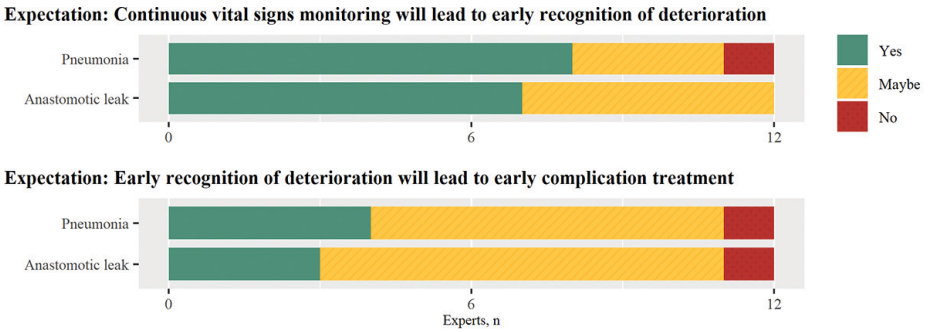
> *Alarms will trigger caregivers to actively search for abnormalities…I think this will specifically improve the continuity of early recognition.*
> Participant 11

By supporting identification of abnormalities, automated alarms can reduce nurse workload and minimize the dependency on nurse expertise. However, it was also mentioned that alarm-based response systems may have unintended consequences, such as neglecting subjective patient observation, which should be prevented, as this is important for adequate patient assessment. Furthermore, it is crucial that notifications

are given at the right time and that the number of false alerts is minimal to prevent alarm fatigue. A total of 3 surgeons stated it would be valuable to complement the static assessment of vital sign values by automatic trend detection.

Most participants mentioned that implementation of continuous monitoring requires training for nurses and physicians in the practical use of the monitoring system or interpretation of continuous vital signs. In addition, 10 participants underlined the need for a clear protocol that defines the responsibilities of clinical staff and describes when and how to act in case of vital sign abnormalities. However, it was also noted that it is first needed to gain more insight into patterns of deterioration that require escalation of care and that it would take time to find out and establish effective monitoring routines.

Figure 1: Participants' expectations on effectiveness of continuous vital signs monitoring

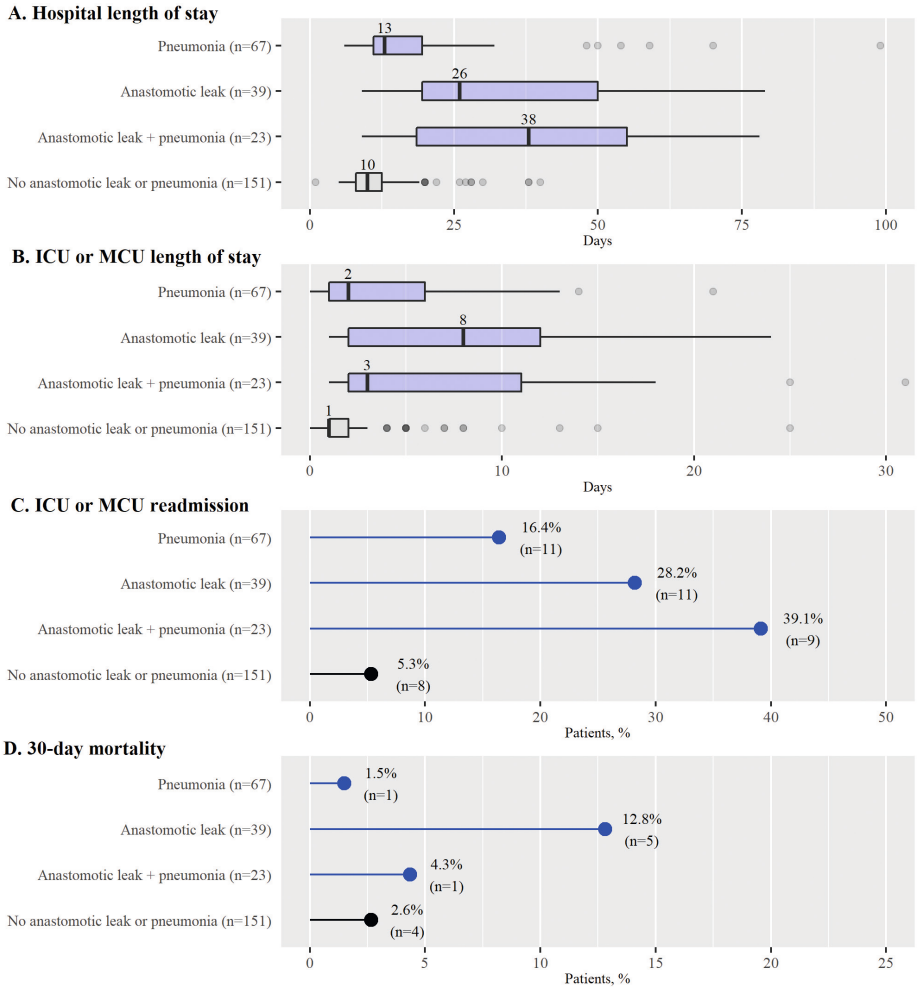


Impact of Continuous Vital Signs Monitoring

The combined data from the 3 participating hospitals (Figure 2) showed that patients who developed postoperative pneumonia, anastomotic leak, or both had a considerably longer length of hospital stay and increased risk of intensive care unit (ICU) or medium care unit (MCU) readmission. Furthermore, the data suggest that anastomotic leak strongly increases mortality. Overall, a minority of participants expected that early recognition and treatment of pneumonia and anastomotic leak effected by continuous monitoring would improve these outcome measures, as shown in Figure 3. Participants who expected a reduced hospital and ICU or MCU length of stay assigned this either to a shortened recovery and treatment period or to earlier onset and hence completion of the treatment period. Improvement in ICU or MCU readmission rate and mortality was attributed to a potential reduction in complication severity. Two participants stated that early recognition is of the highest value in patients with mild complications, as prevention of further deterioration would still be relatively

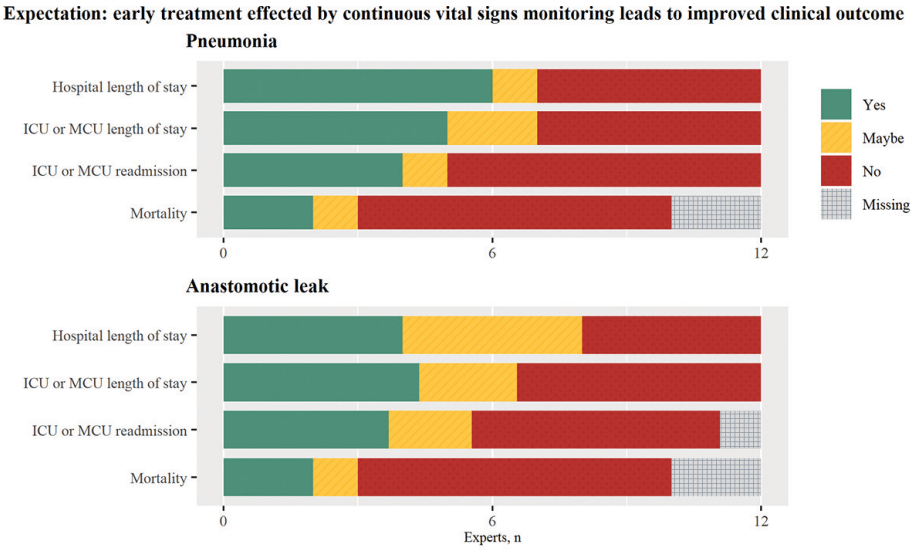
easy. In contrast, 2 other participants expected the most impact in cases of severe complications because there would be more room to reduce the degree of illness. Furthermore, it was mentioned that the largest benefits could be expected in patients with a poor preoperative condition, as these have a higher risk of severe deterioration.

Figure 2: Clinical outcome of patients undergoing esophagectomy



Outcomes are reported for the pooled patient population that underwent elective esophagectomy between 2015 and 2016 in one of the three participating centers (N=280). Subgroups reflect patients with or without pneumonia and/or anastomotic leak within 30 days after surgery. ICU/MCU: Intensive/medium care unit.

Figure 3: Participants' expectations on the improvement of clinical outcome measures. ICU/MCU: Intensive/medium care unit.



A total of 5 participants mentioned that the time gain that could be obtained with continuous monitoring is insufficient for notable improvement of clinical outcome. One nurse stated:

> *The hours that we could possibly gain on top of our current protocol are not enough to impact the progress or severity of the complication.*
> Participant 6

Participants who were doubtful indicated that the minimal time gain required for significant reduction of adverse effects caused by complications would range from 12 to 48 hours. Lastly, it was pointed out that adverse effects of some complications cannot be minimized at all because early onset of treatment does not reduce the duration of hospitalization or change patient outcomes.

Considerations for Implementation

Taking all potential effects into account, 10 participants would consider implementing continuous monitoring on their ward for early detection of deterioration. Most of these participants (n=6) would monitor all patients undergoing esophagectomy, while others preferred preselection of older patients (n=1) or patients with a poor preoperative

condition (n=1). Several participants considered applying continuous monitoring only during the first days of ward stay (n=2) or in case of nurse concerns (n=1).

The main argument against implementation included the expectation that continuous monitoring would not bring sufficient benefit on top of current monitoring protocols due to limited clinical effects. Furthermore, 5 participants mentioned that improvement in patient monitoring is becoming less relevant, as the prevalence and severity of complications is reducing over the years. A surgeon said:

> *Patients have a lower risk of developing complications than a few years ago… Also, the effects of complications are less severe. So, we now have more room to await clinical progress.*
> Participant 5

Participants described additional risks and benefits related to patient experience, nurse workload, and financial consequences but were divided on these topics. Several participants suspected that continuous monitoring would create a feeling of safety for patients. On the other hand, other participants expected worry related to false alarms and the feeling of being at risk. Furthermore, it was noted that the sensor placement and potential overdiagnosis could increase patient burden.

While most participants expected a reduction of nurse workload from (partial) automated vital signs measurement, others warned of increased workload related to vital sign interpretation and management of alarms. Moreover, 3 nurses suspected that the implementation of continuous monitoring would also create increased expectations of the level of care. One of these nurses stated:

> *In case you monitor patients continuously, you will also need to be able to provide continuous response.*
> Participant 6

However, they feared that this level of care could not be met, as the available time and expertise of the ward nurse staff is currently insufficient.

Lastly, participants reported that cost might be saved as a result of reduced hospital length of stay and reduced intensive care readmissions but also noted that expenditures might increase due to the costs of monitoring systems.

DISCUSSION

Principal Findings

This study identified perceptions of surgeons and nurses on the potential clinical effects of continuous vital signs monitoring by means of wearable sensors in patients admitted to the ward after esophagectomy. Caregivers suspected that continuous vital signs monitoring could promote early recognition of clinical deterioration in this population and setting and contribute to early treatment of prevalent complications. However, there were varying expectations regarding whether continuous monitoring would lead to notable improvements in hospital length of stay, ICU readmission, and mortality. Despite an as of yet uncertain clinical impact, most caregivers are positive toward future implementation of continuous vital signs monitoring to support patient monitoring in the surgical ward, provided that their concerns are adequately addressed.

Previous Studies

The perioperative management of patients undergoing esophagectomy has evolved over the years, and there is growing attention to the importance of early complication recognition.[8,11] According to current study results, however, there is still room to improve early detection of complications in a ward setting, which conforms to findings of previous studies.[17,29] Vital signs and related early warning systems have been found to be good predictors of ICU transfer, cardiac arrest, and mortality.[16,30,31] Therefore, there are high expectations of the potential value of continuous wireless vital signs monitoring, which allow more accurate and constant risk evaluation.[14,32,33]

Although evidence is still scarce, previous studies have described how continuous vital signs monitoring using wearable sensors could promote early identification of patient deterioration in a ward setting[21,34-37], which was also expected by these study participants. Furthermore, wireless monitoring has been proposed as a promising aid in other settings, for example, to assist in- or out-of-hospital monitoring of isolated patients during the current COVID-19 pandemic or surgical patients with restricted access to medical services.[38]

However, previous studies have reported variable effects of continuous monitoring on patient outcomes and cost efficiency[21,36], which is in line with the mixed expectations regarding clinical impact found in our study. Part of this inconclusive evidence can be explained by the fact that most studies so far have included small or heterogeneous study populations and used different monitoring strategies. Furthermore, continuous monitoring has often not been implemented at its full potential, restricted by the constraints of current available technology or limited compliance to the monitoring or

response protocols. Moreover, the monitoring protocols have often adopted a classical approach to vital signs assessment based on static vital signs levels. However, as described by current participants and in previous research[39], continuous and automated monitoring creates additional opportunities for trend evaluation and integration with context data, which may improve identification of deterioration. Accordingly, further investigation of adequate methods for trend-based and personalized assessment of vital signs data is encouraged.

On the other hand, these discrepant expectations regarding the possible clinical impact of continuous monitoring may also represent the complexity of managing postoperative surgical complications, where the ability to minimize adverse outcomes depends not only on early detection and treatment but also on the effects of the selected interventions. As the implementation of continuous monitoring introduces a risk of alarm fatigue and patient discomfort[21], studies that identify patients that would benefit most from continuous remote monitoring and early treatment are desired. Correspondingly, our study participants underlined the importance of establishing feasible but effective protocols for escalation of care. Furthermore, the responsibilities of caregivers and work processes should be adjusted with care to encourage adoption by caregivers and promote the effective implementation of continuous monitoring. The results of this interview study indicate that even if vital signs monitoring triggers early suspicion of deterioration, clinical observation as well as complementary diagnostic tests are imperative for the correct interpretation and actual diagnosis of complications. However, the introduction of continuous monitoring could also lead to overreliance in monitoring technology.[29,33] Therefore, careful implementation is required to balance the risks of missed events and overdiagnosis.

Strengths and Limitations

The qualitative design of this study allowed us to obtain estimations from professionals caring for patients undergoing esophagectomy, a highly complex surgical procedure associated with considerable risk, regarding the effectiveness of continuous monitoring technology. By using expert elicitation, the potential of continuous monitoring in the postoperative setting could be evaluated in the early development phase, where technology is evolving rapidly and the reliability, accuracy, and usability of these systems still need to be demonstrated.[14] Another advantage of this theoretical approach is that the results were not affected by the local implementation of technology or compliance of patients and caregivers, which could distort evaluation in clinical studies.[21] Furthermore, the interviews allowed stepwise investigation of individual components of the monitoring and response chain, which is challenging in a clinical setting.

However, as reflected by current findings, there are many patient-related or situational factors that might influence the effectiveness and impact of continuous patient monitoring and also challenge theoretical effect estimation. To promote the validity of estimates from caregivers, we therefore focused on a highly specific patient population and used case examples to minimize uncertainty. Furthermore, we purposely included only experienced caregivers from specialized centers within a single country to participate in the study to compose a homogeneous group of experts (ie, information-rich cases). Last, historical data of the local patient population were used to describe current clinical outcomes and create a consistent anchor point for effect evaluation. Nevertheless, current estimations can only be used hypothetically, and the overall impact on clinical outcome measures requires confirmation in clinical practice.

This study included surgeons and well as nurses from 3 centers. This allowed us to investigate topics and viewpoints from both the nursing and surgical professions and possible local perspectives within the Netherlands. According to national registries, these high-volume centers were responsible for 17% of all esophagectomies performed in the Netherlands in 2015 to 2016, and they reported similar population characteristics as those described for the national population.[40] Furthermore, except for some variation in the frequency and type of routine vital signs measurement, the overall clinical routines and escalation protocols were largely comparable between centers. Therefore, it is likely that the research sample is representative of the situation in the Netherlands. Although we conducted a limited number of interviews, viewpoints of participants or themes that were described by participants did not vary considerably within or between centers or between nurses and surgeons. In addition, as no new themes emerged from the interviews of the last included participants, sufficient saturation was assumed. Still, since the patient population and clinical routines may differ in other centers or countries, careful translation of findings for other settings is required.

Implications

As our study reflects that caregivers see opportunities to improve postoperative care after esophagectomy using wireless continuous vital signs monitoring, future studies that verify this potential in a ward setting are encouraged. By explicating factors that define the need for and ability of early complication recognition, current results may guide stepwise investigation of the effective time gain and corresponding clinical and economic effects of various monitoring strategies. As such, the optimal implementation of continuous wireless vital signs monitoring can be further evaluated as the technology matures.

Conclusions

Despite routine monitoring, identification of postoperative complications in patients undergoing esophagectomy admitted to the ward may be delayed due to limited frequency and diagnostic value of diagnostic measurements and the variable experience and skills of clinical staff. Surgeons and nurses expect that continuous vital signs monitoring by means of emerging wearable sensor technology would provide opportunities for early detection of clinical deterioration, which could promote rapid complication treatment. However, the effective time gain and impact on clinical outcome are yet uncertain and depend on patient and situational factors. Further investigation of the overall benefits and risks and optimal implementation of continuous vital signs monitoring is desired as technology matures.

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APPENDICES

Appendix 1: Interview guide

Instruction

The interview scheme describes main interview topics and corresponding question topics. The introduction of topics or visual aids is described in italic. The checkboxes (□) list items that should be discussed with each participant as part of the topic exploration. If these items were not addressed by participants themselves as response to the open question, these were introduced later by the interviewer.

The interviewer should introduce main topics and the corresponding visual aids in the order as described. The sequence of questions within main topics can be changed, and questions for emerging topic can be added. Rephrasing of questions and probing can be used to encourage detailed answering.

Main topic	Topics of questions
Participants' background	*Introduction of interview goals and set-up* Participant's position in hospital Years of working experience
Current monitoring routine	*Introduction of scope: participants undergoing esophagectomy admitted to ward.* *Introduction of common types of routine measurements: visual aid 1* Type and frequency of measurements in patient monitoring routine in clinical ward Subjective nurse observation Physician round Physical examination Vital signs Lab tests Medical imaging Situations where monitoring routine is performed differently First actions in case of abnormalities Involve other caregivers Additional diagnostic actions Emergency intervention team

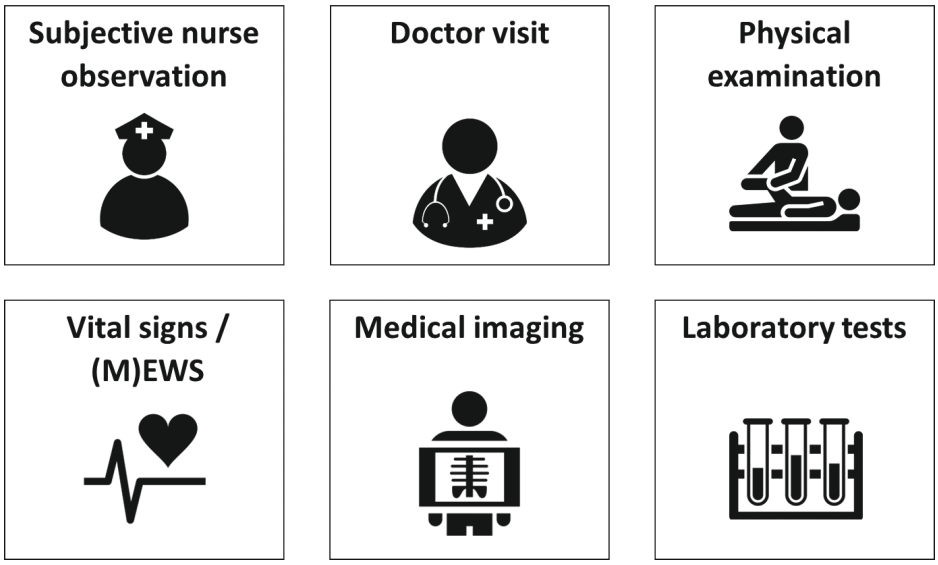
Main topic	Topics of questions
Early recognition of complications	Order of presentation of abnormalities during complication development: pneumonia + anastomotic leak Subjective nurse observation Physician round Physical examination Vital signs Lab tests Medical imaging Ability to detect complications in early phase in current practice Factors influencing the time to detect complications Measurement type Care professionals Consequences of late detection of complications Patient outcome Clinical trajectory of patient
Effectiveness of continuous vital signs monitoring	*Introduction of theoretical mechanism of patient monitoring: visual aid 2* *Introduction of telemonitoring concept: visual aid 3* Expectation: continuous monitoring will lead to earlier detection of deterioration: pneumonia + anastomotic leak Factors influencing or explaining the expected possibility to improve the time to detect of complications by introducing continuous monitoring Expected time gain in detection of complications Complication types that can be detected earlier using continuous monitoring Expectation: the expected time gain to detect complication will lead to earlier treatment: pneumonia + anastomotic leak Factors influencing or explaining the expected possibility to improve time to treat complications by introducing continuous monitoring Prerequisites for early detection and treatment Care protocol Tasks and responsibilities of care professionals
Impact on clinical outcome	*Introduction of demographic data and clinical outcome data of hospital: patient data handout** Expectation: the expected time gain to detect and treat complications will improve clinical outcome: pneumonia + anastomotic leak Length of hospital stay Length of ICU/MCU stay ICU/MCU readmission rate Mortality rate Factors influencing the possibility to improve clinical outcome by introducing continuous monitoring

Main topic	Topics of questions
Considerations for implementation	Risks and benefits for stakeholders: Patient Nurse Physician Hospital Health insurance company Overall interest to implement continuous monitoring in ward Patient where continuous monitoring would be indicated Factors influencing the overall interest in continuous monitoring

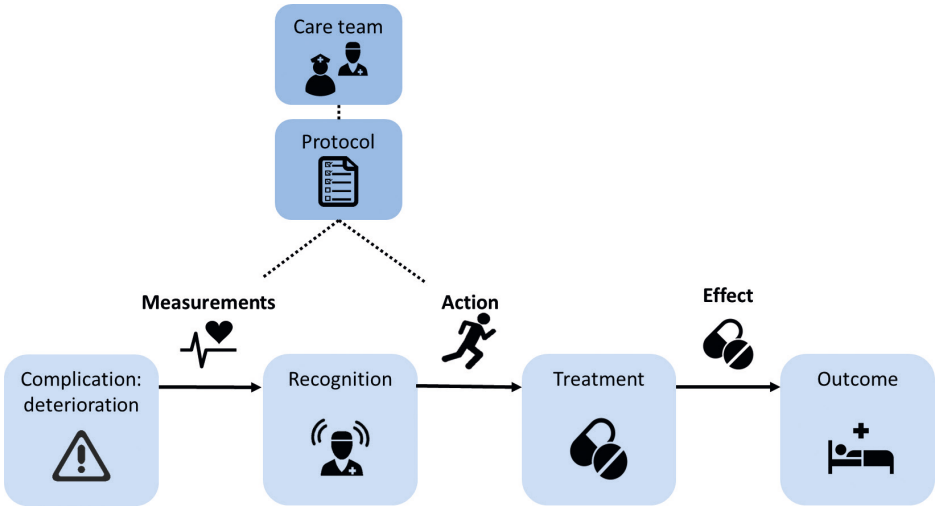
* Handout with data of the population characteristics, complication rates, and clinical outcome measures for all patients that underwent elective esophagectomy for non-recurrent esophageal cancer between January 2015 and December 2016. Only data obtained in the participant's hospital is shown to the participant.

Visual aids

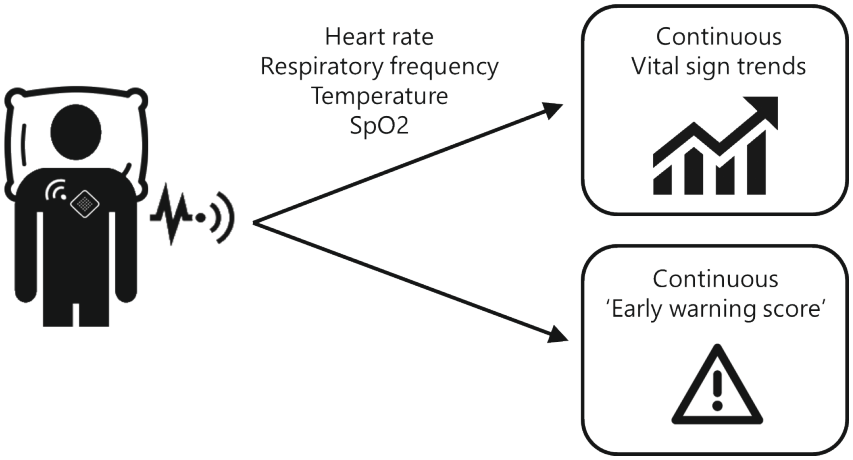
Visual aid 1. Visual aid used to support identification of measurements performed in current patient monitoring routine



Visual aid 2. Visual aid to clarify the theoretical mechanism of patient monitoring



Visual aid 3. Visual aid to clarify concept of continuous vital signs monitoring



Appendix 2: Baseline characteristics of patient population undergoing esophagectomy

Population characteristic	Classification	Result
Number of patients	N.A.	280
Male	N.A.	224 (80%)
Age at time of surgery (years)	N.A.	64 (8.6)
BMI (kg /m2)	N.A.	25.8 (4.1)
ASA classification	I	36 (12.9%)
	II	189 (67.5%)
	III	55 (19.6%)
Comorbidities	Any comorbidity	203 (72.5%)
	Cardiac comorbidity	56 (23.9%)
	Vascular comorbidity	108 (46.2%)
	Pulmonal comorbidity	64 (27.4%)
	Diabetes comorbidity	34 (14.5%)
	Urological comorbidity	23 (9.8%)
	Thrombo-embolic history	12 (5.1%)
Surgery type	Open	19 (6.8%)
	Minimally-invasive	261 (93.2%)
Surgical approach	Transhiatal	15 (5.4%)
	Transthoracic	265 (94.6%)
Anastomosis location	Cervical	118 (42.1%)
	Thoracic	162 (57.9%)
Neoadjuvant therapy	Chemotherapy	8 (3.0%)
	Chemoradiotherapy	247 (92.9%)
	Radiotherapy	1 (0.4%)
	No therapy	24 (8.6%)
Peroperative complication	N.A.	13 (4.6%)
Postoperative complication (within 30 days after surgery)	Pneumonia	90 (32.1)
	Anastomotic leak	62 (22.1)
	Other complication	122 (43.6)
	No complication	85 (30.4)

Baseline characteristics of patient population undergoing esophagectomy[1]
Values reflect the number of patients (% of total) or mean value (standard deviation). N.A.: not applicable; ASA: American Society of Anesthesiologists.
[1]Pooled population characteristics of patients undergoing elective esophagectomy between 2015 and 2016 in one of the three centers participating in this study.

Appendix 3: Themes elicited during context analysis

Main topic	Theme	Specification of theme
Current monitoring routine	Caregivers policy towards speed of activating further diagnostics	The policy towards the use of diagnostic imaging differs between hospitals, as caregivers either promote early activation or a wait-and-see policy
Early recognition of complications	Variable presentation of deterioration	The presentation of deterioration differs per patient
	Absence of early signs	Signs of deterioration are not visible in early phase of complications or in current routine measurements
	Limited specificity of routine measurements	Abnormal results of individual routine measurements are not enough to confirm complication
	Expertise level	Abnormalities may not be recognized or acted upon by less experienced clinicians or nurses
	Incomplete or delayed measurements	Early signs may be missed or delayed due to delayed or incomplete measurements
	Importance of trends	Trends in diagnostic test results are important to identify clinical deterioration or to recognize specific complications
Effectiveness of continuous vital signs monitoring	Limited sensitivity and specificity of vital signs	Vital signs have limited sensitivity and specificity for detection of specific complications, as abnormal vital sign levels may be caused by other factors and because complications do not always present with abnormalities in vital signs
	Effectivity of current patient monitoring approach	Current patient monitoring approach already promotes fast detection and response towards potential complications, and there is little room for further improvement
	Early signs already seen in other measurements	Early signs of deterioration observed in vital signs are preceded or accompanied by signs of deterioration in other measurements or clinical observations
	Continuity of measurements can fill current time gap	Early recognition of deterioration is expected because of the continuity of measuring, such that abnormalities are seen earlier as compared to current intermittent vital sign measurements
	Improved ability to identify trends	Early recognition of deterioration is expected because of the improved ability to identify trends

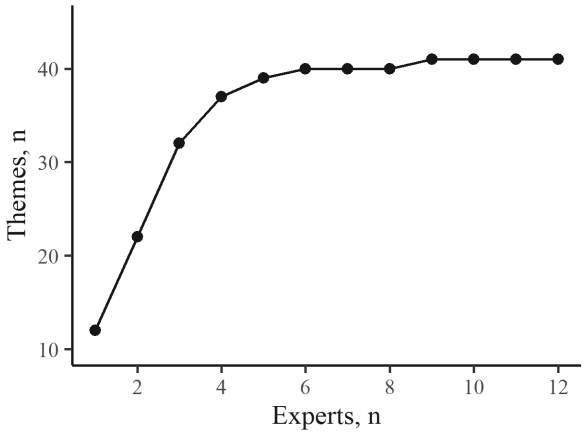
Appendix 3: (Continued)

Main topic	Theme	Specification of theme
	Increased awareness	Early recognition of deterioration is expected because of the increased awareness to vital sign abnormalities, caused by continuous measurements or active alarms
	Objective criteria for care escalation	Early action is promoted by providing an objective description of the patient status that can be used to justify escalation of care
	Confirmation of deterioration	Early action is promoted by providing extra confirmation of event/deterioration
	Clinical progress is awaited	Early recognition of deterioration will not lead to early treatment because clinical progress is awaited
	Diagnostic confirmation is awaited	Early recognition of deterioration will not lead to early treatment because diagnostic confirmation is awaited
	Need for escalation protocol	It should be clearly described what vital signs values are abnormal and which action is required
Effectiveness of continuous vital signs monitoring	Need for training in use of technology	Clinical staff should be trained in how to use the monitoring system and activate measurements
	Need for training in interpretation of vital signs	Clinical staff should be trained in how to interpret the measurements
	Need for automated alarms	Automated alarms / notifications are important for effective monitoring
	Need to retain subjective observations	The subjective evaluation by clinicians is important for adequate patient assessment, and should not be neglected
	Optimal implementation requires more insight	Experience and further research is required to find and establish effective monitoring routines

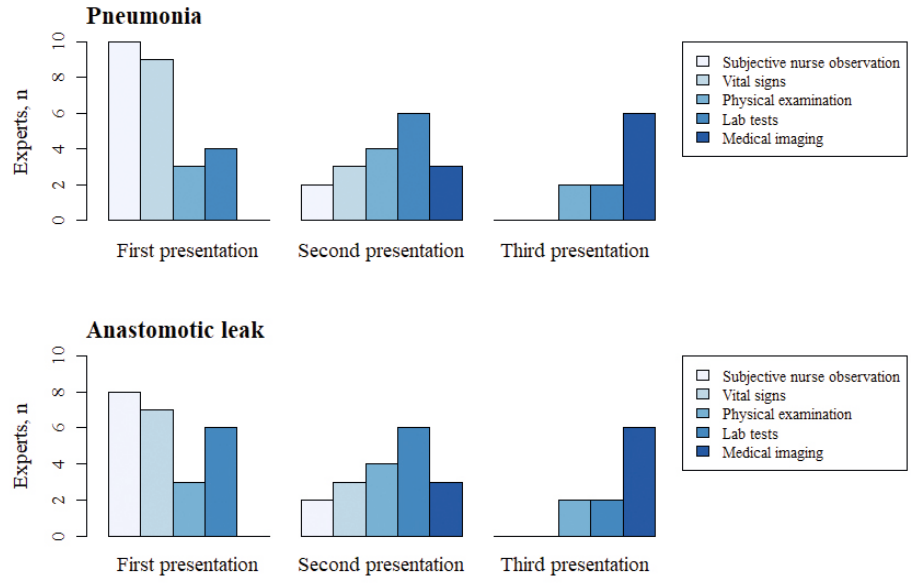
Appendix 3: (Continued)

Main topic	Theme	Specification of theme
Impact of continuous vital signs monitoring	Treatment period cannot be reduced	Complications require a certain treatment trajectory, which cannot be reduced with early recognition
	Insufficient time gain to improve clinical outcome	The expected potential time gain is not enough to improve clinical outcome measures
	Clinical outcome cannot be changed with early treatment	Clinical outcome of a given complication cannot be changed at all with early recognition or treatment
	Shifted treatment period	Early onset of treatment results in early completion, which reduced length of hospital stay
	Reduction of complication severity	Improvement in clinical outcome effected by reduced complication severity
	Faster recovery	Improvement in clinical outcome effected by faster recovery
	Impact depends on situation	The clinical impact affected by complication severity and patient characteristics
Considerations for implementation	Relevance dependent on complication number and severity	The clinical relevance of continuous monitoring depend on the number and severity of complications
	Nurse workload	Risk of increased nurse workload related to vital signs interpretation and response towards abnormalities
	Expectations towards level of care	Risk that the implementation of continuous monitoring will create increased expectations towards the level of care, assuming continuous surveillance and response
	Overdiagnosis or overtreatment	Risk of overdiagnosis and overtreatment
	Patient comfort	Risk of impaired patient comfort
	Patient experience	Effect on patient's experience or feeling of safety
	Financial consequences	Costs or financial gains
	Efficiency	Efficiency related to remote access and automation
	Alarm fatigue	Risk of high (false) alarm rates and associated alarm fatigue

Appendix 3: (Continued) Figure 1. Number of new themes that was elicited during context analysis in order of expert inclusion



Appendix 4: Typical order of early signs observed for pneumonia and anastomotic leak



Overview of the amount of participants (out of 12) that described that pneumonia or anastomotic leak is typically observed in the given routine measurement as first, second, or last sign of deterioration.

4

FEASIBILITY OF CONTINUOUS MONITORING OF VITAL SIGNS IN SURGICAL PATIENTS ON A GENERAL WARD: AN OBSERVATIONAL COHORT STUDY

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ABSTRACT

Objective

To determine feasibility, in terms of acceptability and system fidelity, of continuous vital signs monitoring in abdominal surgery patients on a general ward.

Design

Observational cohort study.

Setting

Tertiary teaching hospital.

Participants

Postoperative abdominal surgical patients (n=30) and nurses (n=23).

Interventions

Patients were continuously monitored with the SensiumVitals wearable device until discharge in addition to usual care, which is intermittent Modified Early Warning Score measurements. Heart rate, respiratory rate and axillary temperature were monitored every 2 min. Values and trends were visualised and alerts sent to the nurses.

Outcomes

System fidelity was measured by analysis of the monitoring data. Acceptability by patients and nurses was assessed using questionnaires.

Results

Thirty patients were monitored for a median duration of 81 hours (IQR 47–143) per patient, resulting in 115 217 measurements per parameter. In total, 19% (n=21 311) of heart rate, 51% (n=59 184) of respiratory rate and 9% of temperature measurements showed artefacts (n=10 269). The system algorithm sent 972 alerts (median alert rate of 4.5 per patient per day), of which 90.3% (n=878) were system alerts and 9.7% (n=94) were vital sign alerts. 35% (n=33) of vital sign alerts were true positives. 93% (n=25) of patients rated the patch as comfortable, 67% (n=18) felt safer and 89% (n=24) would like to wear it next time in the hospital. Nurses were neutral about usefulness, with a median score of 3.5 (IQR 3.1–4) on a 7-point Likert scale, ease of use 3.7 (IQR 3.2–4.8) and satisfaction 3.7 (IQR 3.2–4.8), but agreed on ease of learning at 5.0 (IQR 4.0–5.8). Neutral scores were mostly related to the perceived limited fidelity of the system.

Conclusions

Continuous monitoring of vital signs with a wearable device was well accepted by patients. Nurses' ratings were highly variable, resulting in on average neutral attitude towards remote monitoring. Our results suggest it is feasible to monitor vital signs continuously on general wards, although acceptability of the device among nurses needs further improvement.

INTRODUCTION

The postoperative complication rate after major abdominal surgery is 20%–44%,[1] which may result in reinterventions, prolonged hospital stay, intensive care unit (ICU) admissions and mortality,[2–4] and eventually to lower life expectancy, lower quality of life and higher costs.[5–7] Early detection of postoperative clinical deterioration on the ward may allow for early intervention and better outcomes.[8] Currently, the optimal frequency of vital sign measurements remains unknown. On most surgical wards they are monitored no more than one to three times a day.[9,10] Early warning scores, such as the Modified Early Warning Score (MEWS), are then used to help identify patients at risk.[11–13] A higher MEWS is associated with admission to the ICU, cardiac arrest and mortality.[14–16] However, a critical limitation of current monitoring practice is its infrequent and intermittent nature,[17,18] which may result in delayed detection of clinical deterioration, in particular during night shifts with lower staffing per patient rates.[19]

Recent advances in wearable, wireless sensor technology now facilitate continuous monitoring of vital signs.[20,21] Emerging evidence shows that these monitoring sensors are accurate, may improve outcomes and reduce costs by allowing earlier detection of changes in vital signs in clinical practice.[22] A previous study about continuous monitoring of abdominal surgical patients resulted in earlier antibiotics administration, decreased hospital stay and readmissions within 30 days.[23] Another study by Subbe et al.[24] reported more rapid response teams interventions, decreased cardiac arrests, reduced overall mortality, reduced illness severity and reduced mortality in those patients admitted to ICU, and an increase in proactive decision-making on end-of-life care. In addition, Weenk et al.[25] studied two continuous monitoring devices and reported that continuous monitoring was feasible if frequency and duration of measurements with artefact would be reduced.[25] Several other studies with wearable monitoring devices reported potential benefits such as less patient disturbance and improved sleep, reduced workload among nurses and improved safety during patient transport between departments.[26–29]

A new wearable patch device for wireless remote monitoring of vital signs has recently been tested in several hospitals, the SensiumVitals. The first published reports have shown it to be valid and safe.[23,30,31] However, there is still insufficient insight regarding the feasibility of using such a continuous monitoring device on a general ward, especially because continuous monitoring can be defined as a complex intervention with many interacting components and behaviour change of healthcare professionals.[32] As recommended by the Medical Research Council framework, feasibility testing and piloting are needed before larger scale clinical implementation of such an intervention

can be undertaken.[33] The aim of the study was to determine the feasibility, in terms of acceptability and system fidelity, of continuous vital signs monitoring with the SensiumVitals device among abdominal surgery patients on a general surgery ward.

METHODS

Design

An observational cohort study was conducted for a 3-month period (October–December 2019) on a surgical ward of a large tertiary teaching hospital. This study is reported in concordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[34]

Participants

Patients scheduled for elective colorectal or pancreatic resection were recruited through convenience sampling. Inclusion criteria were age ≥18 years, no cognitive impairments, expected hospitalisation time of 3 days or longer, and fluent in the Dutch language. Exclusion criteria were surgery for a palliative or emergency indication, a cardiac pacemaker in situ, a known allergy for any of the materials of the device or participating in another conflicting study. Emergency surgical patients were excluded because it was deemed not possible to obtain true informed consent. For nurses, eligibility criteria were nursing registration, active involvement in the continuous monitoring system for at least 3 days during the study, and able to speak and read the Dutch language.

Intervention

Current standard of care was intermittent monitoring (once daily) using the MEWS according to hospital policy.[35] In addition to standard care, patients included in the study were continuously monitored by the SensiumVitals system (*Sensium, Abingdon, UK*). This wireless monitoring device is CE (Conformité Européenne)-marked, approved by the Food Drug Administration and worn as a patch on the patient's chest. It continuously monitors heart rate (HR) in beats per minute (bpm), respiratory rate (RR) in breaths per minute (brm), and—via a secondary sensor—axillary temperature (T_{ax}) in degree Celsius.[36] The patch is attached to the skin by two adhesive ECG electrodes (*Skintact, Leonhard Lang, Innsbruck, Austria*), as shown in figure 1.

Figure 1: The SensiumVitals patch

The SensiumVitals patch is attached to the patient's chest and monitors heart rate and respiratory rate. The black 'wire' sensor is the external axillary temperature monitoring device

Every 2 min, the data were transmitted wirelessly through ceiling-mounted bridges to a dedicated server, and from there to a mobile device carried by the nurses and to their desktop. There were two types of alerts: vital sign and system alerts. Vital sign alerts were sent when the parameter value passed the preset thresholds (50 bpm < HR < 120 bpm; 8 brm < RR < 24 brm; or 34.5°C < T_{ax} < 38.5°C). These low and high thresholds were based on the MEWS' lower and upper thresholds.[10] For the upper threshold, the parameters correspond with the median value of MEWS 2. System alerts were sent when the connection was interrupted or when no valid measurement could be obtained. Each type of event had to occur continuously for a period of at least 14 min before an alert was sent out to the nurse. This time frame was based on previous clinical experience of the manufacturer, researchers and in consensus with the ward nurses. Literature about an optimal time frame for alerts is still lacking. Nurses were required to acknowledge each alert by pressing a button on their mobile device. After receiving a vital signs alert, the nurses were asked to measure the patient's vital parameters manually in accordance with the applicable hospital policy (MEWS). When

the nurse did not acknowledge the alert, reminders were sent until acknowledgement was confirmed.

Procedures

Before the start of the study, we tested if the system functioned properly and the nurses were trained in using the system and interpreting the data. Among the 35 nurses who had received training were 10 'key users', who received additional training in correctly applying the patch. Together with the researchers, they provided bedside teaching to other nurses on the general ward during data collection.

From October to December 2019 electively scheduled surgical patients were screened for eligibility by the nurse during preoperative admission on the ward. When patients agreed to participate, informed consent forms were signed. The SensiumVitals patch was attached postoperatively when patients arrived at the ward from the recovery unit or ICU. Continuous monitoring by the patch was continued until discharge. The day before discharge, patients' experiences were obtained using a questionnaire. After completion of enrolment of all 30 patients, nurses were asked to complete their questionnaires.

Data collection

The primary outcomes were acceptability and fidelity of the continuous monitoring system. Acceptability was measured cross-sectionally and fidelity prospectively. Baseline characteristics of patients were obtained from electronic medical record (EMR). Patients' postoperative complications were reported according to the Clavien-Dindo classification.[37,38] This scale classifies complications according to the following: grade I, no intervention needed; grade II, requiring pharmacological treatment; grade IIIa, requiring surgical, endoscopic or radiological intervention not under general anaesthesia; grade IIIb, requiring surgical, endoscopic or radiological intervention under general anaesthesia; grade IV, requiring admission to the ICU; and grade V, death of the patient.

Acceptability was measured as recruitment and retention rates and experiences of patients and nurses.[39] First, patient acceptability was measured by four questions using a 5-point Likert scale (strongly agree to strongly disagree) about comfort, safety and recommendation on future use, as shown in online supplemental appendix A. Second, for nurses the Usefulness, Satisfaction, and Ease of use (USE) questionnaire was used to measure acceptability.[40] This instrument is intended to identify the usefulness, satisfaction, ease of use and ease of learning of the intervention and consists of 30 statements on the beliefs about the monitoring system measured on a 7-point Likert

scale (online supplemental appendix B). The USE questionnaire was translated by two researchers (JPLL and EMD) to Dutch. We asked nurses to assess the concept of continuous monitoring, and not just the SensiumVitals technology. Both questionnaires had a free-text space for remarks.

Fidelity focused on the functioning of the SensiumVitals system and was obtained by analysis of the collected data.[41] Outcomes were total monitoring time, total number of artefacts, total number of (system and vital sign) alerts and the acknowledgement rate of the vital signs alerts. An artefact was registered if no valid measurement was recorded. Invalid values were identified by the algorithm of the system. All vital signs alerts were retrospectively categorised by two researchers (JPLL and EMD) as true positive, false positive or unclear based on clinical condition, nurse MEWS measurements and reports on the EMR.

Statistical analysis

Since a formal power calculation was not possible due to the lack of preliminary data with the SensiumVitals device, a sample size of 30 patients and 20 nurses was estimated to yield sufficient data for determination of feasibility.

All data were analysed by descriptive statistics. For continuous data, median and IQR or mean and SD were calculated based on normal distribution. Every parameter was checked for normality using the Shapiro-Wilk test and visually by a histogram.[42] For categorical data, frequencies and percentages were reported.

The questionnaire on patient acceptability was presented as categorical data. The USE questionnaire for nurses was reported as continuous data and was divided into constructs: usefulness, ease of use, ease of learning and satisfaction. To determine the reliability of the translated version of the USE, a Cronbach's α was determined for each construct. An α of >0.7 was considered consistent and therefore reliable. The remarks patients made were classified as positive, neutral or negative by two researchers, and the remarks of nurses were categorised within the constructs of the USE questionnaire. Finally, the fidelity of the system was analysed at the patient level. All analyses were performed with IBM SPSS Statistics V.24.0 for Mac.

Patient and public involvement

While we did not directly involve patients in the design or conduct of our study, our analyses were motivated by the belief that the patient acceptability outcomes were relevant to patients.

RESULTS

Study characteristics

A total of 36 patients were eligible to participate in the study. Of them, one patient was excluded due to a cognitive impairment, one patient declined to participate and four patients were lost to follow-up due to postoperative admittance at a technically unprepared part of the ward. This resulted in a recruitment rate of 94% (n=34) and a dropout rate of 11% (n=4). Eventually, 30 patients (male: n=17) participated in the study with a mean age of 66±10 years old. They underwent either colon (n=20), rectal (n=8) or pancreatic (n=2) resections. Eleven patients (36.7%) developed 16 complications in total. Of these, 12 were classified as grade I and II according to the Clavien-Dindo classification. An overview of the patient characteristics is given in table 1.

Acceptability: patients' perspectives

Twenty-seven patients (response: 90%) returned the questionnaire (table 2; figure 2). Of these, 25 patients (93%) rated wearing the patch as comfortable. Moreover, 18 patients (67%) felt safer during hospitalisation, although 8 patients (30%) were neutral about this statement. For a future admission in the hospital, 24 patients (89%) would like to wear it and 20 patients (80%) would be willing to wear the patch for postsurgical home monitoring. Patient experiences are quoted in box 1. There were no missing data in the returned questionnaires.

Acceptability: nurses' perspectives

Thirty-five nurses were approached, of whom 23 (response: 66%) returned the questionnaire, as shown in table 3 and figure 2. The median age of nurses was 28 years old (IQR 24–39) and they had a median working experience of 5 years (IQR 3–13). There were no missing data in the returned questionnaires and there was no difference in median age in the non-response group. Quotes of remarks are given in box 1.

The median score of usefulness was 3.5 (IQR 3.1–4.0; Cronbach's α=0.916). Out of 23 nurses, 61% (n=14) agreed that continuous monitoring by the patch was useful. However, 74% of the nurses (n=17) did not think the patch would save time and 70% (n=16) disagreed about the statement 'it does everything I expected'. One nurse reported she recognised the added value for the patient (box 1).

The median score for ease of use was 3.7 (IQR 3.2–4.8; Cronbach's α=0.937). Out of 23 nurses, 61% (n=14) disagreed with the statement that using it was effortless and 65% (n=15) could not use it without consulting the written instructions. Nurses stated it was

easy when the system operated without too many artefacts and alerts which could increase workload (box 1).

The median score of ease of learning was 5.0 (IQR 4.0–5.8; Cronbach's α=0.965). Out of 23 nurses, 15 (65%) agreed they easily remembered how to use it and quickly became skilful with it. No remarks were reported considering this construct.

The median score of satisfaction was 3.7 (IQR 2.9–4.4; Cronbach's α=0.931). Twelve of 23 nurses (52%) stated it was fun to use and 11 (48%) disagreed it was pleasant to use. Fourteen nurses (61%) disagreed with the need to add this device to routine workflow. There were no missing data on the returned questionnaires. Several remarks were made considering satisfaction, predominantly about malfunction of the system, frequency of alarms and the discrepancy with nurse measurements (box 1).

System fidelity

The total monitoring time was 3853 hours with a median of 81 hours (IQR 47–143) per patient. This resulted in a total of 115 217 measurements of the three vital signs. In total, 18.5% (n=21 311) of HR measurements, 51.4% (n=59 184) of RR measurements and 8.9% (n=10 269) of T_{ax} measurements were artefacts.

In total, 972 alerts (median per patient: 18; IQR 8.75–41.75) were sent by the SensiumVitals system, of which 90.3% (n=878) were system alerts and 9.7% (n=94) were about deviating vital signs. Although only three subjects were responsible for nearly half (41.4%) of all alerts, a direct cause for the artefacts and related system alerts was not found. The median alert rate was 4.5 per patient per day. The system alerts were generated because HR was not registered (n=180; 20.5%), RR was not registered (n=145; 16.5%), T_{ax} was not registered (n=151; 17.1%), leads were off (n=281; 32.0%) or the patch was being replaced due to an empty battery (n=28; 3.9%).

Of the 94 vital sign alerts, 12 (12.8%) were not acknowledged by the nurses. No downward trend during the study was seen in the acknowledgement rate. Of the alerts, 35% were true positives, 44% were false positives and 21% uncategorised, as shown in table 4. The percentage of true positive alerts was the highest for HR with 60% (n=9), followed by RR with 40% (n=16) and 20.5% for T_{ax}. T_{ax} had the most false positive alerts with 77% (n=30) vs 13% for HR and 22.5% for RR. False positive T_{ax} was caused by registration of subtemperature.

Table 1: Patient characteristics

N = 30	
Sex (n, %)	
Male	17 (56.7)
Female	13 (43.3)
Age (mean ± SD)	66.3 ± 10.2
BMI (mean ± SD)	25.6 ± 3.9
ASA-class (n, %)	
1	9 (30.0)
2	20 (66.7)
3	1 (3.3)
Type of surgery (n, %)	
Pancreatic resection	2
Rectal resection	8
Colon resection	20
Oncological indication (n, %)	26 (86.7)
Postoperative ICU admission (n, %)	
Yes	2 (6.7)
No	28 (93.3)
Length of stay (median, IQR)	4.0 (3.75-13.0)
Complications (n)	16
Grade I	9
Grade II	3
Grade IIIa	1
Grade IIIb	3

Abbrevations: ASA=American Society of Anesthesiologists

Table 2: Patient acceptability

	Disagree (1-2)	**Neutral (3)**	**Agree (4-5)**
I found the patch comfortable (n, %)	0 (0)	2 (7.4)	25 (92.6)
I felt safer with the patch (n, %)	1 (3.7)	8 (29.6)	18 (66.7)
I would like to wear the patch in the hospital next time (n, %)	1 (3.7)	2 (7.4)	24 (88.9)
I would also like to wear the patch at home after surgery (n, %)	3 (11.1)	2 (7.4)	22 (81.5)

Table 3: Remarks of patients and nurses (translated from Dutch)

Patients
Positive experiences:
'It provided a safe feeling for family also'
'I knew my limits through the system'
Negative experiences:
'It doesn't look reliable to me'
'The patch is comfortable, but glue residues from the stickers remain behind'
'Patch often changed because it was not working'
Neutral experiences:
'I forgot that the patch was there, therefore also neutral in terms of feeling safe.'
Nurses
Usefulness
'I see the added value for the patient'
Ease of use
'It is easy for the patients where it works'
'I found the product promising, but at the moment I think it costs us more work than it saves'
Ease of learning
None
Satisfaction
'I often had different values with the patient that did not match when I started to do manual measurements. This meant that I didn't get so much faith in the device'
'You are always at his bedside because there is no proper image of vital functions.'
'Receiving all alarms from all patients in the nursing ward. This is annoying due to continuous alarms but also for patients.'
'Very often there was no clear picture of breathing and heartbeat.'
'Frequency of alarms was high due to malfunctions'
'The mobile app regularly operates slow'

Table 4: USE questionnaire among nurses

	Median + IQR	Disagree (1-3)	Neutral (4)	Agree (5-7)
Usefulness (α = .916)	3.5 (3.1-4)			
It helps me be more effective.	4 (3-4)	9 (39.1)	10 (43.5)	4 (17.4)
It helps me be more productive.	3 (3-4)	13 (56.5)	8 (34.8)	2 (8.7)
It is useful.	5 (4-5)	3 (13.0)	6 (26.1)	14 (69.6)
It gives me more control over the activities in my work.	4 (3-5)	9 (39.1)	7 (30.4)	7 (30.4)
It makes the things I want to accomplish easier to get done.	3 (3-4)	12 (52.2)	8 (34.8)	3 (13.0)
It saves me time when I use it.	3 (2-4)	17 (73.9)	3 (13.0)	3 (13.0)
It meets my needs.	3 (3-5)	12 (52.2)	5 (21.7)	6 (26.1)
It does everything I would expect it to do.	3 (2-4)	16 (69.6)	4 (17.4)	3 (13.0)
Ease of use (α = .937)	3.7 (3.2-4.8)			
It is easy to use	4 (3-5)	6 (26.1)	6 (26.1)	11 (47.8)
It is simple to use	4 (3-6)	6 (26.1)	7 (30.4)	10 (43.5)
It is user friendly	4 (3-5)	8 (34.8)	4 (17.4)	11 (47.8)
It requires the fewest steps possible to accomplish what I want to do with it	4 (3-5)	11 (47.8)	4 (17.4)	8 (34.8)
It is flexible	4 (3-5)	8 (34.8)	7 (30.4)	8 (34.8)
Using it is effortless	3 (3-4)	14 (60.9)	5 (21.7)	4 (17.4)
I can use it without written instructions	4 (2-5)	15 (60.9)	1 (4.4)	7 (30.4)
I don't notice any inconsistencies as I use it	3 (2-4)	13 (56.5)	7 (30.4)	3 (13.0)
Both occasional and regular users would like it	4 (3-5)	8 (34.8)	7 (30.4)	8 (34.8)
I can recover from mistakes quickly and easily	4 (3-5)	8 (34.8)	9 (39.1)	6 (26.1)
I can use it successfully every time	3 (3-5)	13 (56.5)	4 (17.4)	6 (26.1)
Ease of learning (α = .965)	5 (4-5.8)			
I learned to use it quickly.	5 (4-6)	4 (17.4)	7 (30.4)	12 (52.2)
I easily remember how to use it.	5 (4-6)	5 (21.7)	3 (13.0)	15 (65.2)
It is easy to learn to use it.	5 (4-6)	8 (34.8)	4 (17.4)	11 (47.8)
I quickly became skillful with it.	5 (4-6)	4 (17.4)	4 (17.4)	15 (65.2)
Satisfaction (α = .931)	3.7 (2.9-4.4)			
I am satisfied with it.	4 (3-5)	9 (39.1)	6 (26.1)	8 (34.8)
I would recommend it to a friend.	4 (3-4)	8 (34.8)	10	5 (21.7)
It is fun to use.	5 (4-5)	5 (21.7)	6 (26.1)	12 (52.2)
It works the way I want it to work.	3 (2-4)	12 (52.2)	9 (39.1)	2 (8.7)
It is wonderful.	3 (2-4)	12 (52.2)	7 (30.4)	4 (17.4)
I feel I need to have it.	3 (2-4)	14 (60.9)	7 (30.4)	2 (8.7)
It is pleasant to use.	4 (2-5)	11 (47.8)	6 (26.1)	6 (26.1)

Abbrevations: IQR: Interquartile range; SD: standard deviation; α: Cronbach's Alpha

Figure 2: Diagram of patient and nurses acceptability

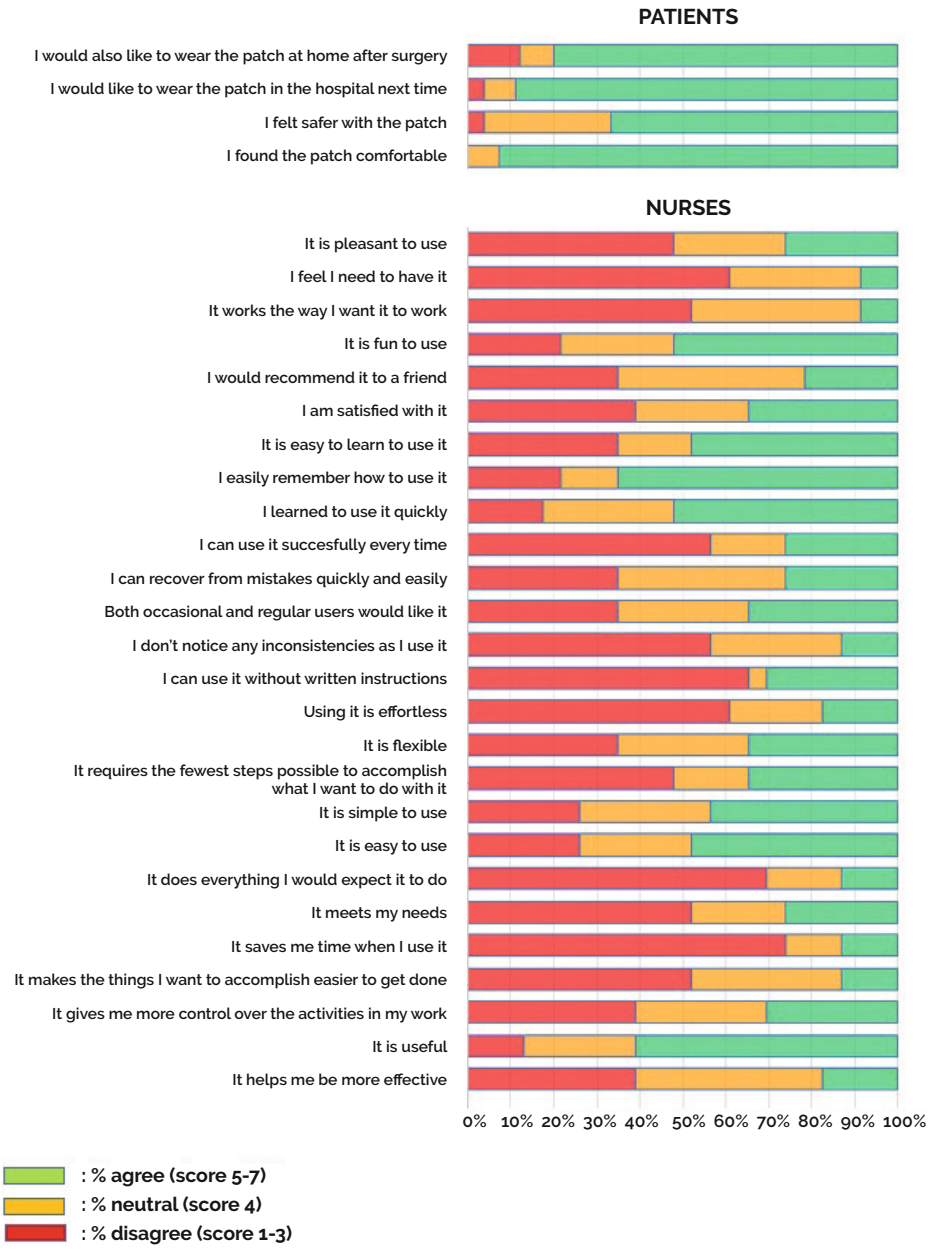

Table 5: Classification of vital signs alerts

	True positives	False positives	N/A*	Total
Total alerts (n, %)	33 (35.1)	41 (43.6)	20 (21.3)	94
HR alerts (n)	9	2	4	15
RR alerts (n)	16	9	15	40
T_{ax} alerts (n)	8	30	1	39

*N/A: uncategorized

DISCUSSION

In this study we aimed to determine the feasibility in terms of acceptability and fidelity of continuous wireless vital signs monitoring of abdominal surgery patients on the general ward. Patient acceptability of the patch sensor was high. Wearing the patch for several days was well tolerated and made patients feel safer. Most patients indicated they wished to be remotely monitored during a possible future hospital stay. However, a significant proportion of nurses were not yet convinced of the added value of continuous monitoring on the general ward.

Comparison with previous work

The high acceptability by patients of this wearable wireless monitoring device, both in terms of 'wearability' and feeling safe, is in line with previous studies.[25,43–47] Nonetheless, one patient expressed scepticism about the reliability of the system. A similar concern was reported in the qualitative study of Downey et al.[44]

The lower acceptability by nurses could be related to the large number of system alerts, which can be considered clinically irrelevant and thus disturbing. This was well reflected in the remarks of nurses and is in agreement with a previous study by Prgomet et al.[48] about the perceptions of nurses before implementation of a continuous monitoring device. The cause of these alerts is the large number of artefacts and the relatively short time frame of 14 min before an alert is generated by the system. As a result, this has likely resulted in increased workload for nurses, which decreases their willingness to fully rely on the system as yet and may lead to alert fatigue.[49]

When considering system fidelity, the number of artefacts encountered in the present study was still considerably lower for all three parameters in comparison with a previous study with the SensiumVitals system: HR: 19% vs 41%; RR: 51% vs 66%; T_{ax}: 9% vs 27%, respectively.[30] The high percentage of RR measurement artefacts is most likely

due to the fact RR was measured by impedance, which is affected by the motion of the patient and rejected by the strict algorithm of the SensiumVitals. Although temperature measurements had the least number of artefacts (14%), this was the parameter with the most false positive alerts (77%). This is probably due to transient dislocation of the sensor generating an apparent low T_{ax} and thereby sending a false alert. Overall, the number of alerts was experienced as unacceptably high, which is in agreement with previous studies with these devices.[25,43] In these previous studies, the alarm thresholds were adjusted and the time intervals increased, to decrease the number of alerts.

Besides frequency and false alarm rate, lower acceptability by nurses can also be explained by the fact that nurses on general wards are not used to working with and interpreting trend data of monitoring devices, as well as the lack of literature on optimal thresholds and a clinically relevant time frame for alerts.[20] Therefore, we believe that the frequency and false alarm rate and acceptability of such remote wireless monitoring systems by nurses might be dramatically improved with the inclusion of a reliable clinical decision support algorithm that takes the vital signs trends, as well as the relationship between various vital signs, into account instead of only generating alarms based on absolute values.[20]

Limitations

Several limitations should be considered when interpreting our results. First, the study population was limited to patients undergoing major abdominal surgery and therefore may not be representative of other patient populations. Emergency surgical patients are more prone to complications and may thus derive more benefit from continuous vital signs monitoring.[50] However, they were not included because of the need for informed consent.

In addition, acceptability of remote wireless vital signs monitoring among healthcare professionals may be influenced by several factors we were unable to account for in this study. The study duration was relatively short, and the intervention was not yet fully integrated into standard care pathways and workflows in the ward. The limited number of patients and exclusion of emergency surgery may account for the fact that we did not observe any life-threatening conditions with the system. Lack of integration with the EMR may have negatively influenced nurses' experiences with the system. Access to the vital signs trend data required many additional, time-consuming steps, resulting in potentially lower commitment and acceptability. Also, during this feasibility study, nurses still had to calculate routine early warning scores, leading to increased total nurse workload. In addition, the results are based on this specific continuous monitoring system while other systems are also available. Lastly, categorising vital

signs alerts was done retrospectively, which may have introduced bias in categorising true and false positive alerts because in some cases adequate documentation was lacking.

Conclusion

Continuous monitoring of vital signs in abdominal surgery patients by the SensiumVitals wearable device was well accepted by patients, but only moderately by nurses. Use of this system was feasible on the surgical ward, but to increase acceptability among nurses the system needs improvements, in particular a significant reduction in artefacts and alerts. One desirable development would be the addition of a well-validated system for clinical decision support and smooth integration into hospital EMR. These results may provide helpful insights for larger scale implementation and (cost-)effectiveness studies of continuous monitoring on the general ward.

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APPENDICES

Appendix A: Questionnaire for patients

I found the patch comfortable				
1	2	3	4	5
Strongly disagree				Strongly agree
The patch made me feel safer				
1	2	3	4	5
Strongly disagree				Strongly agree
I would like to wear the patch in the hospital next time again				
1	2	3	4	5
Strongly disagree				Strongly agree
I would like to wear the patch at home after surgery				
1	2	3	4	5
Strongly disagree				Strongly agree

Appendix B: USE questionnaire (translated from Dutch)

Usefulness				
It helps me be more effective.				
1	2	3	4	5
Strongly disagree				Strongly agree
It helps me be more productive.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is useful.				
1	2	3	4	5
Strongly disagree				Strongly agree
I would like to wear the patch at home after surgery				
1	2	3	4	5
Strongly disagree				Strongly agree
It gives me more control over the activities in my life.				
1	2	3	4	5
Strongly disagree				Strongly agree
It makes the things I want to accomplish easier to get done.				
1	2	3	4	5
Strongly disagree				Strongly agree
It saves me time when I use it.				
1	2	3	4	5
Strongly disagree				Strongly agree
It meets my needs.				
1	2	3	4	5
Strongly disagree				Strongly agree
I found the patch comfortable				
1	2	3	4	5
Strongly disagree				Strongly agree
It does everything I would expect it to do.				
1	2	3	4	5
Strongly disagree				Strongly agree

Ease of Use				
It is easy to use.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is simple to use.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is user friendly.				
1	2	3	4	5
Strongly disagree				Strongly agree
It requires the fewest steps possible to accomplish what I want to do with it.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is flexible.				
1	2	3	4	5
Strongly disagree				Strongly agree
Using it is effortless.				
1	2	3	4	5
Strongly disagree				Strongly agree
I can use it without written instructions.				
1	2	3	4	5
Strongly disagree				Strongly agree
I don't notice any inconsistencies as I use it.				
1	2	3	4	5
Strongly disagree				Strongly agree
Both occasional and regular users would like it.				
1	2	3	4	5
Strongly disagree				Strongly agree
I can recover from mistakes quickly and easily.				
1	2	3	4	5
Strongly disagree				Strongly agree
I can use it successfully every time.				
1	2	3	4	5
Strongly disagree				Strongly agree

Ease of Learning				
I learned to use it quickly.				
1	2	3	4	5
Strongly disagree				Strongly agree
I easily remember how to use it.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is easy to learn to use it.				
1	2	3	4	5
Strongly disagree				Strongly agree
I quickly became skillful with it.				
1	2	3	4	5
Strongly disagree				Strongly agree
Satisfaction				
I am satisfied with it.				
1	2	3	4	5
Strongly disagree				Strongly agree
I would recommend it to a friend.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is fun to use.				
1	2	3	4	5
Strongly disagree				Strongly agree
It works the way I want it to work.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is wonderful.				
1	2	3	4	5
Strongly disagree				Strongly agree
I feel I need to have it.				
1	2	3	4	5
Strongly disagree				Strongly agree
It is pleasant to use.				
1	2	3	4	5
Strongly disagree				Strongly agree

5

NURSES' EXPERIENCES WITH CONTINUOUS VITAL SIGN MONITORING ON THE GENERAL SURGICAL WARD: A QUALITATIVE STUDY BASED ON THE BEHAVIOUR CHANGE WHEEL

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ABSTRACT

Background

To support early recognition of clinical deterioration on a general ward continuous vital signs monitoring (CMVS) systems using wearable devices are increasingly being investigated. Although nurses play a crucial role in successful implementation, reported nurse adoption and acceptance scores vary significantly. In-depth insight into the perspectives of nurses regarding CMVS is lacking. To this end, we applied a theoretical approach for behaviour change derived from the Behaviour Change Wheel (BCW).

Aim

To provide insight in the capability, opportunity and motivation of nurses working with CMVS, in order to inform future implementation efforts.

Methods

A qualitative study was conducted, including twelve nurses of a surgical ward in a tertiary teaching hospital with previous experience of working with CMVS. Semi-structured interviews were audiotaped, transcribed verbatim, and analysed using thematic analysis. The results were mapped onto the Capability, Opportunity, Motivation – Behaviour (COM-B) model of the BCW.

Results

Five key themes emerged. The theme 'Learning and coaching on the job' linked to Capability. Nurses favoured learning about CVSM by dealing with it in daily practice. Receiving bedside guidance and coaching was perceived as important. The theme 'interpretation of vital sign trends' also linked to Capability. Nurses mentioned the novelty of monitoring vital sign trends of patients on wards. The theme 'Management of alarms' linked to Opportunity. Nurses perceived the (false) alarms generated by the system as excessive resulting in feelings of irritation and uncertainty. The theme 'Integration and compatibility with clinical workflow' linked to Opportunity. CVSM was experienced as helpful and easy to use, although integration in mobile devices and the EMR was highly favoured and the management of clinical workflows would need improvement. The theme 'Added value for nursing care' linked to Motivation. All nurses recognized the potential added value of CVSM for postoperative care.

Conclusion

Our findings suggest all parts of the COM-B model should be considered when implementing CVSM on general wards. When the themes in Capability and Opportunity are not properly addressed by selecting interventions and policy categories, this may negatively influence the Motivation and may compromise successful implementation.

BACKGROUND

Serious unexpected adverse events and complications occur regularly on general surgical wards, especially in the group of high-risk postsurgical or elderly frail patients.[1–3] On general wards the current standard of care is intermittent monitoring of vital signs with Early Warning Scores (EWS), in which nurses play an important role in the measurement, recognition of possible deterioration, and follow-up.[4] Common used scores are the New EWS (NEWS) in the UK and the Modified EWS (EWS) in Continental Europe and the USA. However, important limitations of these scores are their intermittent nature and the optimal measurement frequency remains unknown.[5–8] This potentially results in delayed detection of events and thereby inferior patient outcomes.[9]

Over the last few years, wearable, wireless measurement devices, such as smart patches on the chest and wrist worn devices for continuous monitoring of vital signs (CMVS) of patients have become available for ambulant patients on general wards.[10] A systematic review about these devices mostly found studies reporting technical validation and feasibility outcomes.[11] Several of these studies reported a broad range of acceptability rates of nurses in working with CMVS devices.[12–17] We also found moderate rates on usability and satisfaction by nurses in our recent feasibility study with the SensiumVitals® CMVS system on our general surgical ward.[18] It is important to recognize that implementation of CMVS can only be successful if nurses are able to integrate this technology in routine patient care work flow.[19, 20] Importantly, only when successful implementation in nursing care has been realized, one can reliably investigate the potential effect on patient outcomes and value.

The Behaviour Change Wheel

To guide intervention development and implementation of a CMVS system on the general ward a systematic evidence based approach is needed, such as the Behaviour Change Wheel (BCW) (Fig. 1).[21] The BCW enables selection of interventions that influence behaviour, which needs to change to enable and support implementation.

The core layer of the BCW is the Capability, Opportunity and Motivation model (COM-B) (Fig. 2).[21] According to the COM-B model, behaviour is part of an interacting system of the social and physical factors. For an individual nurse to engage in a specific behaviour (B) there is a need for 'capability' (C) to do it, both psychological and physical. There must also be the social (e.g., support from others) and physical (e.g., the necessary resources) 'opportunity' (O) to perform the behaviour. And finally, there must be sufficient strong 'motivation' (M) to undertake the desired new behaviour

over other competing behaviours. Motivation covers automatic processes involving emotional reactions, desires and impulses, as well as reflective processes involving self-conscious planning and beliefs about what is good and bad.[22] Also, Capability and Opportunity may have an influence on Motivation in the model.

Understanding these factors helps to determine which COM-B components needs to shift for the desired behaviour to occur. After this behavioural diagnosis, the BCW identifies intervention functions and policy categories likely to be effective in bringing about change.[22] So, by defining the COM-B, effective interventions can be selected to address behaviour.

Published studies about CMVS monitoring so far mainly assessed nurses' experiences with acceptability questionnaires.[15,16,18] There is a lack of more in-depth insight in the opinions and experiences of this important stakeholder group for the implementation of CMVS. Therefore, the aim of this study is to provide insight in the capability, opportunity and motivation of nurses providing CMVS, in order to inform and support future implementations using the BCW.

Figure 1: The Behaviour Change Wheel[21]

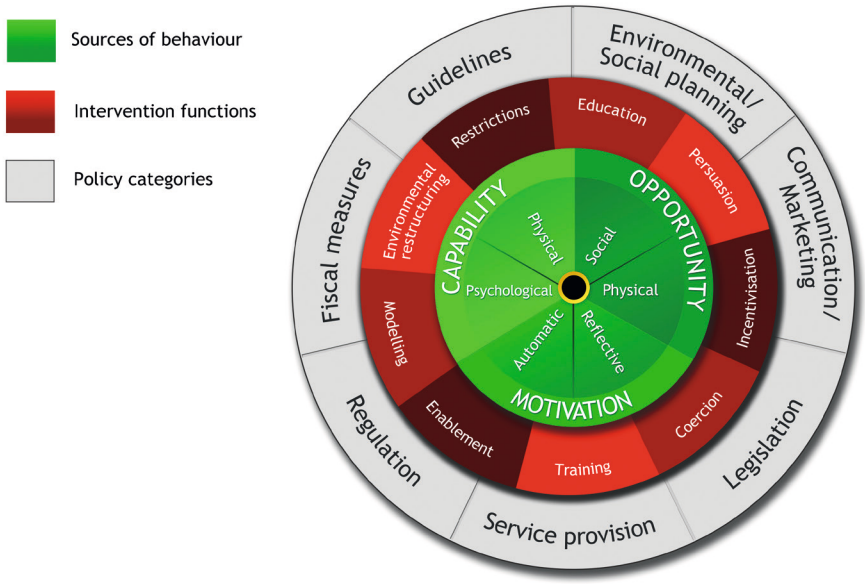
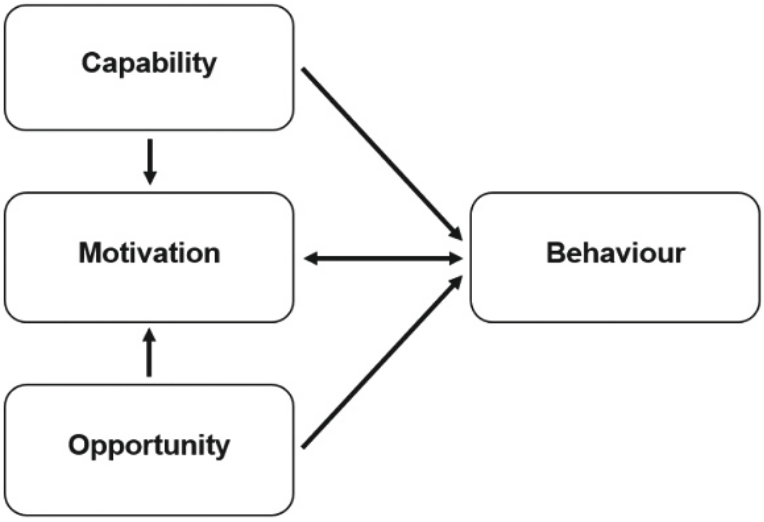


Figure 2: The COM-B model[21]



METHODS

Design

A qualitative study design was applied utilizing semi-structured interviews. This study is reported in concordance with the Consolidated criteria for reporting qualitative research (COREQ).[23]

Recruitment and participants

All nurses (n = 35) who worked with the SensiumVitals® CMVS system in a previous feasibility study on a general surgical ward of Isala, a large tertiary teaching hospital in the Netherlands, were eligible to be interviewed.[18] In our previous study, 30 postoperative abdominal patients were continuously monitored over a three month period resulting in 1–4 simultaneously monitored patients of a total of six patients per nursing shift. When passing vital signs thresholds, alarms were sent out to the nurses on a mobile device. These thresholds were based upon the conventional MEWS thresholds.[3] After receiving a vital signs alert, the nurses were asked to measure the patient's vital parameters manually in accordance with the routine hospital policy; measuring all parameters for a MEWS score. At the end of study, nurses were asked to complete the Usefulness, Satisfaction, and Ease of use (USE) questionnaire.

To explore the nurses' views and judgments about CMVS, we subsequently interviewed a purposive sampled group of nurses. Maximum variation sampling ensured inclusion of a broad range of perspectives. Recruitment continued until maximum variation was met for age, work experience, the median score on the USE questionnaire or non-response on the questionnaire in the previous study. Sampling based on the USE questionnaire scores was divided in positive (score 4.6–7.0), negative (score 1.0–3.4) or neutral. (3.5–4.5 score).[24] Eventually twelve nurses were approached and agreed to participate in the interviews with a median duration of 37.5 min (IQR 33.80-IQR 46.36). All respondents were female with a median age of 27.5 (IQR 23–31.5) years old and a median of 5.5 (IQR 2–8.5) of years' work experience. A broad range of responses on the USE questionnaire of the previous study was represented, namely positive (n = 5), neutral (n = 3), negative (n = 2) and non-response (n = 2). The selected participants were approached by email by JL. After explaining the goal of the study and the voluntary participation, informed consent was gained and an interview was scheduled. At the start of the interview, the researchers were not aware of the interviewee's score on the USE questionnaire to prevent confirmation bias. No new themes emerged after interviewing ten participants.

Data collection

In preparation for the study, the interviewers (JL; male and ED; female) were trained in qualitative research methods. Both interviewers were part-time employed as nurses at the same ward where the CMVS system was implemented and they knew the nurses before the interviews. Semi-structured, face-to-face interviews were conducted with the nurses at the hospital in a secluded office on the ward between April 2020 and August 2020.

The 25 interview questions were divided over the three elements of the COM-B model (see Additional File 1). The topic guide was developed by three researchers (JL, ED and GP), pilot tested with one ward nurse, and revised during the iterative process of data collection and analysis. The interviewer was guided by the topic scheme, but was allowed to change the sequence of questions within the topics or to add questions for emerging topics. Different probing techniques such as remaining silent, echoing, and asking for elaboration were used to gain further insight into experiences.[25]

All interviews were audio-recorded and transcribed verbatim. Keynotes were used to record feelings and thoughts of the researcher.[26]

Data analysis

The interviews were analysed using deductive thematic analysis using the qualitative data analysis software NVivo 11 (*QSR International, London, UK*). The raw data was

analysed using a six-stage thematic analysis as outlined by Braun and Clarke.[27] The stages include: (1) immersion; (2) generating initial codes; (3) searching for and identifying themes; (4) reviewing themes; (5) defining and naming themes; and (6) writing the report.

Stage 1 to 3 were conducted independently by two researchers (JL and ED). During the first and second stage, JL and ED became familiar with the data by listening to the audio recordings, checking the transcriptions against the audio recording, reading, listening sections again and re-reading the final transcripts. During the third stage, both researchers read the transcripts and codes for categorizing similar statements into first themes.

For the fourth and fifth stages, JL, ED, AvH and CK were responsible for reviewing, defining and naming themes, which were discussed with the other authors. AvH is an expert in qualitative research. Eventually, in the sixth stage the themes were mapped to the COM-B model and discussed with all authors. During the sixth stage, the themes were brought to the nurses for member checking by e-mail, which did not result in any changes to the themes.

RESULTS

The analytical process resulted in five key themes: learning and coaching on the job, interpretation of vital sign trends, added value for nursing care, management of alarms and integration and compatibility with clinical workflow.

Learning and coaching on the job

All of the nurses indicated that receiving training and education is conditional to acquire adequate knowledge of the system and to be able to start with CMVS. The preferred educational methods were training sessions, such as an e-learning module, but also information by e-mail. Also, the timing of training and dosage of the amount of information was considered important, preferably shortly before the start of the implementation and repeated regularly during implementation to keep their acquired knowledge up to date. Some nurses who were not trained expressed feelings of insecurity in using the system. However, these feeling were also present in nurses who had gained knowledge by the training. One nurse stated:

> *'In the beginning I had to get used to it for a while and I still felt insecure about some aspects of continuous monitoring. But it did help that we just started doing*

it and having an involved project leader and key users. There was always an opportunity to ask questions and she was also often present in the department, so that you just became really confident in working with it.' (R15).

Several nurses believed it was important to develop skills in CMVS by handling it in daily practice, the learning on the job. Further, supportive for learning on the job, some nurses mentioned to prefer a printed guideline but, more importantly, coaching by the project leader or from key users and colleagues on the ward. During their shift, key users provided information and instructions to the nurses. One nurse mentioned:

'I think that you should also give proper education and training beforehand. But also providing extra training for the people who find it difficult in advance. For example, by setting up a personal coaching plan for the nurse. So, you really have to spend time on one-on-one guidance in the first period, so that nurses feel heard. (...) To be able to ask questions about your patient with continuous monitoring to a colleague who knows the system well, that will get you going.' (R10).

Several nurses indicated that education before the start of the vital signs monitoring in practice, does not work without applying the new knowledge at the bedside. In particular, practical skills such as pairing the patient to the platform or attaching the patch sensor to the patient are best taught at the bedside. One nurse stated:

'To be honest, we had training before the start, but that did not really take root at the time. At the start of the implementation, I really think it would be difficult to work with continuous monitoring. Because you really need the experience in real-life practice, with real patients, if you want to be able to work with this new device properly.' (R4).

Also, some nurses indicated that it required some time to gain the practical skills and get used to the new work process. Several nurses mentioned that only a few patients had CMVS instead of all of them during their shifts. As a result, working with two work processes for vital sign monitoring was difficult, confusing and sometimes experienced as extra work. Therefore, they would prefer a higher patient volume of CMVS in the study. One nurse stated:

'Yes, continuous monitoring is something that if you want to perform well, I think you really should do it structurally. And I mean, just really work with the system every day with every patient. Not only with some of your patients. Then you will easily learn the system during a few shifts, just in your daily work.' (R1).

In summary, nurses favoured learning CMVS by actually dealing with such systems in daily practice. An important success factor was that guidance and coaching was available during the initial period of implementation.

Interpretation of vital signs trends

All of the nurses mentioned their experience with interpreting and judging vital sign trends, but their perspectives varied. On one hand they indicated they were able to assess the trend properly, and on the other hand some nurses experienced difficulty because of the lack of knowledge of what normal trends should look like. Also, the pre-specified vital signs thresholds were guiding in the interpretation, but deviating or irregular trends within the thresholds were challenging to interpret in combination with the clinical status of the patient. Difficulty was also experienced when there were invalid or missing measurements in the trend. One nurse said about this:

> *'I think it is quite hard in the beginning, because you do not know what a vital sign trend should look like. Especially when taking the patient status, activity and missing data in the trend into account. Those factors are important to consider when assessing the trend.'* (R6).

For interpreting the vital sign trends, several nurses thought a clear protocol would be useful. They especially experienced challenges in clinical decision support and follow-up of alarms, because it was unclear what the follow-up actions should be when one vital sign deviated. Also, they found CMVS to be a supplement to current vital signs protocols, mainly because they strongly feel that the full range of vital signs is needed to measure an Early Warning Score. They indicated that measuring more vital signs, provided a more complete insight in the clinical status of the patient. Also they found some specific causes of clinical deterioration are detected by other vital signs, such as blood pressure or body temperature. Therefore, the more vital values are continuously measured, the more complete and informative the scores will be for nurses and physicians. A nurse said about this:

> *'Nowadays we work with the Early Warning Scores. Those are recognizable and guiding in our follow-up actions, like calling a physician when a score is 5. The trends and thresholds did not provide such clear follow-up. Also, because continuous monitoring still does not measure all the vital signs to generate a proper EWS.'* (R2).

Some nurses considered the collaboration with physicians vitally important for successful interpreting the trends and the follow-up. They thought physicians have

more knowledge and experience in trend assessment and should play a major role in the follow-up of deviating trends. They believed the physician has the responsibility to determine medical policy in the event of clinical deterioration. Also, some nurses said it was a shared responsibility of the nurse and physician and that close collaboration is important in vital sign monitoring. For example, one nurse said:

> *'Besides trend assessment by us as nurses, physicians must be involved. They need to know how to act based on deviating trends. Eventually, they are responsible for the medical policy following the trend'* (R3).

Within their reports on the trend, the nurses placed trends in the perspective of their clinical assessment. One nurse stated:

> *'Yes, I think I should see continuous monitoring as a helpful tool. I don't see it as a substitute for me as a nurse, like: "Oh that one patient has a wireless vital sign monitor and I can blindly rely on those measurements". But your own clinical assessment of the patient besides vital signs remains most important. For example, if you observe values measured by the device, it is important that you always use your own observations as a nurse and decide whether it fits the patient's condition.'* (R7).

Also, most of the interviewed nurses mentioned they had no experience with a clinically deteriorating patient with a continuous vital sign monitor during this study period. They thought this would be helpful to learn to interpret the vital sign trends. A nurse said about this:

> *'I think it is helpful if you cared for a patient that had an acute clinical deterioration. Then you possibly have a clear picture of such a deviating vital sign trend in combination with the clinical status of the patient.'*

This statement relates to the previously mentioned theme learning and coaching, on which several nurses mentioned learning in practice with real patients was important for successful use of the CMVS systems. Further, nurses believed that CMVS could support their clinical reflection and judgment during their work, although several believed that their overall clinical assessment of the patient was important for the evaluation of trend monitoring, and that technology alone cannot be relied upon for clinical decision making.

Added value for nursing care

All nurses recognized the potential added value of CMVS for postoperative nursing care based upon their experience in practice. They considered vital signs as an important element of clinical evaluation on the ward and believed this technology may contribute to earlier detection of clinical deterioration by better insight into the vital sign trends and thus increase the safety of care. One nurse stated about this:

> *'I think it can offer a lot for us and patients, especially if you are able to detect the complications earlier. By the insight in trends you may detect clinical deterioration earlier between the routine measurements. In addition, in the end that you also get less intensive care unit (ICU) admissions or patients who spend less time on the ICU.'* (R6).

Also, several nurses thought that CMVS may only prove to be beneficial for patients with a high risk of clinical deterioration, for whom the benefits of rapid recognition of acute deterioration are most obvious. They considered there should be a clear rationale to measure vital signs at a high frequency. Otherwise, they considered current manual measurement intervals to be sufficient. A nurse said:

> *'I would not see much added value for low-complexity care. These patients already have a low risk of complications and so clinical deterioration of vital signs. For example, consider an appendectomy.'* (R1).

In relation to this statement, the same nurse also mentioned that the costs of implementation of CMVS systems should be in proportion to the benefits for patient care. High costs for the implementation and for the purchase of software or hardware should be justified by a reduction in the cost of care through a decrease of complication rate, length of stay, ICU admission or readmissions. A nurse said:

> *'If the wearable sensor is very expensive, it is worth considering whether the investment is worth it for the particular patient group. I do not think it is effective to apply on those low-complex care patients.'* (R1).

Besides, having ability of continuous insight in the patient vital signs, the nurses found the possibility of remote monitoring of the patient especially useful during night shifts because of the higher patient-to-nurse ratio. Also, one nurse mentioned there is a desire not to unnecessarily wake the patient. A nurse said:

'During the night shift you have a direct insight and an overview whether each patient is still breathing or showing abnormalities in vital signs. This is really helpful when you nearly have a half ward of patients to take care of.' (R11).

Overall, nurses believed in the potential added value of CMVS to increase the safety of care by earlier detection of clinical deterioration by better insight into the vital sign trends.

Management of alarms

Most nurses mentioned their experience with the alarms generated by the CMVS system. All of them experienced that the system generated too many and too many false alarms. This was possibly caused by the system's set time frame of only fifteen minutes for sending out alarms. Besides, the false alarms were mainly caused by the system's strict artefact rejection algorithms for respiratory rate and motion artefacts. These alarms were experienced as disruptive and caused feelings of uncertainty and lead to irritation. One nurse said:

'I found the number of alarms that you got on your telephone the most inconvenient for me. There were really too many. This was often already with a deviation or technical problem for a short time. For instance, when you support in mobilization, you don't have time to check the notification on your phone every time. You can't leave the patient at all at that moment so an alarm does not add up to better care. (...) Sometimes I was happy when the alarms didn't ring for a while.' (R1).

This quote reveals feelings of possible agitation about the alarms, potentially related to the extra workload caused by the need to respond to the alarms. Also, feelings of uncertainty raised by alarms were caused by having doubts about their own clinical experience by receiving multiple and frequent alarms. They also mentioned that many alarms and the relatively high rate of false alarms also indirectly may have bothered the patients because of the necessary extra checks conducted at the bedside. Nurses suggested user-adjustable alarm settings to decrease false alarm rate and prevent alarm fatigue. One nurse said about this:

'Often as a nurse you could not do anything with the alarm because the heart rate had already dropped again or the connection had already been restored. Then you start doubting whether you are doing your work right or not missing any abnormalities in the patient condition. (...) Also, adjusting values to the specific patient could be helpful in reducing alarms.' (R5).

In summary, the quantity and frequency of (false) alarms generated by the CMVS system were experienced as excessive. This resulted in feelings of agitation and uncertainty, when they were unable to directly respond to the alarms. In addition, they mentioned that the availability of continuous monitoring on the ward should not be a reason to consider this type of vital sign monitoring to be similar to an ICU setting.

Integration and compatibility with clinical workflow

Nurses found CMVS easy to use overall. However, working with CMVS and the integration in nursing practice was influenced by a number of factors.

Several nurses preferred a CMVS system technically integrated into their existing mobile devices without restrictions in the range of the wireless connection. Also, they strongly favoured integration of vital signs trends into the Electronic Medical Record (EMR) allowing more effective documentation, evaluation and productivity. A nurse said:

> *'It does work better for me if we can assess the trends in the current used systems such as the EMR, but also receiving alarms on the calling system instead of using a separate phone. This makes everyday use much easier'* (R7).

Further, two nurses mentioned that availability of CMVS should not be a reason to discharge patients earlier from the ICU to the ward. They expressed certain fears that this might result in a higher workload and unsafe nursing care. A frequently mentioned reason was the inability to immediately respond to alarms as reported in the previous theme. This also highlights that the focus on and importance of vital signs monitoring is perceived differently by general ward nurses and ICU nurses. One nurse said:

> *'If an alarm rings from one patient and at the moment you are bathing a patient and you also have to care for four other patients, then responding to the alarm can be challenging. I think that's different on an ICU.'* (R9).

Other mentioned reasons relating to clinical workflows were the current high workload at their ward because of the lower nurse-patient ratio. Also, they believed not to have the technical nursing skills and knowledge of vital signs monitoring that ICU patients would need. One nurse said about this:

> *'Continuous monitoring should not be a reason for patients to be discharged from the ICU to our ward earlier. We care for many more patients per nurse and in*

case of acute deterioration we do not have the same resources. It then becomes impossible to provide good quality care. Maybe even dangerous for patients.' (R9).

Several nurses also expressed the hope that in the future CMVS devices will be able reduce the workload of current routine manual measuring and registering vital signs, allowing them to be more productive and have more dedicated time for patient care. One nurse said:

'I hope in the future wearable sensor will measure the full spectrum of vital signs so I don't have to collect them manually several times a day. This will save time which I can still devote to many other tasks during a busy shift.' (R5).

Overall, CMVS was experienced helpful and easy to use, although several improvements were mentioned such as integration in mobile devices and EMR and the need to securely manage clinical workflows and protocols when transferring high-risk patients from the ICU.

Themes in relation to the COM-B

The five generated themes were mapped onto the COM-B model (Table 1). Two themes related to Capability and two themes were related to Opportunity. All themes had a relation to Motivation. One theme was linked to Motivation.

Table 1: Themes mapped onto the COM-B model

Theme	COM-B component
Learning and coaching on the job	Capability, Motivation
Interpretation of vital signs trends	Capability, Motivation
Management of alarms	Opportunity, Motivation
Integration and compatibility with clinical workflow	Opportunity, Motivation
Added value for nursing care	Motivation

DISCUSSION

To our knowledge, this is the first study providing an overview of nurses' perceptions of behavioural factors that influence implementation of a CMVS system on general surgical wards. Application of the COM-B model provides a theoretical framework for understanding nurses' views and behaviour in CMVS systems on the ward and may guide in selecting the relevant interventions and policy categories of the BCW. Using semi-structured interviews five relevant themes were identified a related to nurses' capability, opportunity, and motivation, which were mapped onto the COM-B model. As expected, themes within Capability and Opportunity were also potentially influencing Motivation.

Considering Capability, it was evident that nurses must be adequately trained before starting to work with the CMVS system. However, for successful implementation, bedside learning and coaching to enhance their knowledge and skills in clinical practice, seem to be important for nurses. The desire of developing skills and training with support and coaching during implementation of CMVS was also reported in other studies.[12,15] Although it seems that this type of learning may be most appropriate, it is also advised to offer other types of learning methods to match the various learning style preferences as well as take into account the variation in attitudes towards innovation.[28,29] Related to this, nurses perceived that a certain minimum volume of patients with CMVS on the ward is needed to build routine. Nurses consider this essential, especially in the initial phase of the implementation which is in line with previous findings that eHealth acceptance requires sufficient time and exposure by a high patient volume.[30]

The capability of nurses to interpret vital signs' trends was also important. Nurses mentioned assessing trends instead of the standard absolute EWS values was challenging. This is in line with statements of physicians about nurses not having adequate training to interpret continuous data in an earlier study.[31] Besides training, developing adequate trend interpretation skills is expected to take a high patient volume and specific exposure to clinically deteriorating patients with CMVS, which was limited in this study.

Moreover, nurses' overall clinical assessment, obtained by direct patient contact and based on their professional experience, should be incorporated into the evaluation of vital sign trends. Obviously, nurses' observations on the patient status and possible clinical deterioration is much more than just monitoring vital signs. Current sensors and vital sign trends still do not include factors such as the nurse worry factor and the

critical EWS component 'level of consciousness'.[32–34] In line with other studies, the value of the nurse's clinical observations in detection of deterioration was also with respect to reservations about a potential decrease in the bedside nurse-patient contacts by using CMVS which may limit the value of their clinical judgement.[15,35,36]

Also, nurses strongly valued the role of the physician in trend assessment because of their expertise with vital sign trends interpretation as part of their clinical judgement. Besides, they thought physicians should play a role in the follow-up of the trends. This may also be a relevant factor for implementation of such systems, which was mentioned in a previous study, in the context that CMVS may support interdisciplinary communication between nurses and doctors.[12]

Considering Opportunity, nurses generally believed that CMVS may fit well into their clinical workflow, which was also recognized in other studies.[31,37] Although, we found that smooth integration in IT systems and clinical workflows as well as selective alarm management are important factors to support successful CMVS implementation. Specifically, this includes the need for CMVS data integration into the EMR and in mobile devices and an adequate connectivity and range of the sensor, which was also mentioned in previous studies.[11,36] Also, integration in clinical workflows should be optimized. Especially, clear criteria to prevent premature transfers of patients from ICU to the general ward with CMVS are needed, which was also was mentioned as a potential worry in another study.[32]

Importantly, the multitude of (false) alarms in our study was perceived as excessive, which may cause alarm fatigue and may be a major barrier for successful implementation. In several other studies, nurses also reported frequent (false) alarms to be the biggest disruptive factor for their work processes[31,38], although in one study nurses found alarms were generally appropriate.[16] Currently, alarm strategies used by CMVS systems are mostly based on conventional high or medium care unit protocols, using pre-set thresholds values. However, this does not consider other factors such as the delta of trends over time, the mobilization of the ambulant patient on general wards, and circadian rhythm of the patient. Therefore, for general wards more sophisticated alarm strategies would be desirable, but these are still under development.[39] Alternatively, strategies relying on routine trend assessments only (e.g. several times per day) rather than using pre-set alarms may be a solution to deal with excessive alarms and support implementation and compliance on general wards.

Considering Motivation, nurses seem to be clearly motivated to use this innovation because they believe in the potential for improving the quality and safety of patient

care. The potential benefit for patients was also recognized by nurses in several other studies with a CMVS systems, specifically for earlier detection of clinical deterioration in certain high risk patient groups and providing remote insight in the patients vital signs during night shifts.[14,31,32,36] Unfortunately, contrary to common belief among nurses strong evidence for clinical benefit and cost-effectiveness is still lacking due to the various study designs, low study quality and various outcome measures used in available published reports.[11,40] However, providing nursing care according to the principles of Evidence-Based Practice is more than just the following the evidence, but also consists the preferences of the patient and clinical expertise of the nurses.[41]

Taken all together, based on the five themes identified and subsequent mapping onto the COM-B model, several intervention functions of the BCW may be applied to allow successful implementation (Fig. 1).[22] Bedside training and education could enhance the Capability of nurses about CMVS. Enablement and environmental structuring may address the themes mapped onto Opportunity as described above. Lastly, modelling may strengthen the Motivation of nurses. Supporting to the intervention functions, the possible policy categories of the BCW could be guidelines, environmental planning and legislation.

Limitations

The findings in this study need to be interpreted in light of several limitations. First, our study was performed on a Dutch general surgical ward which may affect transferability to other countries and specialisms. Also, the experience of nurses was with one particular CMVS platform (SensiumVitals®), while many other systems are available.[11, 42] However, we emphasized beforehand to respondents that we wished them to give us their opinion on the concept rather than the particular system we used. Furthermore, we only included female nurses in our study so results may not be transferable for male nurses. However, a previous study did not show a significant effect on technology acceptance between genders.[43] Moreover, respondents' experience with CMVS was based on a relatively short period of working with the new system and a limited number of patients per nursing shift, whereas sufficient exposure is a known condition for successful implementation of innovations. Also, the extensive interview guide gave a broad overview of the nurses' perceptions but limited in-depth insights. Moreover, framing of the themes to the COM-B and BCW model may have limited the openness of the interviews as other frameworks such as the Technology Acceptance model are not considered.[44,45] However, the COM-B model does take the challenging context factors on the ward into account. Finally, JL and ED were part-time employed as nurses at the same ward where the CMVS system was implemented. Although it was explicitly stated that answers had to be given honestly, this may have influenced

the social desirability of the answers. On the other hand, the interviewers had a broad experience in clinical nursing, qualitative research methods as well as the technical aspects of CMVS. This supported the understanding of the context and quality of the study design. Another strength of this study was that the application of analyst triangulation by coding and forming and framing themes was done independently by several authors (JL and ED).

Conclusion

CMVS using wearable wireless devices may support the timely detection of clinical deterioration. Successful implementation of such novel technology is important but challenging. This study provides an overview of the nurse experiences regarding the implementation of CMVS on a general surgical ward. Our findings suggest all parts of the COM-B should be considered when implementing CVSM on general wards, with particular attention to the complexity of interaction of the elements of the model. When the themes in Capability and Opportunity are not properly addressed in the selection of interventions and policy categories, this may negatively influence the Motivation and may compromise successful implementation.

Collectively, our findings related to the COM-B model may guide implementation strategies of CMVS systems on general wards when using the intervention functions and policy categories of the BCW. Further studies should focus on evaluation of implementation strategies of such systems in daily practice.

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Abbreviations

BCW	Behaviour Change Wheel
COM-B	Capability Opportunity Motivation – Behaviour
EMR	Electronic Medical Record
IT	Information Technology
USE	Usefulness, Satisfaction, and Ease of use questionnaire

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Availability of data and materials

All data generated or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The Daily Board of the Medical Ethics Committee of Isala Zwolle, the Netherlands, reviewed the protocol and waived the need for formal ethical approval of the study (protocol no. 200329). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each nurse to participate in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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APPENDICES

Appendix 1: Interview guide (translated from Dutch)

CAPABILITY	
Psychological Capability	
Knowledge	Did you have sufficient understanding of the possible benefits of continuous monitoring? Were you familiar with any guidelines or policies during the study? Can you describe what the guidelines or policies say?
Behavioural Regulation	What do you think is needed to ensure that you consistently provide continuous monitoring to patients?
Memory, Attention, and Decision Process	Are there situations when you think it would be difficult to provide continuous monitoring to patients? (prompt – can you tell me what it is about these situations that make it difficult)
Physical Capability	
Skills	Did you feel you have the skills to provide effective continuous monitoring to patients? (prompt –are there any other skills that you need?) What skills do you think are needed to provide effective continuous monitoring to patients?
OPPORTUNITY	
Social Opportunity	
Social influences	Did you ever discuss continuous monitoring or policies with other nurses at your ward? Did other nurses at your ward influence your decision to provide continuous monitoring to patients? How would they influence your practice? To what extent? Do your colleagues value providing effective continuous monitoring to patients?
Physical Opportunity	
Environmental Context and Resources	What factors outside of your professional/practice environment influenced your ability to provide more effective continuous monitoring? Were there competing tasks or time constraints that would influence your ability to provide more effective continuous monitoring?
MOTIVATION	
Automatic Motivation	
Reinforcement	Were there any incentives for you to provide continuous monitoring? What are they? When you provide continuous monitoring to patients do you feel like you are making a difference? Why or why not?

Appendix 1: (Continued)

MOTIVATION	
Emotion	Does discussing continuous monitoring ever evoke an emotional response in you? (prompt – would you feel worried or concerned about providing continuous monitoring?) Thinking about yourself and how you normally feel as a professional that works with patients, to what extent do you feel inspired to provide continuous monitoring?
Reflective Motivation	
Social/Professional Role And Identity	What responsibilities did you have as a nurse to provide continuous monitoring at the ward? How was continuous monitoring consistent or inconsistent with your profession? How compatible was the provision of continuous monitoring with your profession?
Beliefs About Capabilities	How confident did you feel in your ability to work with continuous monitoring at your ward? How easy or difficult was it to provide continuous monitoring at your ward to patients? What would made it easy or difficult for you?
Beliefs about Consequences	Do you find continuous monitoring at your wards useful?
Optimism	How optimistic are you about the future of continuous monitoring on the general surgical ward?
Intentions	On a scale of 1 to 10 and 10 being very important, how important do you think it is for you to provide continuous monitoring to patients at your hospital? Why?
Goals	Would the goal of improving and implementation continuous monitoring at your wards be compatible with your usual practice? Why?

6

FEASIBILITY OF WIRELESS CONTINUOUS MONITORING OF VITAL SIGNS WITHOUT USING ALARMS ON A GENERAL SURGICAL WARD: A MIXED METHODS STUDY

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ABSTRACT

Background

Wireless continuous vital sign monitoring by wearable devices have recently become available for patients on general wards to promote timely detection of clinical deterioration. Many continuous monitoring systems use conventional threshold alarm settings to alert nurses in case of deviating vital signs. However, frequent false alarms often lead to alarm fatigue and inefficiencies in the workplace. The aim of this study was to determine the feasibility of continuous vital sign monitoring without the use of alarms, thereby exclusively relying on interval trend monitoring.

Methods

This explanatory sequential mixed methods study was conducted at an abdominal surgical ward of a tertiary teaching hospital. Heart rate and respiratory rate of patients were measured every minute by a wearable sensor. Trends were visualized and assessed six times per day by nurses and once a day by doctors during morning rounds. Instead of using alarms we focused exclusively on regular vital sign trend analysis by nurses and doctors. Primary outcome was feasibility in terms of acceptability by professionals, assessed by the Usefulness, Satisfaction and Ease of Use questionnaire and further explored in two focus groups, as well as fidelity.

Results

A total of 56 patients were monitored and in 80.5% (n = 536) of nurses' work shifts the trends assessments were documented. All deviating trends (n = 17) were recognized in time. Professionals (N = 46) considered continuous monitoring satisfying (4.8±1.0 on a 1–7 Likert-scale) and were willing to use the technology. Although insight into vital sign trends allowed faster anticipation and action upon changed patient status, professionals were neutral about usefulness (4.4±1.0). They found continuous monitoring easy to use (4.7±0.8) and easy to learn (5.3±1.0) but indicated the need for gaining practical experience. Nurses considered the use of alarms for deviating vital signs unnecessary, when trends were regularly assessed and reported.

Conclusion

We demonstrated that continuous vital signs trend monitoring without using alarms was feasible in the general ward setting, thereby avoiding unnecessary alarms and preventing alarm fatigue. When monitoring in a general ward setting, the standard use of alarms may therefore be reconsidered.

INTRODUCTION

One of the first signs of major postoperative complications is deterioration of vital signs.[1] On general nursing wards vital signs are routinely monitored intermittently 1–3 times daily to allow timely recognition of deterioration[2] which may reduce mortality rates and length of hospitalization.[3] Studies have shown that vital signs trend changes may already occur 8 to 24 hours before life-threatening events such as cardiac arrest, ICU admission and mortality.[1,4–7] To assist the interpretation of vital signs measurements Early Warning Scores have been developed that consist of weighted vital parameters.[8–11] However, a critical limitation of these early warning score systems is that measurements are intermittent.[12,13] Particularly during the night shift, clinical deterioration may remain undetected until the next morning.[14]

Given the recent advances in monitoring technology, wearable and wireless continuous monitoring of vital signs is now available as a potential solution for earlier detection of clinical deterioration on general wards.[15–17] These wearables have shown to be reasonably accurate and also have the potential to improve patient outcomes and reduce cost.[18,19] Most of these systems come with conventional alarm strategies based on single parameter threshold values comparable with those in high care units for critically ill patients. An alarm may indicate an acute adverse event requiring urgent intervention, or–much more frequently–a transient signal artefact.[20]

In contrast to high care units, vital signs monitoring on general wards serve a different goal. Patients are not critically ill and therefore clinical deterioration typically occurs more gradually and acute events are extremely rare[21], thereby reducing the need for conventional alarm settings for monitoring on general wards. Also, current alarm strategies do not consider factors such as increased physical activity of ambulant patients on general wards[22], which may result in more frequent false alarms and even delayed response and alarm fatigue.[13,23,24]

A crucial element for successful implementation of continuous monitoring systems on general wards is the acceptability to nurses, doctors and patients.[16,20] A major factor influencing acceptance ratings by nurses is the alarm rate and the frequency of false alarms.[25] Given the relatively low nurse-to-patient ratio on general wards, any systems generating unnecessary or unreliable alarms will disrupt nursing work flows and make successful implementation extremely challenging.[26] A high frequency of alarms may also affect patients, resulting in disruptive and undermining confidence in the technology.[20,27]

Therefore, it is questionable whether using alarms adds any value for continuous vital sign monitoring on general wards. An alternative method for vital sign monitoring is using regular interval trend analysis by healthcare professionals. Monitoring while switching off the alarms and structurally focusing on vital signs trends by nursing staff and doctors may lead to better outcomes and at the same time improve acceptability of the continuous monitoring system.[28] To date, we are not aware of any studies demonstrating the feasibility of a continuous monitoring system without setting active alarms. Therefore, the aim of this study is to determine feasibility, in terms of acceptability and fidelity, of continuous vital sign monitoring on a general surgical ward without the use of alarms, exclusively focusing on regular vital sign trend assessments.

METHODS

Design and setting

An explanatory sequential mixed methods design was used to determine feasibility over a 4-month period (July-October 2020) on a 24-bed surgical ward in Isala, a large tertiary teaching hospital in the Netherlands.

Participants

Patients scheduled for elective colorectal, hepatic or pancreatic resection were recruited through convenience sampling to the continuous monitoring intervention. Inclusion criteria were: age ≥ 18 years, no cognitive impairments, expected hospitalization time three days or longer and able to speak and read the Dutch language. Exclusion criteria were: unable to wear a continuous monitoring device due to a pacemaker or allergy, or participating in another conflicting study.

Nurses and doctors who were employed at the ward during the study period were approached. Eligibility criteria were: nursing or medical registration and having worked with the continuous monitoring system for at least one month during the study period.

Intervention and implementation

Current standard of care was intermittent monitoring (once daily) using the Modified Early Warning Score (MEWS) according to the hospital policy.[29] In addition to standard care, patients included in the study were continuously monitored by the Philips Biosensor BX100 and Intellivue Guardian Solution software system (*Philips, Eindhoven, The Netherlands*). This wireless monitoring device is a patch worn on the patient's chest, which continuously monitors heart rate (HR) in beats per minute (bpm) and respiratory rate (RR) in respirations per minute (rpm). The continuous monitoring system

is Conformité Européene–(CE) marked and was developed as a continuous monitoring tool for general wards and not for high care units.

Once every minute, the vital sign measurements were transmitted wirelessly through ceiling-mounted bridges to the Intellivue Guardian Solution system, and displayed on a mobile device carried by the nurses and on desktop computers (for both nurses and doctors). The vital sign measurements were integrated with the Electronic Medical Record (EMR). Within the Guardian software, trends were visualized and, complementary to the hospital MEWS protocol, a sub MEWS-score (D-EWS) was aggregated from the thresholds for HR and RR (S1 Appendix). If the HR and RR were abnormal, a D-EWS score was generated for each system (cardiac, respiratory) and visualized in the trend to promote assessment.

Every four hours, i.e. twice per shift, nurses routinely assessed the vital signs trends and reported the D-EWS score, deviations and possible subsequent actions in the EMR. In addition, every day these trends were discussed during the doctor's morning rounds.

Before start of the study, half of the ward (24-beds) was prepared for continuous monitoring. For participating nurses and doctors, short informative reports were sent weekly by e-mail. These reports contained information about the purpose of the study, the rationale for continuous monitoring, the protocol, the work processes and agreements, the practical use of the continuous monitoring system and assessing the vital sign trends of the monitoring. Prior to the start of the implementation, all the previously provided information was further elaborated and discussed in group education. When providing information, it was clarified that the continuous monitoring system was intended as a trend assessment tool and not as patient surveillance tool as used in high care units.

During the implementation, on-the-job coaching was provided by the researcher (JL) at the start of the day shift and evening shift from Monday to Friday. In addition, there was a biweekly update by e-mail about the progress of the study, initial results at patient level and feedback on the performance of the work process.

Study procedures

From July to September 2020, electively scheduled surgical patients were screened for eligibility by the nurse during pre-operative admission on the ward and received information about the study. When patients agreed to participate, informed consent forms were signed. The biosensor-patch was attached postoperatively when patients arrived at the ward from the recovery or the intensive care unit. Continuous monitoring

by the patch was continued for at least five days. The day before discharge, patients' experiences with continuous monitoring were obtained through a questionnaire. After completion of the study period, nurses and doctors were asked to complete questionnaires and focus groups were conducted.

Sample size

Considering a 66% response rate in our previous study[20] in the same population, we considered a sample size of at least 45 professionals (70% response) as sufficient to determine acceptability resulting in an acceptable margin of error of 8% with a 95% Confidence Interval based up on the total population of 63 nurses.[30] Also, two focus groups of about 6–7 nurses each was expected sufficient to capture all views on acceptability.[31] During the pre-defined implementation period of three months all relevant patients were approached for participation, adding up to a total of 65 patients who could be included in the study.

Ethical considerations

The Medical Ethics Review Committee of Isala waived the need for ethical approval (protocol no. 200632). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient to participate in the study.

Data collection

Quantitative data

Primary outcome was the acceptability by nurses and doctors of the continuous monitoring system. The Usefulness, Satisfaction, and Ease of use (USE) questionnaire was used for measuring acceptability.[32] This instrument is intended to identify the usefulness, satisfaction, ease of use and ease of learning of the intervention and consists of 30 statements on the beliefs about the continuous monitoring system measured on a 7-point Likert scale (1 = strongly disagree; 4 = neutral; 7 = strongly agree).

Secondary outcomes were patient acceptability, fidelity of the continuous monitoring system and clinical outcomes. Patient acceptability was measured as recruitment and retention and by six questions using a 5-point Likert scale (strongly agree to strongly disagree) about comfort, safety and recommendation on future use (S2 Appendix). Fidelity was defined as the quality of technically delivery and adherence to the protocol by the nurses.[33] Quality of technically delivery was obtained from analysis of the automated collected data: total monitoring time, total number of 'artefacts' and total number of (technical and physiological) notifications. Adherence to the protocol was based on the proportion of written reports on trend assessment by nurses and

the follow-up of deviating trends. Besides, registered clinical outcomes of patients were: complications according Clavien-Dindo[34], mortality, reinterventions, unplanned ward transfers and unplanned ICU admissions and readmissions after discharge, and emergency department (ED) admissions. In addition, a description of cases with deviating trends of heart rate and respiration trends were provided.

Qualitative data

The qualitative element of the study aimed to elaborate on the experiences of the professionals working with the intervention by discussing the mean scores found on the four constructs of the USE questionnaire after analysis (S3 Appendix).[35] Two semi-structured focus groups consisting of a minimum of four convenience-sampled professionals each were conducted in a secluded room on the ward in the last week of the study. A topic list guided the focus group (S3 Appendix: Topics focus groups). The focus groups were led by one of the researchers (JL) and audio recorded and transcribed verbatim. No field notes were taken.

Statistical analysis

Quantitative data

Quantitative data were analyzed by descriptive statistics. For continuous data, medians and interquartile ranges (IQR) or means and standard deviations (SD) were calculated based upon normal distribution. Every parameter was checked for normality by the Shapiro-Wilk test and visually by a histogram.[36] For categorical data, frequencies and percentages were reported.

The USE questionnaire was divided in the constructs: usefulness, ease of use, ease of learning and satisfaction. To determine reliability of the translated version of the USE, a Cronbach's alpha was determined for each construct. An α of >0.7 was considered consistent and therefore reliable. All analyses were performed with IBM SPSS Statistics 24.0 for Mac (*IBM Armork, New York, USA*).

Qualitative data

For the focus groups, a six-stage thematic content analysis was used for analysis using the qualitative data analysis software NVivo 11 (*QSR International, London, UK*).[37] The stages include: (1) immersion; (2) generating initial codes; (3) searching for and identifying themes; (4) reviewing themes; (5) defining and naming themes; and (6) writing the report.[37] During the immersion stage, JL and HR became familiar with the data by listening to the audio recordings, checking the transcriptions against the audio recording, reading, listening again and re-reading the final transcripts. The second and third stage, were conducted independently (JL and HR) before discussing themes

with all other authors. Eventually, the themes were brought to the nurses for member checking.

Mixed methods: Integration and interpretation

Integration of the quantitative and qualitative elements of the study occurred through linking the methods of data collection and analysis.[38] Linking of methods occurred through building: the quantitative data of the questionnaire informed the data collection of the focus groups. The scores on the USE-questionnaire were presented and discussed in the focus groups.[38] Linking in the analysis occurred through the weaving approach: writing both quantitative and qualitative findings together on a theme-by-theme basis[38], showing how the quantitative data were supported and explained by the themes identified from the qualitative data.

RESULTS

Study characteristics

A total of 63 patients were approached, of whom 2 declined because they considered participation to be too much effort. Of the 61 included patients, eventually 5 patients were unable to participate due to postoperative admission to an unprepared part of the nursing ward (n = 4) and a palliative indication of surgery (n = 1). Eventually, 56 patients (male: n = 30) participated in the study with a median age of 71 years old (IQR 63–80), as shown in Table 1. In total, 75% (n = 42) had an oncological indication for surgery and colon resection was the indication for surgery in 62.5% (n = 35) of patients. An overview of the patient characteristics is given in Table 1 and test results for normality in S1 Table.

Acceptability by healthcare professionals

After the study period, sixty-three healthcare professionals were approached of which 46 (response: 73%) returned the USE questionnaire (Tables (Tables22 and and3:3; S4 Appendix). Median age was 28 years old (IQR 24.5–41.3) and the median working experience was five years (IQR 3.8–14.0). Two were doctors (4.3%) and 43.5% of the nurses (n = 20) had a higher education. There were no missing data in the returned questionnaires.

Table 1: patient characteristics and outcomes

Patient characteristics (N=56)	
Age in years (median, IQR)	71 (63-80)
Sex (n, %)	
Male	30 (53.6)
Female	26 (46.4)
Body Mass Index (kg/m^2) (median, IQR)	25.9 (23.0-29.4)
Type of surgery (n, %)	
Colon resection	35 (62.5)
Rectal resection	6 (10.7)
Pancreatic reseaction	8 (14.3)
Liver resection	7 (12.5)
ASA classification (n, %)	
1	5 (8.9)
2	32 (57.1)
3	19 (33.9)
Oncological indication (n, %)	42 (75.0)
Tumor stage (n, %)	
T1	3 (5.4)
T2	4 (7.1)
T3	23 (41.1)
T4	5 (8.9)
Metastases	7 (12.5)
n/a	14 (25.0)
Comorbidities (n, %)	
Diabetes Mellitus	9 (16.1)
Cardiovasculair diseases	19 (33.9)
Pulmonary diseases	8 (14.3)
Clinical outcomes	
Length of stay (days) (median, IQR)	5 (4-7)
Complications (Clavien-Dindo classification) (n)	21
I (n,%)	8 (38.1)
II (n,%)	10 (47.6)
IIIa (n,%)	1 (4.8)
IV (n,%)	1 (4.8)
V (n,%)	1 (4.8)

Table 1: (Continued)

Clinical outcomes	
< 30 days mortality (n, %)	1 (1.8)
< 30 days ED admission (n, %)	2 (3.6)
< 30 days readmission (n, %)	4 (7.1)
Reinterventions (n, %)	2 (3.6)
Unplanned ward transfer	2 (3.6)
Unplanned ICU admissions (n, %)	2 (3.6)

Table 2: Healthcare professionals' characteristics

N=46	
Sex (n, %)	
Male	3 (6.5)
Female	42 (93.5)
Age in years (median, IQR)	28 (24.5-41.3)
Work experience in years (median, IQR)	5 (3.8-14.0)
Role (n, %)	
Doctor	2 (4.3)
Nurse	44 (95.7)
Higher nursing education	20 (45.5)
Mid-level nursing education	24 (54.5)

Table 3: Acceptability of healthcare professionals (n=46)

	Total score	Disagree (1-3) (n, %)	Neutral (4) (n, %)	Agree (5-7) (n, %)
Usefulness (α = .906) (mean ± SD)	4.4 ± 1.0			
It helps me be more effective (median, IQR)	4.0 (3.8-5.0)	11 (23.9)	14 (30.4)	21 (45.7)
It helps me be more productive (median, IQR)	4.0 (3.0-5.0)	6 (13.0)	10 (21.7)	30 (65.2)
It is useful (median, IQR)	6.0 (5.0-6.0)	1 (2.2)	7 (15.2)	38 (82.6)
It gives me more control over the activities in my work (median, IQR)	4.0 (3.0-6.0)	14 (30.4)	13 (28.3)	19 (41.3)
It makes the things I want to accomplish easier to get done (median, IQR)	4.0 (3.0-5.0)	13 (28.3)	13 (28.3)	20 (43.5)
It saves me time when I use it (median, IQR)	4.0 (3.0-5.0)	19 (41.3)	13 (28.3)	12 (26.1)
It meets my needs (median, IQR)	4.5 (4.0-5.0)	7 (15.2)	16 (34.8)	23 (50.0)
It does everything I would expect it to do (median, IQR)	4.0 (3.0-5.0)	13 (28.3)	11 (23.9)	22 (47.8)
Ease of use (α = .921) (mean ± SD)	4.7 ± 0.8			
It is easy to use (median, IQR)	5.0 (5.0-6.0)	1 (2.2)	7 (15.2)	38 (82.6)
It is simple to use (median, IQR)	5.0 (5.0-6.0)	0 (0.0)	8 (17.4)	38 (82.6)
It is user friendly (median, IQR)	5.5 (5.0-6.0)	2 (4.4)	5 (10.9)	39 (84.8)
It requires the fewest steps possible to accomplish what I want to do with it (median, IQR)	5.0 (4.0-6.0)	5 (10.9)	17 (37.0)	24 (52.2)
It is flexible (median, IQR)	5.0 (4.0-6.0)	1 (2.2)	15 (32.6)	30 (65.2)
Using it is effortless (median, IQR)	5.0 (4.0-6.0)	6 (13.3)	15 (32.6)	25 (54.3)
I can use it without written instructions (median, IQR)	3.0 (3.0-5.0)	26 (56.5)	3 (6.7)	17 (37.0)
I don't notice any inconsistencies as I use it (median, IQR)	4.0 (3.8-5.0)	11 (23.9)	16 (34.8)	19 (41.3)
Both occasional and regular users would like it (median, IQR)	5.0 (4.0-6.0)	6 (13.0)	9 (19.6)	31 (67.4)
I can recover from mistakes quickly and easily (median, IQR)	4.0 (4.0-5.0)	7 (15.2)	24 (52.2)	15 (32.6)
I can use it successfully every time (median, IQR)	5.0 (4.0-6.0)	5 (11.1)	13 (28.3)	28 (60.9)
Ease of learning (α = .842) (mean ± SD)	5.3 ± 1.0			
I learned to use it quickly (median, IQR)	5.0 (5.0-6.0)	2 (4.3)	8 (17.4)	36 (78.3)
I easily remember how to use it (median, IQR)	5.0 (4.8-6.0)	4 (8.7)	7 (15.6)	35 (76.1)
It is easy to learn to use it (median, IQR)	6.0 (5.0-6.0)	2 (4.4)	3 (6.5)	41 (88.9)
I quickly became skillful with it (median, IQR)	5.0 (4.0-6.0)	2 (4.4)	10 (21.7)	34 (73.3)
Satisfaction (α = .917) (mean ± SD)	4.8 ± 1.0			

Table 3: (Continued)

	Total score	Disagree (1-3) (n, %)	Neutral (4) (n, %)	Agree (5-7) (n, %)
I am satisfied with it (median, IQR)	5.0 (4.0-6.0)	2 (4.3)	11 (23.9)	33 (71.7)
I would recommend it to a friend (median, IQR)	5.0 (4.0-6.0)	5 (10.9)	10 (21.7)	31 (67.4)
It is fun to use (median, IQR)	5.0 (4.0-6.0)	6 (13.0)	6 (13.0)	34 (73.9)
It works the way I want it to work (median, IQR)	5.0 (3.0-6.0)	12 (26.1)	9 (19.6)	25 (54.3)
It is wonderful (median, IQR)	5.0 (4.0-5.0)	7 (15.2)	15 (32.6)	24 (52.2)
I feel I need to have it (median, IQR)	4.0 (3.0-5.0)	14 (30.4)	16 (34.8)	16 (34.8)
It is pleasant to use (median, IQR)	5.0 (4.0-6.0)	3 (6.5)	13 (28.3)	30 (65.2)

Abbreviations: α: Cronbach's Alpha; M: Median; IQR: Interquartile range

Overall, healthcare professionals considered continuous monitoring as easy to use (4.7 ± 0.8), easy to learn (5.3 ± 1.0) and were satisfied with it (4.8 ± 1.0) but were neutral about its usefulness (4.4 ± 1.0) (Table 3). Subsequently, two focus groups with in total nine nurses (male: n = 1) and total duration of 27 minutes were conducted. This resulted in six themes.

Theme 1: Faster anticipation and action upon changed patient status from insight into vital sign trends

Overall, this theme was reflected in the statement that 82.6% (n = 38) of professionals found the continuous monitoring useful. Regarding satisfaction with trend monitoring, the scores showed that nurses were disagreeing on 'the feeling they need to have it' (disagreed n = 14, n = 13 neutral, agreed n = 16), which was reflected in the neutral score for usefulness. In the focus groups the nurses explained that maintaining the standard intermittent vital sign measurements reduced the actual need for continuous vital signs monitoring. However, they also indicated they were able to detect deviations of vital signs earlier using regular trend analysis and recognized the importance of vital sign trends over the intermittent vital sign manual measurements, because of the insight in the periods between intermittent measurements, especially during the night.

By the insight in the trends, nurses indicated that it also enabled them act earlier on deviating vital signs than when using intermittent monitoring alone. In addition, they also mentioned the continuous monitoring enabled them to better monitor the effect of interventions on vital signs. One nurse stated:

'After each administration of metoclopramide, we observed an abnormality in the heart rate trend, which ultimately led the doctors to stop the administration of this drug'.

Theme 2: Successful use of the technology

For successful use of the technology in their work, nurses mentioned a number of preconditions should be met. Overall, 60.9% (n = 28) nurses agreed on the statements successful use and 73.3% (n = 34) agreed with 'quickly becoming skillful with it'. In the focus groups they explained that for successful use of the technology, It was necessary to take clinical status and context factors into account when assessing the vital sign trend, rather than just acting solely on the trend data. A nurse said:

'For example, when the patient is washing and dressing in the morning, you expect a higher breathing and heart rate. In that case, this is not clinically relevant and you should not take any action.'

Regarding the statement of becoming skillful with the technology, they preferred more guidance–such as a helpdesk and/or clear manuals—when there were problems with the technology. They especially found the teaching-on-the-job by the researcher very desirable for adoption of the technology.

Lastly, nurses also mentioned the importance of experiencing an adverse event when continuous monitoring was applied. A nurse said:

'If you once had a patient who developed a complication and that deterioration was reflected in the vital signs trends; that experience in the trend assessment is important and you are easily convinced of the added value of continuous monitoring'.

Finally, consistently reporting the trends in the EMR using a reporting format template was considered helpful and important for successful use of the continuous monitoring.

Theme 3: Integration in the nursing process

Nurses were not unanimous about the effectiveness of continuous monitoring ('to be more effective'; respectively n = 11 disagreed, n = 13 were neutral n = 14 and n = 21 agreed), but to a greater extent on the statements of 'being more productive' (disagreed n = 6, n = 10 neutral, agreed n = 30) and 'effortless use of the technology' (disagreed n = 6, neutral n = 15, agreed n = 25).

In the focus groups, nurses indicated that the intervention could be integrated in their current work processes. They especially mentioned the importance of automated integration of continuous vital signs data in the EMR. Besides, they stated that clinical decision support was helpful for trend assessment, especially the D-EWS scores which were closely related to their conventional way of interpreting vital values with the MEWS system. One nurse stated:

> *'It is recognizable and corresponds to the usual working method with the EWS. This makes it easier for me to consider whether the trend actually deviates and promotes communication with the doctor when needed'.*

Theme 4: Willingness to use the technology

Regarding willingness to adopt the trend monitoring, nurses were divided about 'feeling the need to have continuous monitoring' (disagree n = 14, neutral n = 16, agreed n = 16). Besides, 12 of the nurses agreed with the statement that 'continuous monitoring saves time' (disagree n = 19, neutral n = 13). Also, 11 of nurses 'did notice inconsistencies in the use of the system' whereas 19 did not.

In the focus groups, nurses mentioned several factors which were important for considering the use of the technology in their work. They stated that using this technology should directly and visibly benefit the nurse's daily work. Also, nurses found the multidisciplinary responsibility for monitoring vital signs important for their willingness to use the continuous monitoring system. It is important that both nurses and doctors accept the technology and recognize the benefit of evaluating vital signs trend data to interpret the patient's status. Besides, communication and education about the technology and work process to all stakeholders was important. One nurse said:

> *'It worked for me when I received explanation and education about the possible benefits of adding continuous monitoring'. Lastly, an important factor nurses mentioned was the reliability of the technology. They found the vital sign values and trends must be measured reliably and the technology must not be defective'.*

Theme 5: Gaining practical experience

Considering ease of learning a mean score of 5.3 ± 1.0 was given. On the statement of 'easily remembering how to use the continuous monitoring system', nurses mostly agreed (disagreed n = 4, neutral n = 7, agreed n = 35). This was in contrast with the statement about using the system without written instructions (disagree n = 26, neutral n = 3, agree n = 17).

In the focus groups, nurses stated that practical experience was convenient for their adoption and acceptability of the intervention. Especially, activities such as applying the patch to the patient on the body and pairing patients to the device. Besides, the analysis of trends required experience because they were only used to interpret absolute values of the intermittent measurements of vital signs. To reach sufficient experience, nurses said the implementation time should be long enough to build up routine. They felt that such proficiency had not yet been reached within the study period of four months.

Theme 6: Application of alarm strategy for deviating vital signs

Considering the application of an alarm strategy for deviating vital signs, nurses in the focus groups stated there was no added value of alarms if trend analysis was carried out according to the protocol used in this study. One nurse mentioned:

> *'If every nurse is assessing the trend and reporting it adequately in their shift, then I think receiving an alarm when the trends are deviating is unnecessary'.*

Another nurse did not want alarms:

> *'…Especially because we already have a lot of distractions and interruptions when caring for patients, like calls by patients or other healthcare professionals'.*

Although the nurses did not prefer alarms, they found the D-EWS scores generated by the continuous monitoring system helpful in assessing the vital sign trend data and for their clinical decision making because of the familiarity with the MEWS system. Furthermore, nurses stated alarms were only desirable when they are fully reliable, i.e., when not generating frequent false alarms. Also, an alarm should generally require immediate follow-up by the nurse, such as taking extra vital sign measurements or notifying a doctor, but many nurses wondered whether this is practically feasible on a general ward. One nurse said:

> *'I wonder if this would work in practice. The clinical judgment of us nurses is also important in this regard. In addition, we also have to care for many more patients than our colleagues in the Intensive Care Unit, which means that following up an alarm is different than in a high care department.'.*

Fidelity

Quality of delivery

Total monitoring time was 4898.5 hours with a median monitoring time of 71.5 hours per patient (IQR45.8–114.9) (Table 4). Considering quality of delivery, 9.7% (56 731) of

the 587 858 measurements, were invalid. Of these invalid measurements, 50.7% (n = 28 757) was for HR and 49.3% (n = 27 970) for RR. A total of 984 D-EWS were registered: 11 (IQR7-25) scores per patient and 1 (IQR0-4) score ≥ 3 per patient.

Adherence to protocol

Considering the adherence, the clinical assessment of the trend was registered in 80.5% (n = 536) of the nurses' shifts reports.

Table 4: Fidelity of the monitoring system

Quality of delivery	
Total monitoring time (minutes)	4898.5
Median monitoring time (minutes, median, IQR)	71.5 (45.8 - 114.9)
Total measurements	587,858
Total artefact measurements (n, %)	56 731 (9.7)
Artefact measurements for HR (n, %)	28 757 (50.7)
Artefact measurements for RR (n, %)	27 970 (49.3)
D-EWS scores total	984
D-EWS scores median (IQR)	11 (7-25)
D-EWS ≥ 3 total (n)	212
D-EWS ≥ 3 median (IQR)	1 (0-4)
System notifications total	732
System notifications median (n, %)	6 (2-12)
Adherence to protocol	
Cases of clinical detection by trends (n)	17 (30.4)
Total nurse reports	666
Filled (n, %)	536 (80.5)

Clinical outcomes

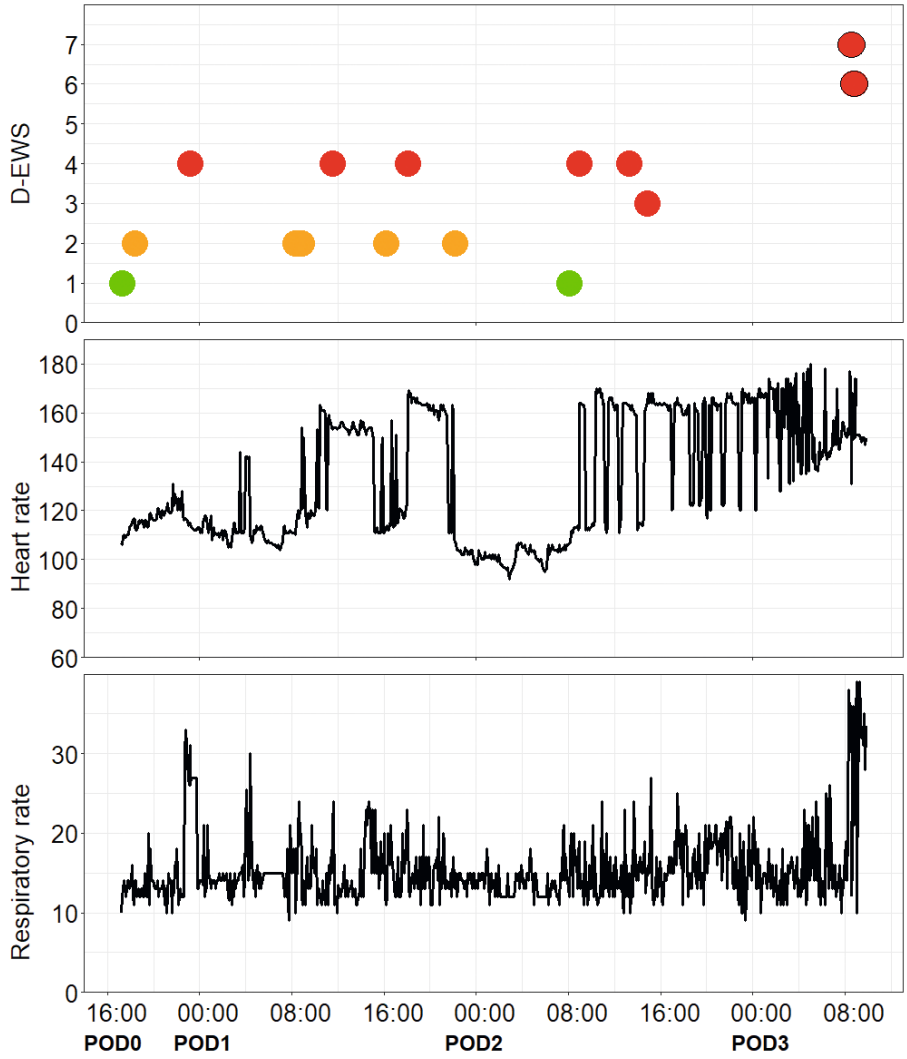
Patients were admitted for a median time of 5 days (IQR4-7) and developed a total of 21 complications of which 18 were Clavien-Dindo class I and II complications, and 3 were class 3, 4 or 5, as shown in Table 1. There were four readmissions, two reinterventions, and two unplanned ICU admissions whereas one of these two patients eventually died at the ICU. One unplanned admission to the ICU was because of respiratory failure from aspiration pneumonia and another for postoperative observation after reintervention because of anastomotic leakage.

Thirteen deviating trends were observed; ten for high heart rate and three for high respiratory rate. Both patients who required re-intervention and who were consequently admitted to the ICU showed deviating trends of heart rate but was this was not the singular indication for admittance, as shown in Figure 1. As a result of the deviating heart rate trends, five electrocardiograms (ECG) were performed which resulted in starting or adjusting medication (n = 3) or no action after consultation with a cardiologist (n = 2). As a result of deviating respiratory rate trends, for one patient a pneumonia was diagnosed and antibiotics were administered and one patient received intensified nurse observations. In the remaining seven cases the trends were consistent with a known complication or diagnosis of the patient resulting in no other treatment.

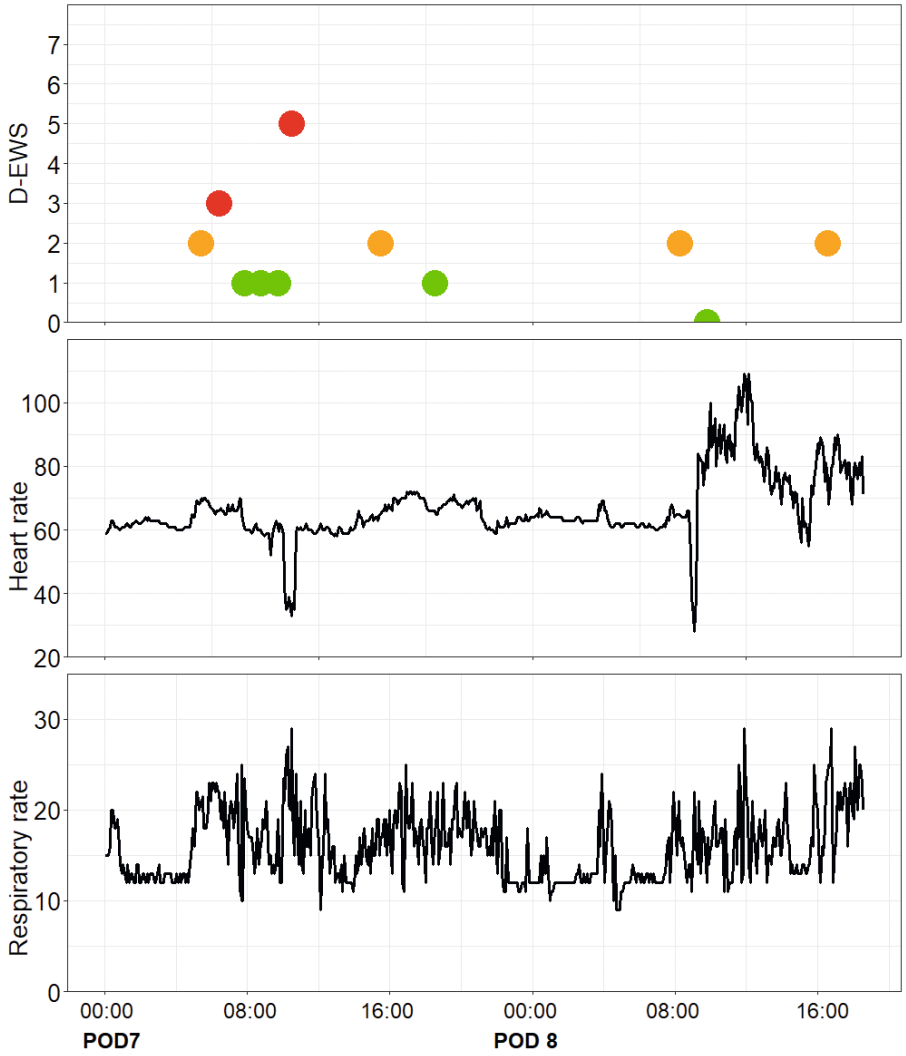
Patient acceptability

Recruitment rate was 97% (62 out of 64) and the dropout rate 8% (5 out of 62). Of the 56 included patients, 45 (response rate: 83%) patients returned the questionnaires (Table 5). 88.9% (n = 40) rated the patch as comfortable and the majority of patients (82.2%; n = 39) recommended it for a next time in the hospital or at home (62.3%; n = 28). In addition, 40% (n = 18) of patients felt safer while wearing the patch and 42.2% (n = 19) were neutral about this statement. Also, 42.2% (n = 19) experienced more involvement in their own health and 50% (n = 22) experienced more access to healthcare professionals. There were no missing data in the returned questionnaires.

Figure 1: Deviating vital sign trends in two patients who were admitted to the ICU unplanned



A. Patient #45 (81 years old male for colon resection): trend data from postoperative day 0 (POD0) 17:00 pm to POD3 10:00 am. On POD1 09:00 am sudden heart rate elevations were detected resulted in D-EWS score of 3 following an electrocardiogram which diagnosed sinus tachycardia but no further action was required. The next day the sinus tachycardia was present several episodes. In the morning of POD3 the patient became respiratory insufficient (with full MEWS scores 6 and 7) following a diagnostic laparoscopic but was negative for abdominal seps. Post-surgical the patient was admitted to the ICU with diagnosis of pneumosepis and eventually died.



B. Patient #53 (76 year old female for colon resection): trend data from POD7 00:00 am to POD8 18:45 pm. On 10:45 am sudden heart rate changes were detected resulted in D-EWS score of 3. The next morning about 10:00 am the heart rate deviated again till patient returned to the operation theater for laparotomy. Eventually abdominal sepsis was diagnosed and postoperatively admitted to the ICU.

Table 5: Patient acceptability

N=45	Median score (IQR)	Disagree (n, %)	Neutral (n, %)	Agree (n, %)
Comfortable	5 (4-5)	2 (4.4)	3 (6.7)	40 (88.9)
Feeling safe	3 (3-4)	8 (17.8)	19 (42.2)	18 (40.0)
More involved in own health	3 (3-4)	9 (20.0)	17 (37.8)	19 (42.2)
More access to healthcare professionals	4 (3-4.25)	10 (22.7)	12 (27.3)	22 (50.0)
Recommendation for clinical use	5 (4-5)	4 (8.9)	4 (8.9)	39 (82.2)
Recommendation for home use	4 (3-5)	11 (24.4)	6 (13.3)	28 (62.3)

DISCUSSION

Main findings

In this study we evaluated the feasibility of continuous vital signs monitoring system without using alarms on a general surgical ward. Our results show that continuous vital signs monitoring without an active alarm system while routinely assessing the vital sign trends was acceptable for nurses, doctors and patients.

In our study, the mean acceptability scores for implementation of trend monitoring for professionals were mostly positive, although they still leave room for improvement. While the potential usefulness was generally well acknowledged, some professionals were not fully convinced which was reflected in score and focus group data. This may have been caused by the relatively short period (3 months) of working with the continuous monitoring system, which is in line with experiences of continuous monitoring in previous studies.[20,39] and also reflected in the qualitative theme about gaining practical experience. Professionals not only mentioned the need for more experience for performing adequate trend analysis, but also better practical skills in applying the sensor or in operating the software. Moreover, a possible factor enhancing the acceptability of continuous monitoring system is having witnessed a serious clinical adverse event in a patient who's vitals sign trends were deteriorating.[39,40] This may not only refer to the need to gain experience in trend assessment, but also to gain trust in the novel vital sign monitoring work process. In our study deteriorating trends were, however, quite rare and observed in only seventeen cases during almost 5000 hours of monitoring,

Importantly, although continuous vital sign monitoring systems are well accepted on high care departments, this is a completely new concept for most care-professionals on general wards. So apart from gaining practical experience, the process of building confidence in novel concepts of continuous monitoring needs to be taken into account when implementing these systems.[39] The introduction of digital health innovations, will therefore have to be done very carefully to increase adoption and acceptance.[41,42] The guidance just after the start of the implementation in the form of coaching and expert support, therefore is crucial for success.

Current alarm strategies for monitoring devices are mostly based on conventional thresholds of high care units and do not take other factors of ambulant ward patients into account, thereby causing frequent (false) alarms.[20] In fact, previous studies which used wireless monitoring systems with active alarms reported that the alarm frequency was experienced as unacceptable.[43,44] In the present study, the acceptability scores were quite high, possibly because alarm overload was never an issue. Frequent alarms on general wards are considered highly disturbing, since nurses already perceive a high burden of interruptions in their work by patient calls. This is in line with previous work about perceived interruptions during nurse shifts.[45] Also, nurses found that active alarms should preferably be followed-up immediately and therefore questioned the practical feasibility and usefulness on a general ward given the expected low clinical urgency and low nurse-to-patient ratio. Regular trend monitoring and proper training may result in more proactive decision-making because healthcare professionals may learn to recognize deteriorating trends or abnormalities at an earlier stage, allowing for timely treatment. On the other hand, a possible disadvantage of not using alarms, is that acute clinical deterioration, such as cardiac arrest, may be detected too late, although this is extremely rare on general wards.[21] However, nurses found there was no added value of using alarms if trend analysis was carried out according to the protocol. Nurses assessed the trends according to protocol in more than 80% of the shifts. They felt trend assessment adequately served the purpose of allowing timely detection of (gradual) deterioration, whereas alarms would only be helpful to detect serious acute events.

Since the concept of trend interpretation is new for nurses on general wards, proper training is considered essential and it would be advisable to develop advanced clinical decision making tools to guide trend interpretation. The clinical decision support for trend monitoring in this study by the automatically generated D-EWS scores was considered helpful, which is in line with earlier studies.[46] Better insight in the patient's condition by continuously monitoring vital signs and the belief that it would help increase patient safety was also mentioned in previous studies by nurses.[43,46,47] Also

the explicit need for training, support during implementation and clinical experience was in line with the theme about training and support found in a previous study.[46] However, the reported worries regarding potentially negative impacts of continuous monitoring on nurse-patient interaction and inflexibility of using clinical judgement in responding to alarms were not observed in our study [46]. One possible explanation may be that we clarified to all users that the monitoring system was intended as a trend assessment tool and not as patient surveillance comparable to high care units.

Limitations

This study has several limitations. First, because of the limited duration of the study—and the relatively small number of monitored patients—the care-professionals were most likely still in their learning curve; a prolonged study period may have further enhanced the acceptability scores. Second, we introduced the continuous monitoring system as a supplement rather than replacement to the standard MEWS protocol with intermittent manual spot check monitoring by nurses. So, part of the routine manual measurements was retained which may have increased total work load and affected nurse acceptability. However, considering the rapid developments in sensor technology and systems, expansion of measurable vital signs, more than just HR and RR, and improvement of clinical decision support tools and alarm strategies by algorithms[16,48], it seems only a matter of time before these manual measurement routines become obsolete. Third, in support of the interpretation of vital sign trends by nurses, only very limited digital tools are currently available. The Philips Intellivue Guardian system used in this study only generates D-EWS scores based on predefined thresholds of absolute values of vital signs, but fails to include patient related and context factors. Fourth, we only included nine nurses in the focus groups, so data saturation may not have been fully reached in the qualitative assessment part of this study. However, given the homogeneity of the group of nurses and low level of complexity of the topic this may not be an issue.[49]

Implications

Further research should focus on the implementation of continuous vital sign monitoring systems for a longer period of time and in larger patient cohorts on general wards, while omitting current standard manual intermittent vital sign measurements altogether. Although training in trend assessment seems important, new advanced clinical decision support tools and more advanced multi-parameter wearable sensors may support implementation and acceptance, and eventually allow complete termination of time consuming manual measurements and improve clinical outcomes.

Conclusion

Continuous vital signs trend monitoring at regular intervals without using alarms was feasible for nurses, doctors, and patients on a general surgical ward, both in terms of acceptability as well as fidelity. Nurses found there was no added value of using alarms if trend assessment was carried out according to the protocol. They felt trend assessment adequately served the purpose of allowing timely detection of (gradual) deterioration, whereas alarms would only be helpful to detect serious acute events, which is extremely rare on general wards. In a general ward setting, the standard use of alarms in continuous monitoring systems may therefore be reconsidered. New advanced clinical decision support tools for trend assessment are needed. Further studies may focus on expanding the intervention to larger cohorts and to non-surgical wards, the assessment of clinical effects of vital sign trend monitoring, and improving skills of healthcare professionals in trend interpretation.

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APPENDICES

S1 Appendix: Thresholds EWS scores of the continuous monitoring system

	EWS score					
Score	2	1	0	1	2	3
Heart rate	<40	40-50	51-100	101-110	111-130	>130
Respiratory rate	<9		9-14	15-20	21-30	>30

S2 Appendix: Questionnaire patients

The questions below are about your experience wearing the "smart patch" to monitor your heart rate and breathing during your admittance on the ward. You should answer the statements below on a scale of 1 to 5. 1= "strongly disagree" and 5 = strongly agree.

	1	**2**	**3**	**4**	**5**
I found the patch comfortable	0	0	0	0	0
I felt safer because of the patch	0	0	0	0	0
The smart patch makes me more concerned with my own health	0	0	0	0	0
The patch increased my access to care and contact with healthcare providers (nurses and doctors)	0	0	0	0	0
I would like to wear the patch again in the hospital next time	0	0	0	0	0
I would also like to wear the patch at home next time after an operation	0	0	0	0	0

S3 Appendix: Topics focus groups

General introduction and purpose of focus group
How did you feel about working with continuous monitoring in general?
We see a score of 4.4 out of 7 for usability and usefulness.
Do you recognize this? Can you explain this score?
We see a score of 4.7 out of 7 for ease of use.
Do you recognize this? Can you explain this score?
We see a score of 5.3 out of 7 for ease of learning.
Do you recognize this? Can you explain this score?
We see a score of 4.8 out of 7 for satisfaction.
Do you recognize this? Can you explain this score?
What is the value to you of active alarms during continuous monitoring?

	n=46	
Useful	**4.4±1.0**	
Ease of use	**4.7±0.8**	
Ease of learning	**5.3±1.0**	
Satisfaction	**4.8±1.0**	

S4 Table: Shapiro-Wilk test results for normality

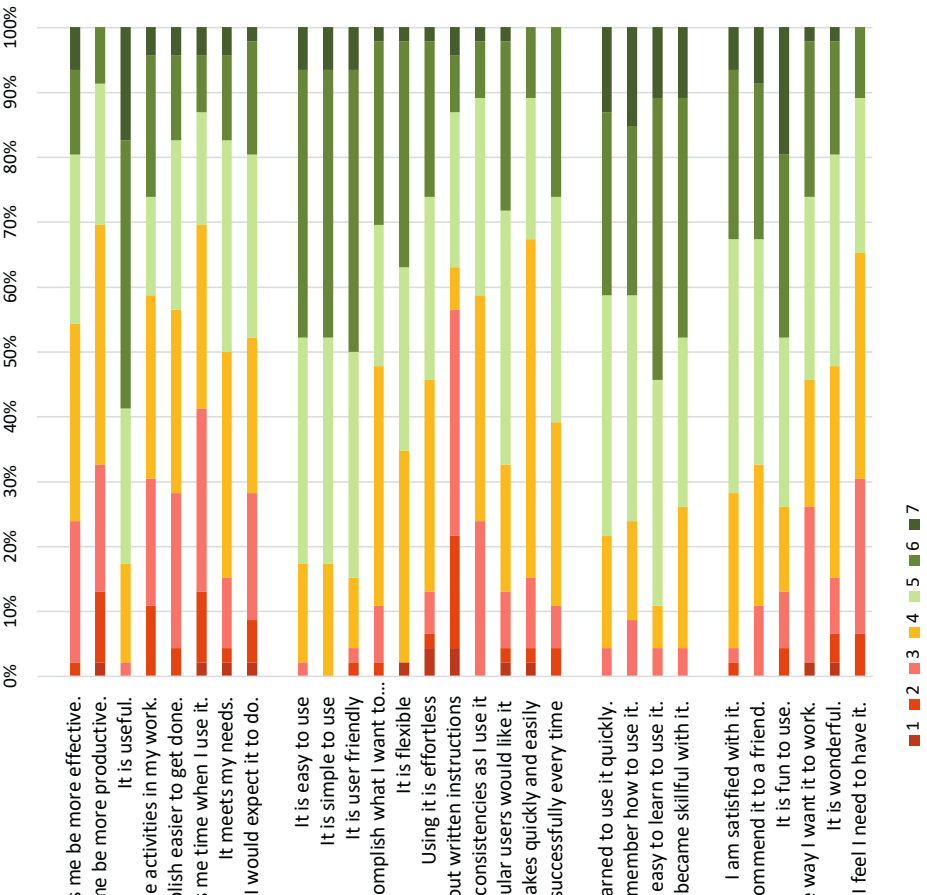
Variable name	Shapiro Wilk test results	
	statistic	p-value
Patient characteristics		
Age in years (median, IQR)	.944	.011*
Body Mass Index (kg/m²) (median, IQR)	.954	.032*
Healthcare professionals' characteristics (n=46)		
Age (median, IQR)	.824	.000*
Work experience (median, IQR)	.803	.000*
USE-questionnaire		
Usefulness (α = .906)	.986	.855
It helps me be more effective.	.926	.006*
It helps me be more productive.	.931	.009*
It is useful.	.890	.000*
It gives me more control over the activities in my work.	.927	.007*
It makes the things I want to accomplish easier to get done.	.933	.007*
It saves me time when I use it.	.945	.011*
It meets my needs.	.928	.030*
It does everything I would expect it to do.	.943	.025*
Ease of use (α = .921)	.964	.169
It is easy to use	.884	.000*
It is simple to use	.863	.000*
It is user friendly	.856	.000*
It requires the fewest steps possible to accomplish what I want to do with it	.902	.001*
It is flexible	.832	.000*
Using it is effortless	.894	.001*
I can use it without written instructions	.919	.004*
I don't notice any inconsistencies as I use it	.889	.000*
Both occasional and regular users would like it	.889	.000*
I can recover from mistakes quickly and easily	.867	.000*
I can use it successfully every time	.877	.000*
Ease of learning (α = .842)	.968	.243
I learned to use it quickly.	.913	.002*
I easily remember how to use it.	.913	.002*
It is easy to learn to use it.	.869	.000*

S4 Table: Shapiro-Wilk test results for normality

Variable name	Shapiro Wilk test results	
I quickly became skillful with it.	.903	.001*
Satisfaction (α = .917)	.981	,655
I am satisfied with it.	.909	.002*
I would recommend it to a friend.	.919	.003*
It is fun to use.	.908	.001*
It works the way I want it to work.	.911	.002*
It is wonderful.	.921	.004*
I feel I need to have it.	.918	.003*
It is pleasant to use.	.913	.002*
Fidelity of the monitoring system		
Median monitoring time (median, IQR)	.751	.000*
Total measurements	.751	.000*
D-EWS scores median (IQR)	.802	.000*
D-EWS ≥ 3 median (IQR)	.581	.000*
System notifications median (n, %)	.598	.000*
Patient acceptability		
Comfortable	.566	.000*
Feeling safe	.878	.000*
More involved in own health	.894	.001*
More access to healthcare professionals	.895	.001*
Recommendation for clinical use	.665	.000*
Recommendation for home use	.766	.000*
Clinical outcomes		
Length of stay (days)	.753	.000*

S5 Table: Distribution of answers on the USE questionnaire

	1	2	3	4	5	6	7
It helps me be more effective.	0 (0)	1 (2.2)	10 (21.7)	14 (30.4)	12 (26.1)	6 (13.0)	3 (6.5)
It helps me be more productive.	1 (2.2)	5 (10.9)	9 (19.6)	17 (37.0)	10 (21.7)	4 (8.7)	0 (0)
It is useful.	0 (0)	0 (0)	1 (2.2)	7 (15.2)	11 (23.9)	19 (41.3)	8 (17.4)
It gives me more control over the activities in my work.	0 (0)	5 (10.9)	9 (19.6)	13 (28.7)	7 (15.2)	10 (21.7)	2 (4.4)
It makes the things I want to accomplish easier to get done.	0 (0)	2 (4.4)	11 (23.9)	13 (28.7)	12 (26.1)	6 (13.0)	2 (4.4)
It saves me time when I use it.	1 (2.2)	5 (10.9)	13 (28.7)	13 (28.7)	8 (17.4)	4 (8.7)	2 (4.4)
It meets my needs.	1 (2.2)	1 (2.2)	5 (10.9)	16 (34.8)	15 (32.6)	6 (13.0)	2 (4.4)
It does everything I would expect it to do.	1 (2.2)	3 (6.5)	9 (19.6)	11 (23.9)	13 (28.7)	8 (17.4)	1 (2.2)
It is easy to use	0 (0)	0 (0)	1 (2.2)	7 (15.2)	16 (34.8)	19 (41.3)	3 (6.5)
It is simple to use	0 (0)	0 (0)	0 (0)	8 (17.4)	16 (34.8)	19 (41.3)	3 (6.5)
It is user friendly	0 (0)	1 (2.2)	1 (2.2)	5 (10.9)	16 (34.8)	20 (43.5)	3 (6.5)
It requires the fewest steps possible to accomplish what I want to do with it	0 (0)	1 (2.2)	4 (8.7)	17 (37.0)	10 (21.7)	13 (28.7)	1 (2.2)
It is flexible	1 (2.2)	0 (0)	0 (0)	15 (32.6)	13 (28.7)	16 (34.8)	1 (2.2)
Using it is effortless	2 (4.4)	1 (2.2)	3 (6.5)	15 (32.6)	13 (28.7)	11 (23.9)	1 (2.2)
I can use it without written instructions	2 (4.4)	8 (17.4)	16 (34.8)	3 (6.5)	11 (23.9)	4 (8.7)	2 (4.4)
I don't notice any inconsistencies as I use it	0 (0)	0 (0)	11 (23.9)	16 (34.8)	14 (30.4)	4 (8.7)	1 (2.2)
Both occasional and regular users would like it	1 (2.2)	1 (2.2)	4 (8.7)	9 (19.6)	18 (39.1)	12 (26.1)	1 (2.2)
I can recover from mistakes quickly and easily	1 (2.2)	1 (2.2)	5 (10.9)	24 (52.2)	10 (21.7)	5 (10.9)	0 (0)
I can use it successfully every time	0 (0)	2 (4.4)	3 (6.5)	13 (28.7)	16 (34.8)	12 (26.1)	0 (0)
I learned to use it quickly.	0 (0)	0 (0)	2 (4.4)	8 (17.4)	17 (37.0)	13 (28.7)	6 (13.0)
I easily remember how to use it.	0 (0)	0 (0)	4 (8.7)	7 (15.2)	16 (34.8)	12 (26.1)	7 (15.2)
It is easy to learn to use it.	0 (0)	0 (0)	2 (4.4)	3 (6.5)	16 (34.8)	20 (43.5)	5 (10.9)
I quickly became skillful with it.	0 (0)	0 (0)	2 (4.4)	10 (21.7)	12 (26.1)	17 (37.0)	5 (10.9)
I am satisfied with it.	0 (0)	1 (2.2)	1 (2.2)	11 (23.9)	18 (39.1)	12 (26.1)	3 (6.5)
I would recommend it to a friend.	0 (0)	0 (0)	5 (10.9)	10 (21.7)	16 (34.8)	11 (23.9)	4 (8.7)
It is fun to use.	0 (0)	2 (4.4)	4 (8.7)	6 (13.0)	12 (26.1)	13 (28.3)	9 (19.6)
It works the way I want it to work.	1 (2.2)	0 (0)	11 (23.9)	9 (19.6)	13 (28.7)	11 (23.9)	1 (2.2)
It is wonderful.	1 (2.2)	2 (4.4)	4 (8.7)	15 (32.6)	15 (32.6)	8 (17.4)	1 (2.2)
I feel I need to have it.	0 (0)	3 (6.5)	11 (23.9)	16 (34.8)	11 (23.9)	5 (10.9)	0 (0)
It is pleasant to use.	0 (0)	0 (0)	3 (6.5)	13 (28.7)	17 (37.0)	10 (21.7)	3 (6.5)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It helps me be more effective.
It helps me be more productive.
It is useful.
It gives me more control over the activities in my work.
It makes the things I want to accomplish easier to get done.
It saves me time when I use it.
It meets my needs.
It does everything I would expect it to do.
It is easy to use
It is simple to use
It is user friendly
It requires the fewest steps possible to accomplish what I want to...
It is flexible
Using it is effortless
I can use it without written instructions
I don't notice any inconsistencies as I use it
Both occasional and regular users would like it
I can recover from mistakes quickly and easily
I can use it successfully every time
I learned to use it quickly.
I easily remember how to use it.
It is easy to learn to use it.
I quickly became skillful with it.
I am satisfied with it.
I would recommend it to a friend.
It is fun to use.
It works the way I want it to work.
It is wonderful.
I feel I need to have it.
1
2
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7

PROCESS EVALUATION OF A WIRELESS WEARABLE CONTINUOUS VITAL SIGNS MONITORING INTERVENTION ON TWO GENERAL HOSPITAL WARDS: A MIXED-METHODS STUDY

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ABSTRACT

Background

Continuous monitoring of vital signs (CMVS) using wearable, wireless sensors is increasingly available to general ward patients, and has the potential to improve outcomes and reduce nurse workload. In order to assess the potential impact of such systems successful implementation is important. We developed a CMVS intervention and implementation strategy and evaluated its success on two general wards.

Objective

To assess and compare intervention fidelity on two wards (internal medicine and general surgery) in a large teaching hospital.

Methods

A mixed-methods sequential explanatory design was used. After thorough training and preparation, CMVS was implemented -in parallel to the standard intermittent manual measurements- and executed for six months at each ward. Heart rate and respiratory rate were measured by a chest-worn wearable sensor and vital signs trends were visualized in a digital platform. Trends were routinely assessed and reported each nursing shift without the use of automated alarms. Primary outcome was intervention fidelity defined as proportion written reports and related nurse activities in case of deviating trends comparing early (month 1-2), mid (month 3-4) and late (month 5-6) implementation periods. Explanatory interviews with nurses were conducted.

Results

The implementation strategy was executed as planned on both wards. A total of 358 patients were included, resulting in 45,113 monitored hours during 6,142 nurse shifts. Ten percent of the sensors were replaced prematurely due to technical failure. Mean intervention fidelity was 71%±20% and higher on the surgical ward (74% vs. 64%;P<.001). Fidelity decreased over the implementation period on the internal medicine ward (76% at early vs. 57% at mid;P<.001 vs. 48% at late implementation;P<.001) but not significantly on the surgical ward (76% at early vs. 74%;P=.561 at mid vs. 70.7% at late implementation;P=.071). In 69% of patients (n=246) no nursing activities were needed based on vital sign trends. In 174 reports of 112 patients, observed deviating trends led to 101 additional bedside assessments of patients and 73 consults of physicians. Main themes that emerged during interviews (n=21) comprehended the relative priority of CMVS in nurse work, the importance of nursing assessment, the relatively limited perceived benefits for patient care, experienced mediocre usability of the technology and future perspectives for application of CMVS.

Conclusions

We successfully implemented a system for CMVS at scale on two hospital wards, but our results show that intervention fidelity decreased over time, to a larger extent on the internal medicine ward than on the surgical ward. This decrease appears to be dependent on multiple ward-specific factors. Perceptions of nurses regarding the value and benefits of the intervention were variable. Implications for optimal implementation of CMVS on general wards are including engaging nurses early, seamless integration into the Electronic Health Records, and developing more sophisticated decision support tools for vital sign trend interpretation and alarms.

INTRODUCTION

The majority of adverse events occurring on hospital wards are preceded by a significant period of changes in vital signs, which are important indicators of clinical deterioration.[1] Monitoring vital signs allows for early detection and timely interventions that may improve outcomes.[1–4] In high-care units with critically ill patients continuous monitoring of vital signs is the norm, while on general wards vital signs are usually monitored intermittently and interpretation is guided by Early Warning Scores (EWS).[5–7] Although the EWS system may facilitate early detection, there are still limitations due to its intermittent nature and variable compliance.[8–10] Consequently, patients may deteriorate unnoticed, which can lead to avoidable adverse events, adverse outcomes and higher costs.[11–13]

Given recent technological developments, continuous monitoring of vital signs (CMVS) using wearable, wireless sensors has become available to general ward patients. Previous studies showed that these systems can accurately measure vital signs and are able to detect deterioration.[14–16] However, evidence on the effect of these CMVS systems on patient outcomes is scarce.[17,18] This may be related to the fact that implementation of CMVS at scale remains challenging and requires considerable up-front financial investment by hospital administrations.[19,20]

Although many healthcare professionals acknowledge the potential benefits of CMVS for patient care, several studies have highlighted significant challenges, such as difficult implementation in existing nursing workflows, poor integration with hospital Electronic Health Record (EHR) systems and primitive alarm management strategies.[21–23] In addition, monitoring vital signs trends may be challenging for most ward nurses, due to a lack of experience with interpreting graphic representations of CMVS trends.[15,24,25]

Given these challenges, implementing CMVS on hospital wards is considered a 'complex intervention' with many interacting components, the need for behaviour change of healthcare professionals and affecting multiple patient outcomes.[26,27] Successful scaled implementation on wards is necessary before any possible beneficial effects of CMVS on clinical outcomes can be expected.[17,21,28] Unfortunately, there is only scant knowledge on facilitators and barriers to CMVS implementation.[24,25,29] We have previously conducted two feasibility studies[15,23] and two qualitative studies[24,30] that aided to develop and refine our CMVS intervention and an implementation strategy. For the current study an implementation-effectiveness hybrid design was used for parallel evaluation of the implementation and effectiveness of the intervention.[31] This report focuses on the process evaluation of the implementation with the primary

aim to assess and compare intervention fidelity on two wards (internal medicine and general surgery). Secondary aims were to assess and compare implementation fidelity, technical fidelity, perceived appropriateness, acceptability, usability, adoption and feasibility by nurses. The effectiveness of the intervention will be analysed and described in a separate paper.

METHODS

Design

A mixed methods sequential explanatory design[32] was used for an 8-month period on a surgical ward and an internal medicine ward (September 2021 – July 2022) of a 1.245 beds tertiary teaching hospital in the Netherlands. The study was reported according the Standards for QUality Improvement Reporting Excellence (SQUIRE 2.0) checklist.[33]

Context

The surgical ward consisted of 49 beds on which gastro-intestinal and vascular surgical patients were admitted. A total of 57.4 fulltime equivalent (FTE) of nurses were employed at the ward. Nurse to patient ratio was for 1:5 for day, 1:6 for evening and 1:12 for nightshift respectively. A nurse specialist or junior resident assessed the patient daily during morning rounds.

The internal medicine ward consisted of 48 beds and was divided over two teams of nurses based on the subspecialties; general internal medicine and gastroenterology. Nurse to patient ratio was for 1:4 for day, 1:12 for evening and 1:12 for nightshift respectively. A junior resident assessed the patient during morning rounds.

Patients admitted to the surgical and internal medicine wards were eligible to receive the CMVS intervention (Appendix 1). Inclusion criteria were: age ≥ 18 years, no cognitive impairments, expected hospitalization time two days or longer and able to speak and read the Dutch language. Exclusion criteria was unable to wear the CMVS sensor due to an allergy. Nurses who were employed at the ward during the study period participated and were eligible for participation in the process evaluation when having worked with the CMVS system for at least one month during the study period. Nurses temporarily employed from the flex pool were excluded from the study.

Intervention

In addition to standard care, patients included in the study were monitored using the Conformité Européene (CE)-marked Healthdot sensor and Intellivue Guardian Solution

(IGS) software platform (*Philips Healthcare, Eindhoven, The Netherlands*). Standard care consisted of intermittent monitoring (at least once daily) by manual measurements performed by the nurse and assessed with the Modified Early Warning Score (MEWS) according to local hospital protocol.[34]

The wireless wearable sensor is a water-resistant disposable patch worn on the patient's chest (Appendix 2); it continuously records heart rate (HR) in beats per minute and respiratory rate (ReR) in respirations per minute both by a accelerometry. Previous studies showed this sensor was accurate.[35,36] The two vital signs measurements are transmitted wirelessly every 5 min through a Long Range, Low Power Internet of Things-connection (LoRa) to the Intellivue Guardian Solution (IGS) software. After connecting the sensor to the patient to the software by scanning the Quick Response (QR) code by a separate mobile phone, the software platform with trends was displayed on the Computer on Wheels (COW) and in a mobile application (Appendix 3). Battery life of the patch was fourteen days and during performance of an ECG, CT or MRI the sensor temporarly was removed.

Within the IGS software, individual vital sign trends were visualized and, complementary to the hospital MEWS protocol, one partial MEWS-score (D-EWS) was presented every hour to promote adequate detection. The D-EWS score was based on the HR and ReR measurement and in line with the MEWS thresholds and scores (Appendix 4). on the preinstalled thresholds for HR and ReR. Patient numbers and names were automatically synchronized with the EHR using a Health Level Seven (HL7) linkage so manual entry was not required. Since the device measures only two vital signs, the routine manual measurements of other relevant vital signs (e.g. temperature, blood oxygen saturation) by nurses were maintained throughout the study. Every four hours, i.e. twice per shift, nurses routinely assessed vital signs trends and reported the D-EWS score, and any deviations and t related actions in the EHR at the end of every shift. When the D-EWS score was 3 or higher, any additional checks and interventions could be performed as deemed appropriate by the nurse. No alarm strategy was applied in this study based on the significant alarm fatigue experienced by the nurses in our previous feasibility studies.[15,23]

Implementation strategy

Before start of the study, the two wards were technically prepared for CMVS and an e-learning was developed (Table 1). This comprehensive 30-minute e-learning (*Articulate 360, Articulate Global, New York City, USA*) was developed by the project manager (JL) together with an educationalist. The e-learning ended with a knowledge assessment which had to be successfully completed. Contents were pilot tested by

four nurses of the project team (Appendix 5). This project team was formed per ward consisting of the project manager, four nurses, the ward manager and one consulting physician. First, information and goals about the project were presented in a regular team meeting two months before the start of the project. Subsequently, the e-learning module for nurses was made available online (Appendix 5). It consisted of information about the purpose of the project, the rationale for CMVS, the protocol of the D-EWS, the work processes and policy, the practical use of the IGS system and how to assess the vital signs trends. Afterwards, there was a week of daily meetings with the project manager to provide ample opportunity for asking further questions. Also, all relevant physicians were informed about the project and the workflow in a team meeting.

Table 1: planning of the implementation process

Preparation period (month)				**Implementation period (month)**	
-4	-3	-2	-1	1	2 – 6
Technical preparation of the ward Development of an e-learning	Plenary team meeting	E-learning online Defining implementation measures with key users	Daily meetings for nurses Education for physicians	Go-live Bedside coaching 3 times a day Weekly feedback updates Monthly evaluation and feedback	Monthly evaluation and feedback

During the first four weeks of the study, bedside training and coaching was provided by the project manager (Monday-Friday) three times daily. Also, weekly status updates and feedback about the implementation were provided to the entire team by e-mail. During the study period, the project manager coordinated the inclusion process (Monday-Friday). A small number of dedicated project team nurses acted as key users to provide support for all nurses.

To accurately monitor the implementation, the use of performance feedback was deemed essential. Each month of the study - as a structured evaluation moment – a dashboard with interim results of the inclusion rate and intervention fidelity were discussed in a project team meeting. In addition, a patient case study with deviating vital signs trends was presented and CMVS experiences were discussed.

Subsequently, actions were defined according Plan-Do-Check-Act (PDCA)[37] resulting in an iterative process of improvement of the implementation strategy. Results of the meeting including dashboard and related actions were communicated to the all team members by e-mail. In addition, every 100th patient with CMVS was celebrated as inclusion milestone in the team meeting.

Study procedures

Admitted patients who met the inclusion criteria were approached and received information about the study. Surgical patients were asked for informed consent during the pre-admission call and internal medicine patients when admitted to the ward. When patients agreed to participate, the nurse started CMVS directly or immediately after the surgical procedure until discharge.

Sample size

The study sample size was based on the primary aim of the project: evaluation of the implementation.

There is insufficient guidance in the literature regarding sample size calculation for this type of implementation evaluation studies. Based on historical data and the recruitment rate of our previous feasibility studies,[15,23] we estimated to be able to include 350 patients across both wards over a period of 6 months.

Ethical considerations

The Medical Ethics Committee Isala reviewed the protocol (protocol 210414 CoMoViSi study) and declared the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO) did not apply for this study. The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient participating in the study. All patient data was registered in Case Report Forms and stored securely.

Data collection

Quantitative data

Based on the outcome definitions of Proctor et al.[38], a broad range of implementation outcomes was assessed - overall and per ward - to comprehend the full extent of the implementation. An overview of the measured constructs and timing is given in Table 2.

Main outcome was the 'intervention fidelity', defined as the proportion of written nurse EHR reports on the CMVS trend assessment per patient per nursing shift. A 100% score would be three reports per 24 hours per patient. We considered 70% of written

reports per patient to be sufficient for implementation success based on our previous feasibility study.[15] Also, any follow-up nursing activities in case of deviating trends were described.

Secondary outcomes were implementation fidelity, technical fidelity and survey for nurses about appropriateness acceptability, usability, adoption, and feasibility. For the implementation fidelity, the proportion of nurses who had completed the e-learning, the proportion of monthly evaluations with the project team and implementation measures were documented and described. In addition, exposure (defined as the proportion of hospitalized patients receiving the intervention at the ward during implementation), recruitment (defined as the proportion of actual willing to participate) and retention rate (defined as retention of the patient with CMVS during the admission) were registered. Moreover, considering the technical fidelity, data of the CMVS system were collected: number of measurements, proportion of data artefacts, D-EWS scores and premature replacement of the sensor due to technical failure. An artefact was defined as an invalid measurement as identified by the algorithm of the system and presented as -?-.

The surveys for nurses were sent via e-mail and consisted of several questionnaires (Table 2). The 4-item Acceptability of Intervention Measure (AIM) measured acceptability, the 4-item Intervention Appropriateness Measure (IAM) measured appropriateness and the 4-item Feasibility of Intervention Measure (FIM) measured feasibility. All on a 5-point Likert scale (score 1-5) with a median score of ≥ 3.5 was considered as sufficient.[39]

Table 2: Overview of study outcomes per ward

Outcome	**Month**					
	1	**2**	**3**	**4**	**5**	**6**
Intervention fidelity	AD	AD	AD	AD	AD	AD/I
Implementation fidelity	AD	AD	AD	AD	AD	AD/I
Technical fidelity	AD	AD	AD	AD	AD	AD/I
Appropriateness	S					
Acceptability			S			S/I
Usability			S			S/I
Adoption			S			
Feasibility			S			S/I

Abbreviations: AD: Administrative Data from the patient record, S: Survey collected via e-mail, I: Interviews

The 10-item System Usability Scale (SUS) measured usability on a 5-point Likert scale resulting in a score of 0-100. A usability score ≤50 was considered unacceptable, 51-70 marginal >70 as acceptable.[40]

The 15-item Evidence-Based Practice Attitude Scale (EBPAS) on a 5-point Likert scale measured adoption (score 0-4) with the subscales: requirements, appeal, openness and divergence. Scores were reported overall score and per subscale. A higher score indicated better adoption. A median score of ≥ 2.5 was defined as sufficiently adopted.

Lastly, we collected patient characteristics (gender, age, Body Mass Index, American Society of Anesthesiologists (ASA) classification, urgency of admission, Short Nutritional Assessment Questionnaire (SNAQ)[41], smoking status, alcohol use and comorbidities (Charlson Comorbidity Index score ranging 0-12).[42,43] and outcomes (length of stay, mortality, unplanned Intensive Care Unit (ICU) admissions and Rapid Response Teams (RRT) from administrative data from the EHR. Nurse demographics (gender, age, job position, working experience in years and working hours per week) were collected from the hospitals personnel registration.

Qualitative data

In addition to the quantitative data, semi-structured interviews were conducted with nurses (Table 2). The qualitative element of this study aimed to clarify the quantitative data. A pilot-tested topic list guided the interviews (Appendix 6), which were conducted by two nursing students who were trained and supervised by the project manager (JL). Interviews were audio recorded and transcribed verbatim. No field notes were taken. Per ward, at least ten semi-structured interviews were conducted in a secluded room on the ward in the last month of the study.

Data analysis

Quantitative data

Data were analysed by descriptive and inductive statistics performed with IBM SPSS Statistics 26 for Windows (*IBM Armork, New York, USA*). Each continuous parameter was checked for normality by the Kolmogorov–Smirnov test and visually by a Q-Q plot and histogram. Normality-based reporting was performed using means with standard deviations (SD) or medians with interquartile ranges (IQR). For categorical data, frequencies and percentages were reported.

To explore for differences between wards, unpaired T-test, Mann-Whitney U test, $\chi 2$ test of Fisher Exact test was performed based on normality and test assumptions. Also, multiple linear regression was performed for explorative analysis of intervention fidelity

of the nurses based on the reports. Independent variables were Charlson Comorbidity Index,[42] length of stay, amount of D-EWS scores ≥3, amount of artefact data (in %) and the month of implementation. Implementation month was a dummy variable with early (month 1-2), mid (month 3-4) and late implementation (month 5-6). For all tests, $P < .05$ was considered statistically significant.

Qualitative data

The interviews were analysed by deductive thematic analysis using the qualitative data analysis software NVivo 12 (*QSR International, London, UK*). The raw data were analysed using a six-stage thematic analysis as outlined by Braun and Clarke.[44] The stages include: (1) immersion; (2) generating initial codes; (3) searching for and identifying themes; (4) reviewing themes; (5) defining and naming themes; and (6) writing the report.

Two researchers (JL and HR) conducted stage 1 to 3 independently. During the first and second stage, JL and HR became familiar with the data by listening to the audio recordings, checking the transcriptions against the audio recording, re-reading, listening sections again and re-reading the final transcripts. During the third stage, both researchers read the transcripts and codes for categorizing similar statements into first themes. For the stage 4 to 6, all authors were responsible for reviewing, defining and naming themes by discussion. During the sixth stage, the themes were brought to the nurses for member checking by e-mail, which did not result in any changes to the themes.

Mixed methods: integration and interpretation

Integration of the quantitative and qualitative elements of the study occurred through linking the methods of data collection and analysis. Linking of methods occurred through building: the data of the inclusion and intervention fidelity per month served as the start for the interview and possible explanations based upon the nurses' experiences were discussed. Interpretation and reporting occurred through the contiguous approach: presentation of qualitative and quantitative findings in consequent, but different sections.[45]

RESULTS

Study characteristics

A total of 384 patients were screened for participation of which 6 (1.6%) patients declined. Of the 378 patients included during the implementation period,20 were excluded because of conversion to palliative surgery (n=5), known allergy (n=1), lost-to-follow up (n=8), surgery cancelled (n=3), retracted (n=2) or postoperatively admitted to another ward (n=1). Eventually, 358 patients were included in the analysis; 248 from the surgical ward and 110 from the internal medicine ward (Appendix 7). Median length of stay at the surgical ward was 6.0 days (IQR3.5-10.5) versus 8.8 (IQR5.5-14.1) days at the internal medicine ward (P<.001). Nearly all internal medicine patients (99.1%) were emergency admissions, in contrast to 7.3% at the surgical ward (P<.001) and in-hospital mortality was considerably higher on the internal medicine ward (7.3% vs. 0.8%; P=.002). For all characteristics, see Table 3. In total, 148 nurses participated in the study, 71 from the surgical ward and 77 from the internal ward. Median age of nurses was 29 years (IQR 24-42); they were predominantly female (91.9%) and 37.2% were senior nurses. Median work experience was 5 years (IQR 2-16) with a median of 32 working hours (IQR 24-32) per week. There were no significant differences between characteristics the two wards (Table 3).

Intervention fidelity

Eventually, 6,142 shifts were analysed. Overall mean intervention fidelity for both wards was 70.7%±20.4%; it was considered sufficient in the surgical ward but not in the internal medicine ward (73.6% vs 64.1% %; P<.001). Multiple regression analysis showed that intervention fidelity remained stable over time on the surgical ward, but decreased over time on the internal medicine ward (76.3% at early vs. 56.5% at mid vs. 48.2% at late implementation; P<.001) (Table 4; Figure 1). Changes in intervention fidelity could not be explained by other variables (Appendix 8).

With respect to the documented nursing activities (total: n=174; range: 1-9 per patient), in the majority of patients (68.7%) no nursing activities were needed based on the vital sign trend assessments. A total of 101 interventions was carried out by nurses individually; it mostly consisted of an extra bedside assessment of the patient followed by wait-and-see (n=73). In addition, 73 activities were performed after consultation with the physician (80.8% of these were at the surgical ward (Table 5).

Implementation fidelity

Considering implementation fidelity, the majority of nurses attended the e-learning, all elements of the strategy were delivered and monthly evaluations were performed.

There were 27 implementation measures conducted but no major changes in the intervention itself (Table 4; Appendix 9). Furthermore, recruitment rate and retention rate were respectively 98.4% and 99.4% and did not significantly differ between wards (Table 4). Exposure to the intervention was 33.6% of patients at the surgical ward versus 21.8% of patients at the internal medicine ward (P<.001). Also, the number of participated patients over time on the internal medicine ward from 51 patients (early) to 38 patients (mid) and 21 patients (late).

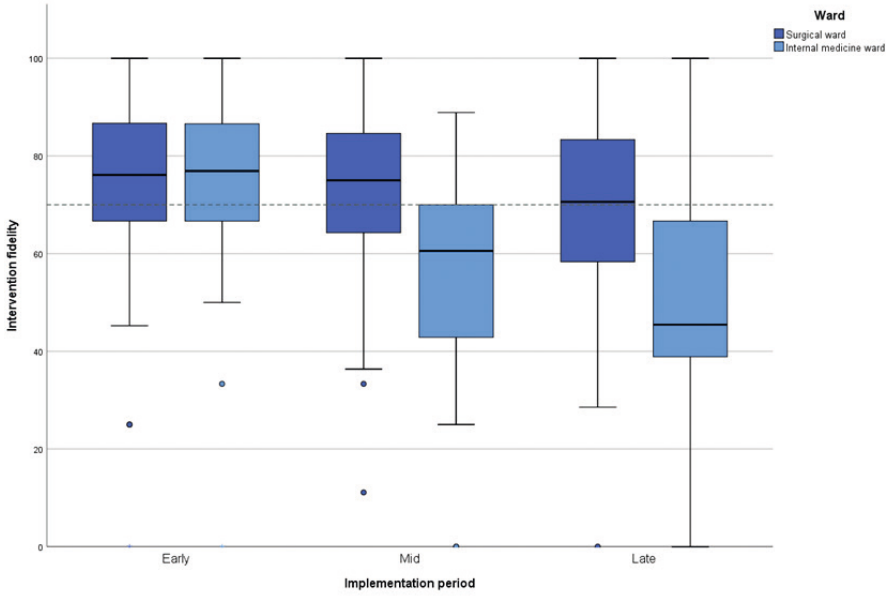
Technical fidelity

Considering technical fidelity, a total of 45,113 hours of monitoring were available (Table 4). Median monitoring time was 96 hours (IQR 48-163) per patient, resulting in 1,017,467 vital sign measurements. Monitoring data from 340 patients were successfully retrieved. There were artefacts in 27% of the HR measurements and in 15% of the ReR measurements. HR artefacts were significantly higher in the internal medicine ward (36.9% vs. 22.9%; P<.001) for unknown reason. Of all devices, 10.3% (n=37) were prematurely replaced due to technical failure. A total of 32,730 D-EWS scores were generated by the system of which 5.3% had a score of 3 or higher. The distribution of scores was different for the two wards (Table 4; P<.001).

Nurses' surveys

A total of 194 surveys were returned (Table 5). At the start of the study, 74.4% of surgical nurses versus 45.8% of internal medicine nurses found the intervention sufficiently appropriate (median score 4.0 versus 3.1; P=.032). In addition, overall attitude towards adoption of new interventions was high (score 3.5) for both wards (p=.818). Nurses of both wards found the intervention sufficiently acceptable during the study, but not at the end (score 3.5 versus 3.0; P=.020). Acceptability was significantly lower at the internal medicine ward at the end of the study (P=.018). Usability was rated marginal for both wards at both measurement moments. Feasibility was rated as sufficient, but decreased at the end of the study (score 4.0 versus 3.4; P=.002).

Figure 1: Intervention fidelity per ward over time.



Note: Early: month 1-2, Mid: month 3-4, Late: month 5-6, - - - : 70% threshold.

Table 3: Study characteristics

Patients (n=358)	**Surgery (n=248)**	**Internal medicine (n=110)**	***P*-value**
Gender, male, n (%)	138 (55.6)	77 (70.0)	.011[a*]
Age in years, median (IQR)	67.8 ± 12.5	71.2 ± 12.3	.012[b*]
Body Mass Index, median (IQR)	26.4 ± 4.8	28.5 ± 6.8	.003[b*]
Length of stay in days, median (IQR)	(3.5-10.5)	8.8 (5.5-14.1)	.000[c*]
Charlson Comorbidity Index, mean (SD)	5.0 ± 2.5	4.0 ± 1.9	.000[a*]
ASA, n (%)			.000[a*]
1-2	141 (56.9)	27 (32.9)	
3-4	107 (43.1)	55 (67.1)	
Unknown	0	28	
Urgency, n (%)			.000[d**]
Elective	230 (92.7)	1 (0.9)	
Urgent	18 (7.3)	109 (99.1)	
SNAQ score, n (%)			.985[a]
0-2	214 (86.3)	95 (86.4)	
3-5	34 (13.7)	15 (13.6)	
KATZ-ADL score, n (%)			.000[a]
0	214 (86.3)	72 (65.5)	
1-6	34 (13.7)	38 (34.5)	
Smoking, n (%)			.336[a]
Yes	39 (15.7)	18 (16.4)	
No	80 (32.3)	49 (44.5)	
Prior	129 (52.0)	43 (39.1)	
Alcohol, current use, n (%)	123 (49.6)	47 (42.7)	.230[a]
Mortality, n (%)	2 (0.8)	8 (7.3)	.002[d*]
RRT calls, n (%)	3 (1.2)	0 (0.0)	n/a
Unplanned ICU admissions, n (%)	5 (2.0)	5 (4.6)	.184[d]
Professionals (n=148)	**Surgery (n=71)**	**Internal (n=77)**	
Gender, male, n (%)	3 (4.2)	9 (11.7)	.097[a]
Age in years, median (IQR)	29 (25-44)	29 (24-41)	.991[a]
Job position, n (%)			.896[a]
Nurse	45 (63.4)	48 (62.3)	
Senior Nurse	26 (36.6)	29 (37.7)	
Work experience in years, median (IQR)	5 (1-15)	5 (2-17.5)	.782[b]
Working hours per week, median (IQR)	32 (24-32)	32 (24-32)	.602[b]

* significant with p<0.05, [a] χ^2 test, [b] Unpaired T-test, [c] Mann-Whitney U test, [d] Fisher Exact test
Abbreviations: n/a: not applicable, IQR: interquartile range, SD: standard deviation, , n: frequency

Table 4: Fidelity: intervention, implementation, technology

	Total	Surgery	Internal medicine	*P*-value
Intervention fidelity				
Written nurse reports (n/N, %)	6142	3134 / 4428 (70.1)	1153 / 1714 (67.3)	.008*[e]
Patients above 70% threshold (n, %)	198 / 358	150 / 248 (60.5)	48 / 110 (43.6)	.003*[e]
Overall fidelity, %	70.7 ± 20.4	73.6 ± 18.1	64.1 ± 23.7	.000*[c]
Early (month 1-2)	75.8 ± 17.2	75.6 ± 17.2 (n=104)	76.3 ± 17.4 (n=51)	.804[c]
Mid (month 3-4)	67.4 ± 21.4	73.8 ± 18.5 (n=65)	56.5 ± 21.8 (n=38)	.000*[c]
Late (month 5-6)	65.9 ± 22.3	70.7 ± 18.8 (n=79)	48.2 ± 25.9 (n=21)	.000*[c]
Recruitment rate (n/N, %)	358 / 364	248 / 252 (98.4)	110 / 112 (98.2)	1.000[a]
Retention rate (n/N, %)	358 / 360	248 / 250 (0.01)	110 / 110 (0)	1.000
Implementation fidelity				
Nurses attended e-learning, n/N (%)	147/158 (93)	60/67 (89.6)	87/91 (95.6)	.206[a]
Monthly evaluations, n/N (%)	10/10	5/5	5/5	
Exposure (n/N, %)	358 / 1242	248 / 738 (33.6)	110 / 504 (21.8)	.000*[e]
Technical fidelity (n=340)		N=235	N=105	
Monitoring time in hours, median (IQR)	96.6 (47.6-163.6)	96.2 (47.5-164.9)	97.4 (47.3-157.8)	.600[b]
Total measurements, n	1 017 467	729 622	287 845	
HR measurements, n	508 226	364 285	143 941	
HR measurements artefacts, n (%)	136 753 (26.9)	83 527 (22.9)	53 226 (36.9)	.000[c]
ReR measurements, n	509 281	365 377	143 904	
ReR measurements artefacts, n (%)	74 785 (14.7)	51 758 (14.2)	23 027 (16.0)	.035[c]
D-EWS scores, n	32 730	24 267	8463	.000[d]
Score 0, n (%)	6610 (20.2)	5500 (22.7)	1110 (13.1)	
Score 1-2, n (%)	24 385 (74.5)	17 849 (73.6)	6536 (77.2)	
Score ≥3, n (%)	1734 (5.3)	917 (3.8)	817 (9.6)	
Sensors replaced, n (%)	37 (10.3)	27 (10.9)	10 (9.1)	.708[e]

* significant with p<0.05, [a] Fisher Exact test, [b] Mann-Whitney U test, [c] Unpaired T-test, [d] Fisher Freeman Halton test, [e] χ^2 test

Abbreviations: IQR: interquartile range, SD: standard deviation, , n: frequency

Table 5: Documented nursing activities in CMVS reports

	Surgery (n=248)	**Internal medicine (n=110)**
No reports available, n (%)	0 (0.0)	5 (4.5)
No activities, n (%)	168 (67.7)	78 (70.9)
Activities performed by nurse, n	75	26
Assessment (wait-and-see), n (%)	61 (81.3)	13 (50.0)
Addition manual check measurement with MEWS, n (%)	14 (18.7)	13 (50.0)
Activities performed in consultation with a physician, n	59	14
Consulted physician but wait-and-see	1 (1.7)	2 (14.3)
Diagnostics	18 (30.5)	5 (35.7)
Blood test: Blood culture	5 (8.5)	2 (14.3)
Chest X-ray	4 (6.8)	0 (0.0)
Electrocardiogram	2 (3.4)	2 (14.3)
CT-scan	3 (5.1)	0 (0.0)
Urine sediment	2 (3.4)	1 (7.1)
Blood test: Arterial Blood Gas	1 (1.7)	0 (0.0)
COVID-19 PCR test	1 (1.7)	0 (0.0)
Therapy	40 (67.8)	7 (50.0)
Analgesics	18 (30.5)	0 (0.0)
Oxygen administration	6 (10.2)	2 (14.3)
Bronchodilators	6 (10.2)	0 (0.0)
Fluid challenge	3 (5.1)	0 (0.0)
Beta-blockers	2 (3.4)	1 (7.1)
Diuretics	2 (3.4)	2 (14.3)
Breathing exercise	2 (3.4)	1 (7.1)
Digoxin	1 (1.7)	0 (0.0)
Antibiotics	0 (0.0)	1 (7.1)

Abbreviations: MEWS: Modified Early Warning Score, CT: Computer Tomography, PCR: polymerase chain reaction

Table 6: Nurses' survey

	Total	Surgery	Internal medicine	P-value $_{wards}$	P-value $_{time}$	
Appropriateness, median (IQR)	3.75 (3.0-4.00)	4.00 (4.00-5.00)	3.13 (2.31-4.00)	.032[a*]	n/a	
Adoption, median (IQR)	3.47 (3.33-3.73)	3.50 (3.33-3.68)	3.47 (3.27-3.73)	.818[a]		
Openness	4.00 (3.75-4.00)	4.00 (3.75-4.00)	4.00 (3.75-4.00)	.536[a]		
Divergence	3.00 (2.50-3.00)	3.00 (2.50-3.00)	2.75 (2.38-3.25)	.935[a]	n/a	
Appeal	4.00 (3.75-4.00)	4.00 (3.75-4.00)	4.00 (3.50-4.00)	.276[a]		
Requirements	3.67 (3.00-4.00)	4.00 (3.00-4.00)	3.67 (3.00-4.00)	.746[a]		
Acceptability, median (IQR)					Overall	.020*
T1	3.5 (2.75-4.00)	3.75 (3.00-4.00)	3.25 (2.25-3.75)	082[a]	Surgery	.098
T2	3.0 (2.25-3.75)	3.25 (2.25-3.75)	3.25 (2.25-3.75)	.018[a*]	Internal	.069
Usability, mean (SD)					Overall	.790
T_1	60.4 ± 10.8	62.0 ± 10.8	58.6 ± 10.6	.226[b]	Surgery	.513
T_2	61.0 ± 13.0	63.8 ± 10.7	57.2 ± 15.1	049b*	Internal	.688
Feasibility, median (IQR)					Overall	.002*
T_1	4.00 (3.5-4.0)	4.00 (3.75-4.50)	3.75 (3.13-4.00)	.078[a]	Surgery	.017*
T_2	3.38 (3.0-4.0)	3.75 (3.00-4.00)	3.00 (3.00-3.75)	.029[a*]	Internal	.017*

* significant with p<0.05, [a] Mann-Whitney U test, [b] Unpaired T-test, Appropriateness, Acceptability, Feasibility: Likert-scale (1=disagree to 5=agree). Adoption: Likert-scale (0=disagree to 4=agree). Usability: scale 0 to 100 (score 68 or higher=sufficient).

Abbreviations: n/a: not applicable, IQR: interquartile range, SD: standard deviation, T_1: month 3, T_2: month 6

Qualitative data

A total of 21 semi-structured interviews were performed with a mean duration of 10.9 ± 3.3 minutes. Of the interviewees, n=11 worked at the surgical ward, n=8 were senior nurses and n=3 males. Five themes were identified.

Theme 1: Prioritizing CMVS

Nurses indicated that prioritization of CMVS depended on the caseload during the shift. A commonly mentioned factor was perceived workload, frequently mentioned as tasks, that they must perform during their shift. One nurse said:

> *'Yes, I think it is when the workload is high, and then it easily forgotten because of it is not your priority to check and report the trend. If it's just a quiet shift, then it's easier to perform.' (Internal medicine nurse #2)*

In addition, some nurses indicated that this varied by type of shift. Day shifts had higher workload than evening and night shifts. Although night shifts were predominantly experienced as quieter, actual intervention fidelity was not better during evenings/ nights. One nurse explained:

> *'During night shifts, I do not assess the vital signs trends because patients are supposed to be asleep and the standard manual measurement rounds are enough to assess their condition properly'. (Internal medicine nurse #5)*

Nurses also experienced CMVS as relatively unnecessary addition to their manual measurements especially during the morning rounds, where the priority for additional trend assessments was less. One nurse said:

> *'Because in the morning you still measure your vital signs with the spot-check monitoring and then CMVS is on top of that. I am able to perform without those trends.'* (Surgical nurse #9).

Furthermore, they indicated that if the patients had an uncomplicated course, the direct need for assessing the vital signs trends was also considered less and thus regular trend assessments were less likely to be performed. However, when deemed clinically relevant, for instance, when the patient already had deviating vital signs or complications, they indicated that correct assessment of trends was performed better.

One nurse said:

> *'If I only just once had a case where you can actually see deviating trends, then you'll probably use CMVS better. My experience is (mainly) with stable patients who have CMVS that shows the same (stable) trends over three consecutive shifts; I think in that case actual use and usefulness fades a bit.'*
> (Internal medicine nurse #9).

Theme 2: The importance of a bedside nursing assessment

Related to the priority of CMVS in the previous theme, nurses mentioned the importance of their clinical bedside assessment. During routine morning round vital sign measurements allowing assessment of other dimensions besides vital signs, such as skin colour, presence of sweating, dyspnoea, and mental status and pain symptoms. Also, other dimensions of nursing care can be assessed, such as checks on infusion therapy and excretion but also the need for physical care and care needs for upcoming discharge could be inventoried through the patient interaction. A nurse said:

> *'During rounds we assess more than just measuring the values of the vital signs. For instance, in patients with oxygen supplementation, you really want to know what that the breathing looks like. (…) Besides, by talking to the patient you can also obtain a more comprehensive impression of the patient who is lying in bed.' (Internal medicine nurse #8).*

Many nurses found CMVS an additionto and sometimes support for their nursing work. Several said that trends were often a confirmation of their clinical perspective of the patient rather than that it prompted them to reconsider their assessment. This was well reflected in a statement:

> *'I do find that when a patient is more ill, you asses the CMVS more often. (…) But I do not often experience that it really detects something I did not know yet. (…) However, I think it's a very nice addition to our work and may possibly stimulate clinical reasoning; especially for young nurses.'*
> (Surgical nurse #7).

Also, few nurses indicated that they did not yet fully trust the accuracy of the technology without physically assessing the patient. They indicated that ReR trends in particular were regularly found discrepancy in what they observed and what the trend indicated.

One nurse said:

> *'And you have to compare trends to the patient context. For instance, with the respiratory rate. You have to verify if the patient is mobilized and assess if the trend deviation is clinically relevant.'*
> (Surgical nurse #9)

Theme 3: Experiencing CMVS as an added value for patient care

Nurses differed in their opinion about the benefits for patient care of the intervention. Nurses who were positive about the added value of CMVS mentioned that it provides more insight into the patient clinical status, especially during night shifts and in the critically ill patients. However, they also indicated that these types of patients do not often present at the general ward. In addition, several nurses mentioned they had limited experience with the intervention and even no experience with deviating vital sign trends and performing actions on them. Nurses therefore questioned whether proactive trend assessment was feasible as standard care, because in many cases it did not alter their nursing care at that time. One nurse said about this:

> *'You have to assess regularly with most of the time not performing any actions based up on the trends. In my opinion, this does not bring any benefit to the patient, nor to us as professionals.'*
> (Internal medicine nurse #2).

However, some nurses mentioned that when they had witnessed a deviating trend and performed actions as a result, the added value of the intervention was clearer afterwards. One nurse said:

> *'I had a patient during my night shift with deviating trends, so I did an extra check and administered additional pain medication.'*
> (Surgical nurse #8).

Theme 4: Experienced usability of CMVS system

The nurses frequently mentioned the experienced usability of the hardware and software as an explanation for the decreasing intervention fidelity. Although some nurses found that the necessary time investment was limited, and CMVS was feasible during their shifts, several barriers to regular daily use were mentioned. Most often mentioned was the pairing of the sensor to the software platform, as this had to be done through a separate web-based application on a prepared mobile phone rather than via the regular used phone with call system.

One nurse said:

> *'Sometimes the separate mobile phone with the specific codes malfunctions and it simply takes too much time, which eventually results in that you leave it at that.'*
> (Internal medicine nurse #5)

Another barrier mentioned was the convenience to gain visibility into trends. The software for assessing trends was not integrated well enough into the EHR. Although the bed overview with patient names and numbers was paired, they preferred that also the trends were presented in the EHR or that trends could be viewed through a central monitoring display on the ward. Finally, removing the sensor when performing diagnostics for the prevention of interference was considered as a barrier; in particular, they felt this was important because diagnostic tests such as electrocardiograms or computer tomography scans are often ordered in ill patients. One nurse said:

> *'It is annoying when a sick patient has to go for a scan and then just at that important moment, the sensor must be removed.'*
> (Surgical nurse #4).

Theme 5: Future perspectives of CMVS on the general ward

Several nurses shared their thoughts on what improvements are needed for future routine use. In addition to full integration of the software into the EHR, as mentioned in the previous theme, nurses considered it important that the sensor should be able to measure more vital signs than only HR and ReR. A main reason for this was that manual measurements of the other routine parameters (such as blood pressure and blood oxygen saturation) are still considered necessary and therefore CMVS with just HR and ReR does not result in measurable timesaving benefits. This would only be possible when all vital signs measurements and trends are directly visualized in the EHR. Although this would save time, it would not would not remove the need and value of bedside nursing assessments during the rounds, as discussed in the previous theme. One nurse said:

> *'It would help enormously (all data and trends visible in the EHR), but even if everything is measured automatically, you still have to go and assess the patient yourself'*
> (Surgical nurse #11).

Another future perspective mentioned by some nurses, was that specific alarm strategies for deviating trends could be an alternative to timely detect deterioration. However, they questioned whether the current MEWS scoring is sensitive enough to

detect many of the common complications where abnormal vital signs values are not always present. One nurse said:

> *'Yes I also hear my colleagues about it: when scoring a (MEWS of) 3 or higher, they do not perform repeat measurements because the respiratory rate is normal for this patient. (…) I do think it's sometimes way too sensitive for a lot of patients.'*
> (Internal medicine nurse #7).

Furthermore, some nurses thought there might be benefit in continuing the intervention after discharge from hospital. Two reasons given for this were that remote clinical assessment is more difficult in the home situation. Moreover, they found it potentially could encourage early discharge by incorporating CMVS in an early recovery protocol such as Enhanced Recovery After Surgery (ERAS).

Finally, nurses indicated that the use of assistive technology is desirable for the future of nursing care, considering the enrichment of nursing care and in view of future challenges in terms of capacity shortages. One nurse said:

> *'I do support the inclusion of technology and innovation in nursing care. I think we still integrate technology too little and therefore we are less familiar with it in nursing care. Support by technology can bring so much, and I think my colleagues sometimes forget that.'*
> (Internal medicine nurse #6)

DISCUSSION

Key findings

In this study we evaluated the process of implementation of CMVS on two general wards. Using a comprehensive implementation strategy, our overall results suggest that CMVS was sufficiently implemented on both wards, although intervention fidelity was highly variable and decreased over time. This decrease was explained to a large extent by the declining intervention fidelity in the internal medicine ward (it remained stable on the surgical department). Another contributing factor was that nurses on both wards perceived little added value of the intervention. Taken together, the results show the complexity and interconnectedness of the implementation and intervention fidelity with the technology and perceptions of nurses.

While recruitment and retention rates of the intervention were high indicating high patient acceptance, both wards showed a decline on several dimensions of the implementation: intervention fidelity (although not statistically significant for surgery), but also on perceived acceptance, usability and feasibility. Interestingly, this decline was less on the surgical ward than on the internal ward. There are several possible explanations for this discrepancy between the surgical and internal medicine ward. Although 110 patients were included on the internal medicine ward, compared to the surgical ward exposure to the intervention was still limited (21.8%) and decreased over time - especially during the last two months of implementation. Second, nurses on the internal medicine ward considered the intervention less relevant for their practice. A first possible explanation, as far as the internal medicine department is concerned, is the hospitalisation procedure of emergency patients. After presentation in the ER and subsequent admission to the acute ward for a maximum of 48 hours, the patient was then transferred to the internal medicine ward. At that time, the diagnosis was established and treatment had started and so these patients had already passed the precarious, critical stage of their condition, and deviations in vital signs may be considered of lower clinical relevance.[46] This was different in the surgical ward, where CMVS was started directly after surgery, the period the patient is at highest risk for complications and deterioration.[47] This also may be an explanation for the low ratings of appropriateness from nurses on the internal medicine ward. Nevertheless, it is noteworthy that the proportion of patients with abnormal D-EWS was highest on the internal medicine ward, but possibly this was not deemed clinically relevant.

Although a broad range of interventions was performed by nurses based on the trend assessments, several reasons might explain the perceived low added value of the intervention for nursing care. First, the rationale for using CMVS is likely to be less convincing when also maintaining the conventional manual nurse measurements to calculate MEWS. This could be explained by the fact that nurses highly value being at the bedside and observing the patient themselves while performing their manual measurements. Nurses explained they use this moment to perform a more comprehensive patient evaluation, including assessing other domains of clinical deterioration than vital signs but also other nursing domains by patient interaction. Secondly, the high degree (nearly 70% of all patients) to which no subsequent activities were initiated based on the trend analysis may indicate that intervention fidelity was limited for this reason. In general, nurses stated that they had little or no experience with interpreting deviating vital signs trends. In specific cases, trends may have prompted more timely additional measurements or diagnostics, such as blood tests or imaging or initiating a doctor's consult, but overall it remains difficult to say to what extent the vital signs trends monitoring actually contributed to the decision making.

In addition, the current state of the technology may have affected the intervention fidelity. Despite generating a very large amount of data, technical difficulties remain. Around 10% of the sensors had to be replaced prematurely due to different types of failure, such as malfunctioning of the sensor during pairing, unexplainable sensor failure or high artefact ratios in some patients. This was also reflected in the high artefact rate for HR measurements which may have had a negative influence on intervention fidelity and acceptability. Possible explanation is that adequate HR measurements by an accelerometer may be more complicated, but this has not yet been adequately studied.[35] The higher HR artefact rate in the internal medicine ward is also unclear. We checked patients with high artefact rates for incorrect sensor placement, but this was rarely the cause. Current limitations of the technology have likely contributed to the low usability scores during the implementation period on both wards. In the interviews, nurses commented that these issues made it cumbersome to use the system, while reducing trust in the technology. Furthermore, the current threshold-based D-EWS scores to guide trend assessment do not sufficiently take into account the context of the patient (e.g., 'in bed', or 'actively mobilizing'), resulting in contamination of the vital sign trends, e.g., simultaneously HR and ReR, that is actually normal, because the patient is actively mobilizing. Consequently, it will be harder to recognize true deterioration early. In contrast, when the nurse manually records an abnormal set of bedside vital signs, CMVS trends may show an important correlation with the current (abnormal) bedside observation, and can support the nurse's decision to seek consultation with the on-call physician. Correlation between vital signs and direct bedside observations are important for clinical decision-making, which are missing when entirely relying on remote trend assessments.

Comparison with other work

Comparison of our results with prior studies is challenging, because of differences in patient population, monitoring devices and outcomes addressed. Intervention fidelity in the present study was somewhat lower in comparison with our previous feasibility study over a period of three months with a similar CMVS intervention;[15] respectively 71% versus 81%. However, if we compare the first months, this difference is smaller (75.8% versus 80.5%).

Regarding the need to still perform manual vital signs measurements and lack of experience in assessing deteriorating trend patterns – as previously mentioned by nurses - are likely to have affected nurses' perspectives and may have influenced intervention fidelity. This observation is also in line with results of our previous feasibility study.[15] Moreover, while abnormal HR and ReR are important signs of patient deterioration, evidence is still lacking that CMVS monitoring of only two vital signs is

sufficient to capture most cases of deterioration. In contrast to our results, Verillo et al. showed when CMVS by a more bulkier multi-parameter device is used as the single method for vital signs monitoring, nurses acceptance and compliance over a period of only six weeks increased over a six-week period (initial 38% to a sustained average of 62% compliance).[48] This may indicate that automating the manual measurements is better for acceptability of nurses. Nonetheless, larger devices measuring all vital signs may possibly result in poorer patient acceptance. Early termination of the intervention was rare in our study, which is in contrast to 21% of patients in a previous study with a wrist worn multi-parameter device.[14] However, in our study about 10% of the sensors was prematurely replaced due to a technical error like connectivity issues. Furthermore, the need for gaining experience with use of the wearable device in clinical practice was also mentioned by nurses in the study of Izmailova et al.[49] Further, in line with previous studies, nurses also sometimes questioned the accuracy of the device and doubted the benefits of being able to observe their patients' vital signs remotely.[50,51] In contrast, many nurses also expressed a positive attitude towards CMVS interventions, mentioning that it could increase patient safety by providing more insight.[52] Lastly, experienced usability by ward nurses of a similar wearable patch device was higher in the study of Boatin et al., although this may be because of the relative small, short-term study in 32 pregnant woman.[53]

Other studies have also reported on technical fidelity. Our observed artefact rates were slightly higher (26.9% versus 20% for HR and 14.7% versus 12% for ReR) compared to a validation study in surgical patients at the post-anaesthesia care unit (PACU) with the same sensor.[35] One potential explanation is that motion artefacts are more present in ward patients than in patients during the early stages of recovery after anaesthesia and surgery on the PACU.

Limitations

To our knowledge, this is the first study which extensively focused on evaluating the process of a CMVS implementation at scale in daily clinical practice on general hospital wards. The data can provide valuable information to other hospitals considering a CMVS implementation, and highlight some important issues to consider when developing an implementation strategy. However, several limitations should be considered when interpreting the present results. First, on both wards exposure to the intervention was still limited, which forced nurses to work with two systems of vital signs monitoring (intermittent and continuously) and may hampered implementation. Third, it is important to note that the development of the implementation strategy and intervention took place on the surgical ward, which might have resulted in an intervention more fitting to a surgical ward than an internal medicine ward. In addition, goodwill towards the

project manager, a former nurse on the surgical ward, might partly explain the higher intervention fidelity on the surgical ward. Fourth, even after analyzing every individual nurse trend assessment report, it is still not possible to determine with certainty to what extent these vital signs trends actually influenced subsequent diagnostic and/or therapeutic decisions. This is mainly because several other factors contribute to additional activities and medical decision-making. Moreover, it is not clear how large the variation is between nurses interpreting similar trends. This would require a separate study. Finally, we did not include the magnitude of nurses' exposure to the intervention as a factor in the regression analysis, which could possibly cause bias. However, we have extensively focused on education and bedside training in the implementation strategy.

Implications

Our study highlights the complexity of implementation a CMVS system with a wearable wireless sensor on hospital nursing wards. Therefore, policy makers should early involve nurses in establishing the intervention and implementation strategy and selecting the appropriate patient populations in order to enhance the fit with the needs of current nursing practice. To leverage the full potential of CMVS on general wards, several barriers for implementation in the routine workflow need to be addressed, for which we suggest the following recommendations:

1. Secure full and seamless integration of the CMVS into the hospital EHR, avoiding any separate software platforms or dashboards. This will improve fidelity and usability for caregivers.
2. Use advanced and validated multi-parameter CMVS sensors, which are sufficiently accurate and comprehensive to allow the discontinuation of standard manual vital sign measurements by nurses, thus reducing nursing workload.
3. Combine CMVS with reliable personalized clinical decision support tools to facilitate correct and timely interpretation of these measurements. Algorithms still need to be developed that can incorporate patient-specific baseline data, facilitate routine automated input of contextual factors such as patient movement, and perform automated trend analysis and event detection to timely detect and alert clinical deterioration.[22] When such systems are available, this will obviate the need to have vital sign trends proactively monitored and interpreted by nurses, which currently increases nursing workload and is difficult because of their lack of experience in this respect.
4. Lastly, carefully select (high-risk) patient populations that are likely to benefit most from CMVS. This could potentially include all acute care admissions (especially those without a clear diagnosis at admission), and all intermediate and high-risk surgical patients in the postoperative phase (both on the ward and at home directly after discharge). Thus, the intervention could be integrated into an early discharge protocol with extended telemonitoring at the patient's home.[54]

Conclusion

We successfully implemented a system for continuous wearable remote vital signs monitoring at scale on two hospital wards, but our results show that intervention fidelity decreased over time, to a larger extent on the internal medicine ward than on the surgical ward. This decrease appears to be dependent on multiple ward-specific factors. Perceptions of nurses regarding the value and benefits of the intervention were variable. Our study provides valuable insights for optimal implementation of CMVS on general wards. Specifically, we conclude that implementation of a CMVS, while at the same time maintaining routine manual vital sign measurements, is not advisable as it increases nurse workload. Pro-active vital signs trend assessment by nurses is feasible, but challenging to embed sustainably at scale in current workflows, even when using an extensive implementation strategy. Wearable wireless monitoring technology should further be developed and optimized, including seamless integration into the EHR, and developing more sophisticated decision support tools for interpretation and alarms that are suitable for general wards, before it can consistently improve nursing workflows, increase patient safety and enhance quality of care.

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Conflict of interest statement

None of the authors have conflicting interests. The manufacturer of the wearable sensors and digital platform (Philips Healthcare, Eindhoven, the Netherlands) did not play a role in the design, implementation, interpretation, and reporting of the study. Sensors were provided at a reduced price for the study.

Abbreviations

AD:	Administrative Data
ASA:	American Society of Anesthesiologists
CCI:	Charlson Comorbidity Index
CMVS:	Continuous vital signs monitoring
CT:	Computer Tomography
D-EWS:	Deel Early Warning Score
EHR:	Electronic Health Record
HL7:	Health Level Seven
HR:	Heart Rate
I:	Interviews
IGS:	Intellivue Guardian Solution
IQR:	interquartile range
LoRa:	Long Range, Low Power Internet of Things connection
MEWS:	Modified Early Warning Score
n:	frequency
n/a:	not applicable
PACU:	post-anaesthesia care unit
PCR:	polymerase chain reaction
ReR:	respiratory rate
S:	Survey
SD:	standard deviation
SNAQ:	Short Nutritional Assessment Questionnaire
T1:	month 3
T2:	month 6
USA:	United States of America

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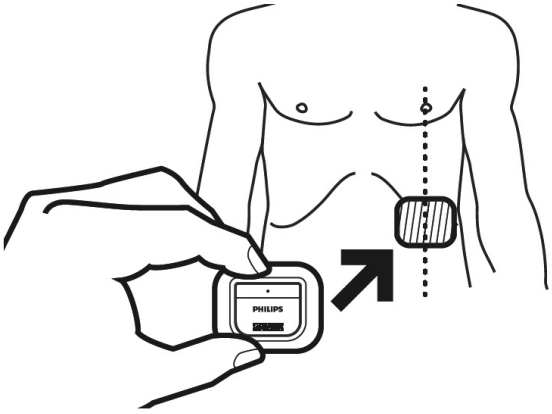
APPENDICES

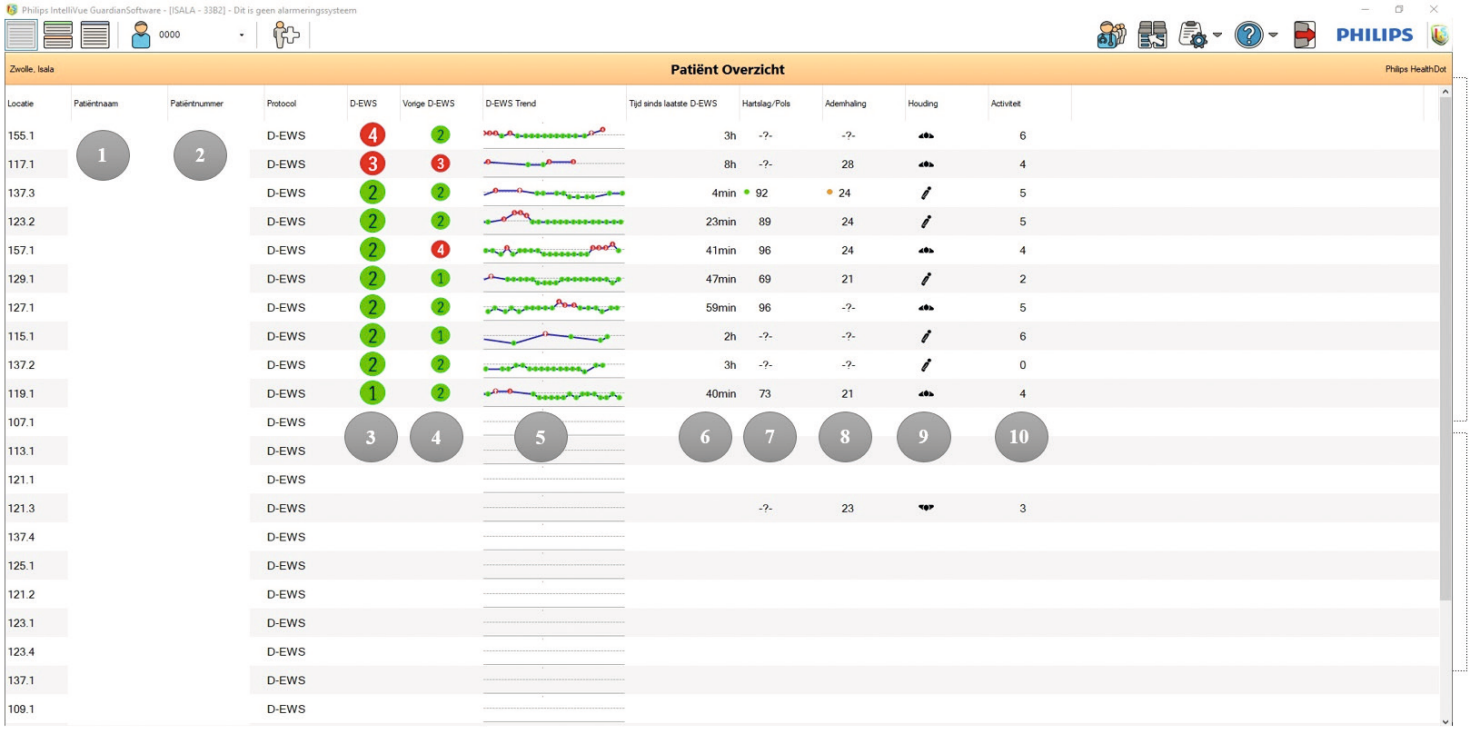
Appendix 1: Admission indications of patients

Surgical ward		**Internal ward**	
Gastro intestinal	Colorectal resections Liver resections Pancreatic	Gastroenterology	Pancreatitis Acute gastro-intestinal bleeds Liver cirrhosis
Vascular	Diabetic feet Abdominal aortic aneurysm Peripheral arterial disease (Fontaine III or IV)	General	Erysipelas Pneumonia Urinary tract infection Multiple organ disorders

Appendix 2: The Philips Healthdot wearable sensor



Appendix 3: Example of the Philips Intellivue Guardian Solution (IGS) dashboard



1: Patient's name, 2: Patient ID, 3: latest D-EWS score, 4: previous D-EWS score, 5: trend of D-EWS scores over a period of 24 hours, 6: Time since latest D-EWS score, 7: latest heartrate measurement, 8: latest respiratory rate measurement, 9: latest posture measurement, 10: latest activity score

Appendix 4: Thresholds of the partial Early Warning (D-EWS) scores

	D-EWS score					
Score	2	1	0	1	2	3
Heart rate (HR)	<40	40-50	51-100	101-110	111-130	>130
Respiratory rate (ReR)	<9		9-14	15-20	21-30	>30

Appendix 5: Contents and study goals of the e-learning for nurses

Contents

1. About wearable continuous vital signs monitoring on the ward
2. About the wearable sensor and nationwide developments
3. About the project in Isala
4. Getting started with continuous vital signs monitoring
   - 4.1. The D-EWS protocol
   - 4.2. Inclusion phase
     - Activation and applying the wearable sensor
     - Connecting the wearable sensor to the EHR
   - 4.3. Monitoring phase
     - Assessments of vital signs trends
   - 4.4. Closing phase
5. Guardian software
   - 5.1. About the software
   - 5.2. The software at your desktop
   - 5.3. The software at your mobile application
6. Assessment

Study goals

1. You understand the rationale for using the continuous vitals sign monitoring and you are familiar with the project design.
2. You understand which and how vital signs are measured by the continuous vitals sign monitoring.
3. You understand how to include the patient and how to counsel patients about continuous vitals sign monitoring.
4. You are able to activate the sensor, pair it to the software and attach it on the patient's body at the right location.
5. You are able to manually add a new patient to the software. You can link the continuous vitals sign monitoring to the right patient via the app.
6. You are familiar with the two methods (at your desktop and mobile device) to display the data of the continuous vitals sign monitoring.
7. You are familiar with how the measurements of the continuous vitals sign monitoring are shown.
8. You understand when to assess the trend and what the follow-up interventions of deterioration trends should be.
9. You understand how to assess vital signs trends properly.
10. You are able to discharge the patient from the continuous vital sign monitoring.
11. You understand how you and your ward are supported during the project.

Appendix 6: Topic list for the semi-structured interviews with nurses

Introduction	**Presenting the dashboard of the study with the monthly inclusion and intervention fidelity of the ward**
1	Considering these interim results, what was your overall experience of working with the intervention?
2	Could you clarify these results when considering your experience?
3	To what extent does working with the intervention improve your daily work?
4	What would be your recommendations for the future with regard to working with the intervention?

Appendix 7: List of Admission indications

Surgical ward (n=248)		**Internal ward (n=110)**	
Gastro-intestinal surgery (n=201)		**General internal medicine (n=56)**	
Colorectal resection	126 (62.7)	Pneumonia	21 (37.5)
Pancreatic resection	36 (17.9)	Urinal tract infections	13 (23.2)
Liver resection	15 (7.5)	Infectious disease, other	9 (16.1)
Anus praetor construction	15 (7.5)	Multiple organ disorders	8 (14.3)
Other	9 (4.8)	Erysipelas	5 (8.9)
Vascular surgery (n=47)		Gastroenterology (n=54)	
Peripheral occlusion	36 (76.6)	Pancreatitis	21 (38.9)
Bypass	14 (29.8)	Gastrointestinal bleed	20 (37.0)
Endarterectomy	13 (27.7)	Liver cirrhosis	11 (20.4)
Percutaneous Transluminal Angioplasty	9 (19.1)	Other	2 (3.7)
Central occlusion	6 (12.8)		
Amputation	4 (8.5)		
Other	1 (2.1)		

Appendix 8: Outcomes of multiple linear regression for both wards

Surgical ward

Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95,0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	79.703	3.145		25.344	.000	73.508	85.897
	CCI score	-.038	.612	-.004	-.062	.951	-1.243	1.168
	D-EWS scores ≥3	-.094	.114	-.057	-.821	.412	-.318	.131
	Length of stay	-.289	.162	-.123	-1.780	.076	-.609	.031
	Artefact rate	-.064	.079	-.052	-.811	.418	-.218	.091
	Mid implementation (month 3-4)	-1.690	2.903	-.041	-.582	.561	-7.408	4.028
	Late implementation (month 5-6)	-4.902	2.698	-.126	-1.817	.071	-10.217	.413

Internal medicine ward

Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95,0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	79.274	6.433		12.323	.000	66.516	92.032
	CCI score	-.656	1.088	-.052	-.603	.548	-2.814	1.501
	D-EWS scores ≥3	.023	.110	.018	.207	.837	-.195	.240
	Length of stay	.140	.240	.050	.584	.561	-.335	.615
	Artefact rate	-.065	.106	-.053	-.618	.538	-.275	.144
	Mid implementation (month 3-4)	-20.200	4,604	-.407	-4.388	.000	-29.331	-11.070
	Late implementation (month 5-6)	-28.616	5.498	-.477	-5.205	.000	-39.519	-17.712

Abbreviations: CCI: Charlson Comorbidity Index

Appendix 9: List of implementation measures of the monthly evaluations

Month	Surgical ward	Internal ward
1	Describing a deterioration case study and communicate this by monthly mail	Request a schedule from assistant physicians to proactively provide education
	Creating a dashboard for nurses for the daily meeting	Daily calls by the project manager about the status inclusions again in the afternoon Explanation of the added value of trend monitoring after the acute phase of illness in the monthly evaluation Discussing trends of actual patients in the daily education meeting four times
2	Adjusting activity plan in the EMR to make it more visible	Maintaining daily contact with project manager about inclusion
	Using the daily boards in day and evening shifts. For nights shifts in handover-file.	Informing physicians about the progress of the project
	Identify 'stragglers' based on file research and providing feedback to these nurses by key users.	Discussing trends of actual patients in the daily education meeting four times
	Organizing of four education moments in the coming month about deteriorating trends	
	Sending an e-mail to all physicians as reminder of the project	
3	Analysing a case study of deviating trend of a patient unplanned admitted to the ICU	Weekly training during the daily meeting on the potential added value of CMVS and with case studies
	Providing feedback by e-mail on use in night shifts and added value of CMVS	Planning a presentation about the project in the team meeting
	Promoting of verbal handover of CMVS between day and evening shift	Maintaining daily contact with project manager about inclusion
	Identification of reasons of non-compliance during night-shifts	
	Planning a presentation about the project in the team meeting	
4	Informing new physician assistants	Informing new physician assistants
	Generating an educational quiz for the daily educational meeting	Maintaining daily contact with project manager about inclusion
	Increasing the standard time intervals of trend software to maximum of four days	
5	Checking whether logging in to the app still works on the mobile device	Maintaining daily contact with project manager about inclusion

8

IMPACT OF WEARABLE WIRELESS CONTINUOUS VITAL SIGN MONITORING IN ABDOMINAL SURGICAL PATIENTS ON A GENERAL WARD: A BEFORE-AFTER STUDY

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Submitted

ABSTRACT

Background

Technological advances have enabled continuous monitoring of vital signs (CMVS) by wearable, wireless devices on general hospital wards. These devices facilitate early detection of clinical deterioration, which could potentially improve clinical outcomes. However, evidence on the impact of these CMVS systems on patient outcomes is limited.

Aim

To explore the effect of CMVS on length of hospital stay (LOS) and a broad range of other clinical outcomes in elective colorectal (CR) and hepato-pancreatobiliary (HPB) surgery patients on a general surgical ward.

Methods

A single-centre before-after study was conducted from October 2019 to June 2022. Patients in the intervention-group received CMVS in addition to conventional intermittent vital sign monitoring (standard care for control-group). With CMVS, heart rate and respiratory rate were measured every 5 minutes by a patch sensor. Proactive vital signs trends assessments and, when necessary, subsequent nursing activities were performed every nursing shift. Besides LOS as primary outcome, 19 patient-related outcomes were analysed. In the CMVS-group, follow-up nursing activities of deviating vital signs trends were described and patient acceptability was measured.

Results

A total of 908 patients were included (CR:n=650;HPB:n=257). Overall, median LOS was lower in the CMVS-group (5.0 vs 5.5 days; p=.012), respectively. In subgroup-analysis, reduced LOS was observed only in CR-patients, but not HPB-patients. Apart from a decrease in nurse-to-house-officer calls (from 15.3% to 7.7%;p=.007), all secondary clinical outcomes were similar in CMVS and control-groups. However, a non-significant trend towards less severe complications and reduced ICU LOS was observed in the CMVS-group. In CMVS-patients 109 additional nursing activities were performed and 83% of patients indicated CMVS was acceptable.

Conclusion

CMVS was associated with a significant reduction in LOS for CR-surgery patients, but not for HPB-surgery patients, while other clinical outcomes were unchanged. CMVS triggered additional nursing activities such as extra patient assessments and therapeutic interventions.

INTRODUCTION

Postoperative complications after major abdominal surgery may occur in up to 44% of all patients,[1,2] impact a broad range of patient outcomes and also considerably increase costs.[3–10] They not only increase mortality and prolong hospital stay, but also result in the need for an increased level of post-discharge care and a higher readmission rate. Furthermore, long term outcomes such as Quality of Life (QoL) and functional performance are negatively affected.[10,11]

Severe postoperative complications are commonly associated with clinical deterioration and, when detected early, timely intervention may reduce morbidity and mortality.[12] Vital sign deviations usually precede clinical deterioration. To promote identification of patients at risk, simple physiological parameter-based protocols are broadly implemented on general wards.[13,14] Generally, the five key vital signs[15] (blood pressure, blood oxygen saturation, heart rate, respiratory rate, and body temperature) are measured manually 1-3 times a day in general wards and aggregated into a single number using the Early Warning Scores (EWS) system. A critical limitation of these systems is that the physiological measurements are intermittent, there is poor protocol adherence and sometimes inaccurate vital sign recording.[16–18] Patients may unexpectedly deteriorate which may go unnoticed in between routine vital signs measurements.[19]

Over the last decade, new technological advances facilitated the introduction of continuous monitoring of vital signs (CMVS) by wearable, wireless devices on general wards. These CMVS interventions allow earlier detection of clinical deterioration and may improve clinical outcomes, in particular reduced complication severity, reduction of failure to rescue events, and less ICU admissions, all of which combined may decrease total length of stay.[12,18,20–22] Evidence for a positive effect on clinical outcomes in general ward patients with wearable devices is however scarce.[23,24] This may be explained by the challenging implementation of CMVS in clinical workflows.[25,26]

Successful implementation is essential before any potential effectiveness of continuous monitoring can be reliably demonstrated. Therefore, we first developed a CMVS intervention and evaluated the feasibility in two previous studies.[27,28] Subsequently, we set up an interventional study with a hybrid design focusing on both evaluation of the implementation and the effectiveness of the intervention.[29] The success of our implementation strategy is described elsewhere.[30] Here, we describe our findings regarding the impact of CMVS on the surgical ward on clinical outcomes in elective colorectal (CR) and hepato-pancreaticobiliary (HPB) surgery patients as compared to

a historical control group. Primary aim was to explore the effect of CMVS on length of hospital stay (LOS). Secondary aims were to explore the effects of CMVS on a broad range of other clinical outcome measures.

METHODS

Study design

A single-centre before-after study as part of a type 2 hybrid design[29] was conducted from October 2019 to July 2022 in a 1250-bed teaching hospital in the Netherlands. This study is reported in concordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and was registered in the ISRCTN registry (ISRCTN37125996).[31]

Participants and setting

Patients admitted to the surgical ward for elective major abdominal surgery, including both colorectal and hepato-pancreatobiliary resections, were eligible to participate in the study. Inclusion criteria were: ≥18 years old and expected hospitalization of ≥2 days. Patients admitted between October 2019 and November 2021 were retrospectively included in the pre-implementation group as controls. From November 2021 till June 2022 patients were prospectively included in the intervention group (post-implementation group). No substantive changes were made to unit staffing, nor to hospital protocols, departmental safety, and quality policies during the 2.5-year study period. Patients were excluded when the primary indication for hospitalization was acute (not elective), had a palliative indication, a known allergy for any of the materials of the sensor or when they participated in another (potentially conflicting) study.

CMVS intervention

Pre-implementation, the standard of care was intermittent manual monitoring using the Modified Early Warning Score (MEWS) according to the local hospital protocol. For every MEWS, besides subjective measurements, five vital signs were recorded: respiratory rate (RR), heart rate (HR), blood pressure (BP), core temperature and oxygen saturation (SpO2).[32] (Appendix 1) Vital signs were measured manually using a blood pressure measuring device with a pulse oximeter, an ear thermometer, and by visual inspection of RR.

Post-implementation, in addition to the standard MEWS protocol, patients were continuously monitored by the Conformité Européene marked Philips Healtdot and Intellivue Guardian Solution (IGS) software system (*Philips, Eindhoven, The Netherlands*).

The wireless monitoring sensor is embedded in a patch worn on the patient's chest (Appendix 1); it continuously records heart rate (HR) in beats per minute (bpm) and respiratory rate (RR) in respirations per minute (rpm) using a chest accelerometer. Every 5-minute interval, the vital signs measurements were wirelessly transmitted to the Intellivue Guardian Solution (IGS) software. Within the IGS software, vital sign trends are visualized and, complementary to the hospital MEWS protocol, a partial MEWS-score (D-EWS) was aggregated every hour based on the thresholds for HR and RR. Since the device measures only two vital signs, the intervention was used in addition to the standard-of-care intermittent manual measurements. Based on our feasibility study findings, instead of using an alarm strategy, nurses routinely assessed current vital signs and their trends every four hours (i.e. twice per 8 hour shift) without alarms. At the end of every shift, they reported the D-EWS score, possible abnormalities, deviations, and subsequent nursing activities in the Electronic Health Record (EHR). Full description of the intervention and implementation strategy are reported elsewhere.[30]

Variables

The following patient characteristics were collected: gender, age, length, weight, Body Mass Index, American Society of Anaesthesiologists (ASA) classification, procedure (laparoscopic or open), malignancy (none, solid tumour or metastasis), nutritional status (the short nutritional assessment questionnaire score with score ≥3 or higher as malnutrition[33]), smoking status (yes, no or prior), alcohol use (yes, no), preoperative haemoglobin (Hb) and comorbidities (Charlson Comorbidity Index score ranging 0-12).[34,35]

Primary outcome for the study was the effect of CMVS on hospital LOS in days. Discharge time before 2 p.m. was considered as a 0.5 day based on routine workflows for operating room and ward bed capacity. Secondary postoperative outcomes were divided in in-hospital and post-discharge outcomes. In-hospital outcomes were: a) proportion of long LOS (defined as +1 standard deviation or 3th quartile or higher of the control group) b) Rapid Response Team (RRT) calls, c) nurse-to-House-Officer (HO) calls (defined as junior resident calls between 18 pm and 8 am) regarding deviating vital signs, d) unplanned Intensive Care Unit (ICU) admissions, e) ICU LOS, f) reoperations, g) mortality <30 days after surgery, h) severe complications (severity IIIa to V according to the Clavien-Dindo classification[36]), i) incidence of falls, pressure ulcers, delirium (as diagnosed by geriatrics consult) and, j) postoperative unplanned CT or MRI scans. Post-discharge outcomes were; a) readmissions <30 days after discharge, b) days alive at home37 (DAH30), c) discharge disposition and, d) type and amount of required post-discharge nursing care.

All nursing activities that were initiated and performed based on the CMVS trend assessments were documented by the nurses. These were divided into performing: 1) additional checks and 2) interventions in consultation with a physician. In addition, patients completed a questionnaire consisting of the Acceptability Intervention Measurement (AIM), a Patient Reported Experience Measurement (PREM) about comfort of the sensor and recommendation score on a scale of 1-5, an overall score on a scale of 1-10 and free space for remarks. The AIM questionnaire consisted of four statements about acceptance on a 5-point Likert scale (score 1-5). A median score of ≥ 3.5 was defined as sufficient acceptability.[38]

Study size

Estimation of the sample size was calculated with MedCalc (*MedCalc Software Ltd, Ostend, Belgium*). A two-tailed alpha of 5%, power of 0.80 and LOS (in hours) with 150.1 (intervention) versus 187.7 hours (control) in ratio 1:4, resulted in at least 180 patients required for the intervention group and 720 for the control group. LOS in the CMVS group was prospectively recorded, and LOS in the control group was derived from the hospital EMR. An additional 10% for potentially non-parametric testing resulted in at least n=198 patients in the intervention group and n=792 patients in the control group.

Statistical analysis

LOS was compared between the CMVS and control groups. Multiple imputation was performed to handle missing data when present. Normally distributed continuous data were presented as means and standard deviations (SD) and tested with unpaired t-tests. Likewise, non-normally distributed data are presented as median and inter-quartile range(IQR) and were tested with Mann–Whitney U-tests. Normality was checked by the Kolmogorov–Smirnov test and visually by a Q-Q plot and histogram. Nominal data were presented with frequencies and percentages (n, %) and tested with χ^2 test or Fisher exact Tests based on assumptions. Subgroup analysis were performed to compare outcomes between CMVS and control groups in patients with only CR or only HPB surgery.

A multivariable analysis to determine impact of CMVS on log-transformed LOS was performed while controlling for gender, type of surgery (colorectal or hepato-pancreaticobiliary), urgency, procedure, Charlson Comorbidity Index, complications and group. Multicollinearity was present if Variance Inflation Factor (VIF) was ≥5. All data were analysed with IBM SPSS Statistics 26 for Windows (*IBM Armork, New York, USA*) and a p-value < 0.05 was considered significant.

Ethics

The Daily Board of the Medical Ethics Committee Isala reviewed the protocol (protocol 20211114) and declared the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO), did not apply for the study. The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from patients participating in the post-implementation group.

RESULTS

Study characteristics

A total of 978 patients were screened and after exclusion, 908 were eligible for analysis of which 714 controls and 194 intervention patients (Figure 1). Table 1 presents the characteristics of all patients. Proportion of ASA class 3-4 was higher in the CMVS group (35.1% versus 25.9%; p=.012) although CCI score was lower for the CMVS group (5.2 versus 5.8; p=.004).

In the subgroup analysis, several statistically significant baseline differences were observed (Table 3). In the CR CMVS-group, higher ASA class (3-4) was more prevalent, less rectal resections were performed and patients had slightly lower preoperative Hb in comparison with the control group. In the HPB CMVS-group, more pancreas resections were performed, CCI score was lower, and there were more active smokers in comparison with the control group.

Length of stay

Median (IQR) LOS for the total CMVS group was 5.0 (3.5-8.6) days versus 5.5 (4.0-10.0) days in the control group (*p*=.012). After controlling for patient and surgical characteristics with multivariate analysis this difference was maintained with an unstandardized coefficient of -.043 (95% CI -.077 - -.009). Except for gender and CCI score, all other variables in the model added statistically significantly to the prediction of LOS (Appendix 2).

Subgroup-analysis showed that in patients undergoing colorectal procedures LOS in the CMVS group was lower than in the control group (median LOS 4.0 versus 4.5 days; p=.001). In the patients undergoing HPB surgery, median LOS was similar between CMVS and control groups: 9.0 versus 9.0 days; p=.754) (Table 4). After multivariate analysis, this difference was maintained for the CR patients, whereas LOS remained similar in HPB patients (Appendix 2).

Secondary outcomes

In-hospital outcomes

The number/percentage of nurse-to-HO calls was significantly lower in the intervention-group, 7.5% versus 15.3% in the control group (p=.007) and in the sub-group analysis for both groups (8.3% versus 14.6%; p=0.05 in CR patients and 16.9% versus 6.0%; p=.051 in HPB patients) (Table 4). None of the other outcomes differed statistically significantly between CMVS en control groups including complication rates, the number of RRT calls and unplanned ICU admissions. This was also true for the subgroup analysis. Although overall complication rates did not differ between groups, a non-significant increase in complication severity IIIb (49.4% to 56.5%) and decrease of severity IVb (from 7.2% to 0%) was observed. We also observed a trend towards a reduced median ICU LOS in the CMVS group (3.0 versus 8.0 days).

Post-discharge outcomes

DAH_{30} was higher in the CMVS-group (median 24.5 versus 24.0 days; p=.005) and more patients were discharged with a need of home care (38.9% versus 29.6%; p=0.015). Although readmission rate did not differ between groups, LOS of readmissions was lower in the control group (median 6.5 versus 4.0 days; p=.014). None of the other outcomes were different between intervention and control groups (Table 2). In the subgroup-analysis, DAH_{30} and LOS of readmissions were different only in CR patients (Table 4). In HPB patients, more patients in the CMVS group were discharged with a need for care (59.4% versus 42.0%; p=.026) resulting in more patients who were discharged with a need for home care (58.0% versus 35.7%; p=.004).

Performed nursing activities

Based on trends assessments, 109 nursing activities were performed in 68 patients (35.1%) of which 70 (64.2%) independently by the nurse and 39 (35.8%) in consultation with a physician (Table 5). Nurses independently performed 9 (8.3%) additional measurements and 61 additional patient assessments resulting in wait-and-see (56.0%). In consultation with a physician, 10 (9.2%) diagnostic and 28 (25.7%) therapeutic interventions were performed.

Patient experiences

A total of 163 questionnaires were completed (84%). 76.7% (n=125) of patients rated the intervention 8 out of 10 or higher resulting in a median satisfaction of 8.0 out of 10 (IQR 8-9) (Table 6). 83.4% (n=136) of patients found the intervention acceptable resulting in a median (IQR) acceptability of 4 out of 5 (3.6-5.0). The majority of patients found the patch easy to wear (88.6%), felt safer (71.2%) and would wear the patch again (92.6%). There were no significant differences between CR and HPB group.

In addition, patients (Table S2) made 47 remarks. There were statements about the desire to have more insight in their own vital signs measurements and the results and impact of the CMVS intervention. Furthermore, most patients mentioned they were not bothered at all by wearing the sensor. In contrast, several patients mentioned negative aspects of the wearability of the sensor about being too hard, especially when laying on their side in bed, and the need for replacement when diagnostic tests had to be done. Also, patients mentioned an increased feeling of safety by wearing the sensor.

Figure 1: Flowchart of the study

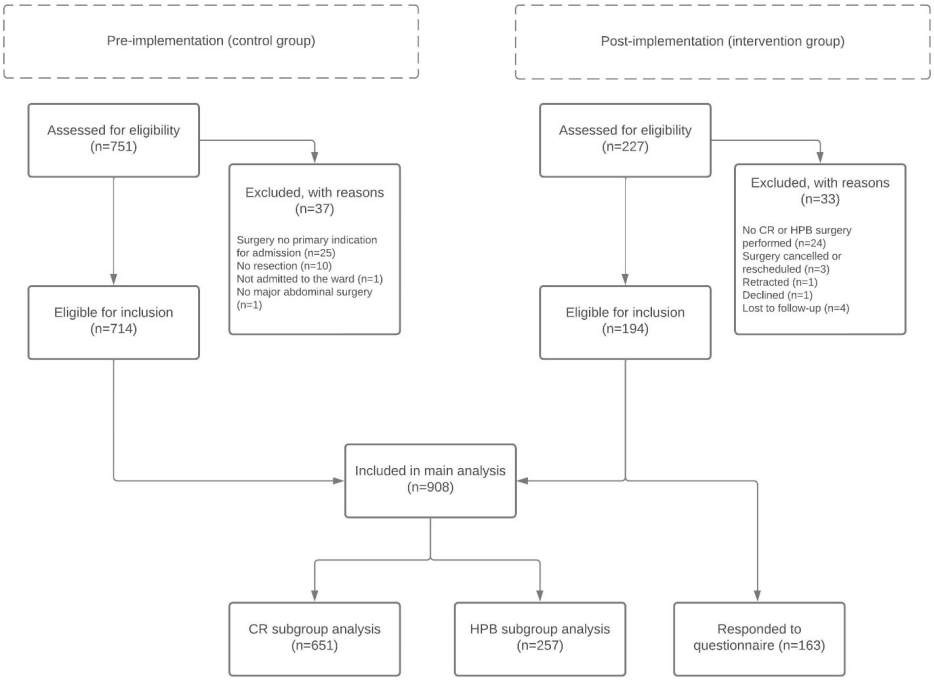

Table 1: Patient characteristics

	Control-group (n=714)	CMVS-group (n=194)	p-value
Gender, male, n (%)	361 (50.6)	106 (54.6)	.313
Age, mean (SD)	66.8 ± 13.1	68.1 ± 11.9	.236
Length, mean (SD)	172.8 ± 11.7	174.1 ± 10.2	.163
Weight, mean (SD)	79.0 ± 15.9	80.5 ± 16.8	.258
Body Mass Index, mean (SD)	26.3 ± 4.7	26.5 ± 4.7	.607
ASA classification, n (%)			.012*
1-2	529 (74.1)	126 (64.9)	
3-4	185 (25.9)	68 (35.1)	
Type, n (%)			.399
CR	507 (71.0)	143 (74.1)	
HPB	207 (29.0)	50 (25.9)	
Procedure, n (%)			.299
Laparoscopic	552 (73.1)	149 (76.8)	
Open	192 (26.9)	45 (23.3)	
Malignancy, n (%)			.310
No tumour	126 (17.6)	35 (18.0)	
Solid tumour	480 (67.2)	138 (71.1)	
Metastasis	108 (15.1)	21 (10.9)	
CCI, mean (SD)	5.8 ± 2.8	5.2 ± 2.5	.004*
Preoperative Hb, mean (SD)	7.9 ± 1.1	7.7 ± 1.2	.061
Smoking status, n (%)			.963
No	281 (39.4)	75 (38.7)	
Prior	353 (49.4)	96 (49.5)	
Yes	80 (11.2)	23 (11.9)	
Alcohol use, n (%)	364 (51.0)	88 (45.6)	.184
Nutritional status, n (%)			.161
no malnourishment	584 (81.8)	167 (86.1)	
malnourishment	130 (18.2)	27 (13.9)	

*statistically significant

Abbreviations: SD: standard deviation. n: frequency, CR: colorectal surgery, HPB: Hepato-pancreaticobiliary surgery, ASA: American Society of Anaesthesiologists, CCI: Charlson Comorbidity Index, Hb: hemoglobine

Table 2: Clinical outcomes of major abdominal surgery

	Control-group (n=714)	CMVS-group (n=194)	p-value
Length of stay (median, IQR)	5.5 (4.0-10.0)	5.0 (3.5-8.6)	.012*[a]
In-hospital outcomes			
Long LOS, n (%)	179 (25.1)	40 (20.6)	.199
RRT calls, n (%)	2 (0.3)	3 (1.5)	.068[b]
HO calls, n (%)	109 (15.3)	15 (7.7)	.007*
ICU admissions, n (%)	17 (2.4)	3 (1.5)	.592[b]
ICU LOS, median (IQR)	7.0 (3.0-18.5)	3.0 (2.25-3.00)	.132[a]
Mortality, n (%)	5 (0.7)	1 (0.5)	1.000[b]
Reoperations n (%)	53 (7.4)	14 (7.2)	.922
Unplanned diagnostics n (%)			
CT	96 (13.4)	28 (14.4)	.722
MRI	5 (0.7)	0 (0.0)	.590[b]
Complication, rate, n (%)	70 (9.8)	19 (9.8)	.997
Complication, severity, n (%)	83 (100.0)	23 (100.0)	.808[b]
IIIa	25 (30.1)	7 (30.4)	1.000[b]
IIIb	41 (49.4)	13 (56.5)	.545
IVa	8 (9.6)	2 (8.7)	1.000[b]
IVb	6 (7.2)	0 (0.0)	.336
V	3 (3.6)	1 (4.3)	1.000[b]
Falls, n (%)	4 (0.6)	2 (1.0)	.614[b]
Decubitus, n (%)	39 (5.5)	6 (3.1)	.178
Delirium, n (%)	31 (4.3)	6 (3.1)	.435
Post-discharge outcomes			
Readmissions, n (%)	77 (10.8)	25 (12.9)	.411
Readmissions' LOS, median (IQR)	6.5 (4.0-9.5)	4.0 (2.0-7.0)	.014*[a]
DAH_{30}, median (IQR)	24.0 (18.9-26.0)	24.5 (20.5-26.5)	.005*[a]
Discharge disposition, n (%)			
Independent	467 (65.4)	116 (59.8)	.148
Home care	211 (29.6)	75 (38.9)	.015*
Rehabilitation centre	24 (3.4)	2 (1.0)	0.093
Nursing home	3 (0.4)	0 (0.0)	1.000[b]
Other ward	5 (0.7)	0 (0.0)	0.590[b]
Deceased	3 (0.4)	1 (0.5)	1.000[b]
Hospice	1 (0.1)	0 (0.0)	1.000[b]

Table 2: (Continued)

	Control-group (n=714)	CMVS-group (n=194)	p-value
Frequency of post hospital care, n (%)			.123
1	152 (61.8)	44 (61.1)	
2	66 (26.8)	25 (34.7)	
≥3	28 (11.4)	3 (4.2)	
Type of post hospital care, n (%)			
ADL	116 (16.2)	33 (17.1)	.827
Stoma	114 (16.0)	24 (12.4)	.259
Medication	77 (10.8)	26 (13.5)	.307
Tube feeding	17 (2.4)	6 (3.1)	.605[b]
Wound care	57 (8.0)	19 (9.8)	.384
Drain care	14 (2.0)	12 (6.2)	.005*
Catheter	13 (1.8)	6 (3.1)	.263[b]
Other	6 (0.8)	0 (0.0)	.351

a Mann-Whitney U-test
b Fisher Exact test
*statistically significant
Abbreviations: IQR: Interquartile range, SD: standard deviation, n: frequency, LOS: length of stay, RRT: rapid response team, HO: house-officer, ICU: intensive care unit, CT: computer tomography, MRI: magnetic resonance imaging, DAH30: days alive at home 30 post-surgery

Table 3: Patient characteristics of subgroup

	CR surgery (n=651)			HPB surgery (n=257)		
	Controls (n=507)	**CMVS (n=144)**	**p-value**	**Control (n=207)**	**CMVS (n=50)**	**p-value**
Gender, male, n (%)	248 (48.9)	75 (52.1)	.502	113 (54.6)	31 (62.0)	.343
Age, mean (SD)	67.0 ± 13.5	68.6 ± 12.2	.201	66.3 ± 12.0	66.4 ± 11.0	.962
Length, mean (SD)	172.7 ± 9.8	174.0 ± 10.3	.188	173.0 ± 15.3	174.5 ± 9.8	.522
Weight, mean (SD)	79.1 ± 16.1	80.9 ± 16.0	.238	78.6 ± 15.6	79.4 ± 19.5	.828
Body Mass Index, mean (SD)	26.4 ± 4.8	26.6 ± 4.4	.553	26.0 ± 4.4	26.0 ± 5.6	.948
ASA classification, n (%)			.008*			.449
1-2	393 (77.5)	96 (66.7)		136 (65.7)	30 (60.0)	
3-4	114 (22.5)	48 (33.3)		71 (34.4)	20 (40.0)	
Type, n (%)			.011*			.019*
Colon / Liver	366 (72.2)	119 (82.6)		100 (51.7)	15 (70.0)	
Rectal / Pancreas	141 (27.8)	25 (17.4)		107 (48.3)	35 (30.0)	
Procedure, n (%)			.288			.883
Laparoscopic	441 (87.0)	130 (90.3)		81 (39.1)	19 (38.0)	
Open	66 (13.0)	14 (9.7)		126 (60.9)	31 (62.0)	
Malignancy, n (%)			.563			.058
No tumour	103 (20.3)	26 (18.1)		23 (11.1)	9 (18.0)	
Solid tumour	382 (75.3)	109 (75.7)		98 (47.3)	29 (58.0)	
Metastasis	22 (4.3)	9 (6.9)		86 (41.5)	12 (24.0)	
CCI, mean (SD)	5.4 ± 2.6	5.1 ± 2.3	.225	6.8 ± 3.0	5.5 ± 2.9	.005*

Table 3: (Continued)

	CR surgery (n=651)			HPB surgery (n=257)		
	Controls (n=507)	**CMVS (n=144)**	**p-value**	**Control (n=207)**	**CMVS (n=50)**	**p-value**
Preoperative Hb, mean (SD)	7.9 ± 1.1	7.7 ± 1.2	.038*	8.0 ± 1.1	8.0 ± 1.1	.967
Smoking status, n (%)			.197			.002*
No	202 (39.8)	64 (44.4)		79 (38.2)	11 (22.0)	
Prior	244 (48.1)	70 (48.6)		109 (52.7)	26 (52.0)	
Yes	61 (12.0)	10 (7.0)		19 (9.2)	13 (26.0)	
Alcohol use, n (%)	276 (54.4)	70 (486)	.216	88 (42.5)	19 (38.0)	.561
Nutritional status, n (%)			.239			.581
no malnourishment	439 (86.6)	130 (90.3)		145 (70.0)	37 (74.0)	
malnourishment	68 (13.4)	14 (9.7)		62 (30.0)	13 (26.0)	

*statistically significant

Abbreviations: n: frequency, SD: standard deviation, ASA: American Society of Anaesthesiologists, CR: Colorectal, HPB: Hepato-pancreaticobiliary, CMVS: Continuous Vital Signs Monitoring intervention, CCI: Charlson Comorbidity Index, Hb: hemoglobine

Table 4: Clinical outcomes of subgroups

	CR surgery (n=651)			HPB surgery (n=257)		
	Control (n=507)	**CMVS (n=144)**	**p-value**	**Control (n=217)**	**CMVS (n=50)**	**p-value**
Length of stay, median (IQR)	4.5 (3.5-7.5)	4.0 (3.0-6.0)	.001*[a]	9.0 (6.0-15.0)	9.0 (7.0-13.6)	.754[a]
In-hospital outcomes						
Long LOS, n (%)	127 (25.0)	25 (16.4)	.054[a]	53 (25.6)	11 (22.0)	.597
RRT calls, n (%)	2 (0.4)	2 (1.4)	.214[b]	0 (0.0)	1 (2.0)	.195[b]
HO calls, n (%)	74 (14.6)	12 (8.3)	.050	35 (16.9)	3 (6.0)	.051
ICU admissions n (%)	9 (1.8)	2 (1.4)	1.000[b]	8 (3.9)	1 (2.0)	1.000[b]
ICU LOS, median(IQR)	8.0 (3.0-15.0)	3.0 (3.0-3.0)	.150[a]	4.0 (2.3-18.8)	n/a	n/a
Mortality, n (%)	4 (0.8)	1 (0.7)	1.000[b]	1 (0.5)	0 (0.0)	1.000[b]
Reoperations, n (%)	42 (8.3)	12 (8.3)	.967	11 (5.3)	2 (4.0)	1.000[b]
Unplanned diagnostics, n (%)						
CT	60 (11.8)	17 (11.8)	.992	36 (17.4)	11 (22.0)	.449
MRI	2 (0.4)	0 (0.0)	1.000[b]	3 (1.4)	0 (0.0)	1.000[b]
Complication, rate, n (%)	44 (8.7)	14 (9.7)	.698	26 (12.6)	5 (10.0)	.618
Complication, severity, n (%)	51 (100.0)	18 (100.0)	.916[b]	32 (100.0)	5 (100.0)	.790[b]
IIIa	9 (17.6)	4 (22.2)	.730[b]	16 (50.0)	3 (60.0)	1.000[b]
IIIb	34 (66.7)	12 (85.7)	1.000[b]	7 (21.9)	1 (20.0)	1.000[b]
IVa	3 (5.9)	1 (5.6)	1.000[b]	5 (15.6)	1 (20.0)	1.000[b]
IVb	3 (5.9)	0 (0.0)	.562[b]	3 (9.3)	0 (0.0)	1.000[b]

Table 4: (Continued)

	CR surgery (n=651)			HPB surgery (n=257)		
	Control (n=507)	**CMVS (n=144)**	**p-value**	**Control (n=217)**	**CMVS (n=50)**	**p-value**
V	2 (3.9)	1 (5.6)	1.000[b]	1 (3.1)	0 (0.0)	1.000[b]
Falls, n (%)	2 (0.4)	1 (0.7)	.528[b]	2 (1.0)	1 (2.0)	.479[b]
Pressure ulcers, n (%)	23 (4.5)	5 (3.5)	.579	16 (7.7)	1 (2.0)	.208[b]
Delirium, n (%)	12 (2.4)	4 (2.8)	.763[b]	19 (9.2)	2 (4.0)	.386[b]
Post hospital outcomes						
Readmissions, n (%)	55 (10.8)	19 (13.2)	.434	22 (10.6)	6 (12.0)	.780
Readmissions' LOS, median (IQR)	6.3 (4.0-9.4)	3.0 (2.0-7.5)	.014*[a]	6.5 (3.1-12.5)	5.5 (2.8-8.5)	.397[a]
DAH_{30}, median IQR	25.0 (21.0-26.5)	25.5 (23.0-27.0)	.001*[a]	20.5 (14.0-24.0)	20.8 (16.4-23.0)	.874[a]
Discharge disposition, n (%)						
Independent	344 (67.9)	94 (65.7)	.634	123 (59.4)	21 (42.0)	.026*
Home care	137 (27.0)	46 (32.2)	.227	74 (35.7)	29 (58.0)	.004*
Rehabilitation centre	18 (3.6)	2 (1.4)	.274	6 (2.9)	0 (0.0)	.600[b]
Nursing home	2 (0.4)	0 (0.4)	1.000[b]	1 (0.5)	0 (0.0)	1.000[b]
Other ward	3 (0.6)	0 (0.0)	1.000[b]	2 (1.0)	0 (0.0)	1.000[b]
Deceased	2 (0.4)	1 (0.7)	.526[b]	2 (1.0)	0 (0.0)	1.000[b]
Hospice	1 (0.2)	0 (0.0)	1.000[b]	0 (0.0)	0 (0.0)	n/a
Frequency of post hospital care, n (%)			.223			.635
1	113 (66.9)	26 (60.5)		39 (53.4)	18 (62.1)	
2	44 (26.0)	16 (37.2)		25 (34.2)	9 (31.0)	

Table 4: (Continued)

	CR surgery (n=651)			HPB surgery (n=257)		
	Control (n=507)	**CMVS (n=144)**	**p-value**	**Control (n=217)**	**CMVS (n=50)**	**p-value**
≥3	12 (7.1)	1 (2.3)		9 (12.3)	2 (6.9)	
Type of post hospital care, n (%)						
ADL	65 (12.8)	19 (13.3)	.883	51 (24.6)	14 (28.0)	.624
Stoma	107 (21.1)	22 (15.4)	.130	7 (3.4)	2 (4.0)	.688[b]
Medication	33 (6.5)	15 (10.5)	.108	44 (21.3)	11 (22.0)	.908
Tube feeding	2 (0.4)	1 (0.7)	.526[b]	15 (7.2)	5 (10.0)	.566[b]
Wound care	25 (4.9)	13 (9.1)	.061	32 (15.5)	6 (12.0)	.536
Drain care	2 (0.4)	0 (0.0)	1.000[b]	12 (5.8)	12 (24.0)	.000*[b]
Catheter care	11 (2.2)	5 (3.5)	.366[b]	2 (1.0)	1 (2.0)	.479[b]
Other	3 (0.6)	0 (0.0)	1.000[b]	3 (1.4)	0 (0.0)	1.000[b]

[a] Mann-Whitney U-test. [b] Fisher Exact test *statistically significant

Abbreviations: IQR: Interquartile range, SD: standard deviation, n: frequency, CR: colorectal, HPB: Hepato-pancreaticobiliary, CMVS: Continuous Vital Signs Monitoring intervention, LOS: length of stay, RRT: rapid response team, HO: house-officer, ICU: intensive care unit, CT: computer tomography, MRI: magnetic resonance imaging, DAH30: days alive at home 30 post-surgery

Table 5: Performed nursing activities based on trend assessments

Nursing activity	n (%)
Activity performed by nurse, n	70 (100)
Patient assessment (wait-and-see), n (%)	61 (87.1)
Addition manual check measurement with MEWS, n (%)	9 (12.9)
Interventions performed in consultation with a physician, n	39 (100)
Consulted physician but wait-and-see	1 (2.6)
Diagnostics	10 (25.6)
Blood test: Blood culture	3 (7.7)
Chest X-ray	2 (5.1)
Electrocardiogram	1 (2.6)
CT-scan	3 (7.7)
Blood test: Arterial Blood Gas	1 (2.6)
Therapy	28 (71.8)
Analgesics	11 (28.2)
Oxygen suppletion	4 (10.3)
Bronchodilators	4 (10.3)
Fluid challenge	3 (7.7)
Beta-blockers	1 (2.6)
Diuretics	2 (5.1)
Breathing exercise	2 (5.1)
Digoxin	1 (2.6)

Abbreviations: n: frequency, MEWS: Modified Early Warning Score, X-ray: energetic high-frequency electromagnetic radiation, CT: computer tomography

Table 6: Patient experience based on the questionnaire

Question(naire)	N=163		
Acceptability score, range 0-5, median (IQR)	4.0 (3.75-5.0)		
Satisfaction rating, range 0-10, median (IQR)	8.0 (8.0-9.0)		
	Disagree (1-2)	**Neutral (3)**	**Agree (4-5)**
Comfort, range 0-5, median (IQR)	6 (3.7)	11 (6.8)	145 (88.9)
Feeling safer, range 0-5, median (IQR)	9 (5.5)	38 (23.3)	116 (71.2)
Wear again, range 0-5, median (IQR)	2 (1.2)	10 (6.1)	151 (92.6)

Abbreviations: IQR: Interquartile range, SD: standard deviation, n: frequency

DISCUSSION

In this study we explored the effect of CMVS on the general ward on LOS and a broad range of other clinical outcomes in major abdominal surgery patients. Adequate implementation of the CMVS intervention on our surgical ward was previously demonstrated and reported.[30] The results of the current study show that the addition of CMVS to the standard care was associated with a small, but statistically significant reduction in LOS. Besides, in the CMVS-group, the number of nurse-to-HO calls was significantly reduced (15% to 8%). Based on trends assessments 35% of patients received additional nursing activities. Patients highly accepted the CMVS intervention.

In the subgroup analysis, the association of CMVS with reduced LOS was maintained in the CR-group but not in the HPB-group. This may be explained by a difference in post-operative complication profile. Both surgery types may be complicated by anastomotic leaks, intra-abdominal abscess, or bleeding, all of which are accompanied by deviating vital signs.[39] In the HPB group, however, pancreatic resections result in delayed gastric emptying in 10-30% of patients, which delays normal oral intake and significantly prolongs LOS, but is not associated with deviating vital signs.[40,41]

Importantly, LOS in CR surgery has been significantly reduced since the introduction of Enhanced Recovery After Surgery (ERAS) protocols over a decade ago.[42] In this study the ERAS protocols were unchanged and strictly applied throughout the entire study period (including historical controls). The study period coincided in part with the COVID-19 pandemic, but this did not affect outcomes, since the care for elective major abdominal (mostly oncological) surgery patients was not affected in our hospital, as they were given priority over all other usual care.

Even though the observed reduction in LOS may suggest that CMVS has enabled more rapid detection and intervention in case of clinical deterioration, no significant differences were found in complication rate, complication severity, RRT calls, ICU admissions, and ICU LOS. This study may not have had sufficient statistical power to determine differences in these rare outcomes. Nonetheless, a non-significant trend towards less severe complications was noted in the CMVS-group, which could have been the result of additional interventions triggered by early detection. Also, in the CMVS group we did observe a trend towards a reduced median ICU LOS (3.0 versus 8.0 days), which is closely associated with the severity of complications.[43]

LOS is considered an important indicator for assessing the efficiency of hospital management, quality of patient care and functional evaluation.[44] From the point of view

of the healthcare provider, a shorter LOS results in lower medical costs and increases bed capacity, which in especially important in times of scarcity as during COVID-19 pandemic and ongoing nursing shortages.[45–47] However, early discharge may increase the need for home care and other resource utilization, which must to be accounted for in total healthcare cost estimations.[46] This is supported by our finding showing of increased use of home care in the CMVS group.

Given the successful implementation of CMVS in this study, nurses may have been more attentive to vital signs monitoring, resulting in proactive assessment of the patient condition allowing for accurate and thorough nursing care. In fact, 35% of patients received additional nursing activities based on trends assessments, including interventions such as optimizing analgesia, which may have contributed to timely patient discharge and reduced LOS. Also, we observed less nurse-to-HO calls for both groups during evening and night shifts after implementation of CMVS, which is important because it may unburden the on call physicians.[48,49] Although this decrease is difficult to explain based on our data, it is possible that abnormalities were noticed earlier and were adequately dealt with by nurses obviating the need for care escalation to physician on-call.

In the present study, we used a proactive method of trend assessment every 4 hours as opposed to a reactive method with threshold-based alarms for trend monitoring. In one of our feasibility studies, we found that an active alarm strategy impaired nurses' acceptance and compliance, which may be caused by alarm fatigue.[25,27,28] The optimal frequency of vital sign measurements on general wards is unknown, but should be high enough to detect early changes in vital signs well before the onset of life threatening events.[50] Routine monitoring vital sign trends every 4 hours without alarms may be considered adequate to detect vital sign trend deviations indicating an imminent SIRS caused by post-operative complications.[51–53] More frequent monitoring assessments may not be needed, as vital signs monitoring in the general ward setting is not aimed at detecting severe acute events such as cardiac arrest.

Besides clinical outcome measures, other positive effects of CMVS on patient-centred outcomes are important to consider when assessing the utility of CMVS (or considering the pros and cons of implementing CMVS as standard care). For instance, this study shows that patient satisfaction and acceptance of the CMVS was very high. The perceived feeling of safety and high comfort of the sensor should be considered as important patient-reported outcome for implementation of CMVS, especially considering these outcome measures scored much higher than other wearable

devices in previous studies, in which significant proportions prematurely discontinued the CMVS.[54,55]

Comparison with other work

Comparison of results with prior studies is complicated given the heterogeneity in study designs, patient populations and outcomes and, more importantly, because of the wide range of different CMVS interventions, with regard to sensors, alarm strategy and follow-up of deviating vital signs.

The results from previous studies on the impact of CMVS on LOS are diverse. In our study, the reduction in hospital LOS was modest but statistically significant. Two other before-after studies, in relatively large cohorts of medical and surgical patients with comparable LOS, did not show a significant reduction by CMVS.[54,56] Interestingly, one of these studies reported beneficial results for patients on unplanned ICU admissions and RRT calls.[54] One meta-analysis covering five studies showed a non-significant weighted mean reduction in LOS of 0.09 days.[57] One possible explanation for these results is that the incidence of major adverse events was rare, and therefore had no impact on median LOS. Another meta-analysis, covering three studies comparable to this study, did show a trend towards a reduction of LOS by a weighted mean reduction of 3.3 days.[21] However, confidence intervals were wide (-8.8 – 2.2 days) and therefore this meta-analysis failed to demonstrate a significant association between CMVS and LOS. A recent before-after study with a comparable intervention also showed a significant LOS reduction of 0.7 days.[58] However, the mean LOS in that study was twice as long as our CR-group (8.0 days versus 4.0 days), which is not considered state-of-the-art when using ERAS protocols. Another study with a bed-based continuous monitoring device, measuring the same two vital signs, was in line with our findings showing a significant reduction in LOS of 0.4 days.[56] However, these patients could not be monitored during mobilization on the ward (only when supine).

Lastly, we found high patient acceptability of the CMVS patch device used in this study. This outcome was in line with previous studies using disposable finger probes or patches as devices.[23,56] In contrast, in another study, in 21% of patients a wrist-worn device was prematurely removed indicating patient acceptability was relatively low compared to the patch device worn in our study.[54]

Strengths and limitations

Important strengths of this study are the selective inclusion of highly complex abdominal surgery (CR and HPB), robust characterization of patient characteristics

(including CCI and ASA scores) and an array of clinical outcome data, as well as the significant length of the study period.

Several limitations should be considered when interpreting the results. First, due to the before-after design time trends and unobserved confounding factors may have affected changes in the outcomes and it precludes strong inferences regarding causal effects. On the other hand, the design enabled us to assess the impact under "real-world conditions" ensuring results are better translatable to clinical practice than a randomized controlled study.[29,59] In fact, the complex nature of the CMVS intervention and implementation impedes randomization of two different vital signs monitoring protocols in parallel on the same ward.[60] Importantly, during the entire study period no changes were made in patient management or policies in e.g. Early Warning Scores system and early discharge (ERAS) protocols. This was confirmed as median LOS data of historical controls during the study period showed no significant changes over time. In addition, despite the COVID-19 pandemic, the clinical care and workflow for major abdominal surgery patients was unaffected and continued in similar fashion in our hospital. Second, we did not completely reach the calculated sample size and this study may not have had sufficient statistical power to detect differences in rare outcomes (such as unplanned ICU admissions, RRT calls, and ICU length of stay). This is especially true for subgroup analysis. Third, our study was limited to elective surgery and not emergency surgery. It is conceivable that the effects of the intervention are larger in emergency surgery patients given that postoperative complications occur more frequently in this group.[61] Fourth, the study was conducted in a single hospital setting, and the results might not be generalizable to other institutions or types of hospitals. Finally, besides patient, diagnosis and intervention related factors, LOS is determined by multiple factors unrelated to clinical outcomes such as discharge delay due to rehabilitation or home care capacity shortages.[62–68] Given the sizable control group and prolonged study period, we assume any variation in these factors were adequately controlled for in this study.

Implications

Despite our promising findings, more robust prospective multicentre studies are needed to establish the true added value of CMVS for clinical care and analyse its causal effects on general wards. Such prospective trials should include a simultaneous evaluation of the quality and success of CMVS implementation, which is essential before any clinical value can be established. Analysis of the follow-up nursing activities on deviating trends and its consequences should also be included in such studies rather than just focusing on major patient outcomes such as complication severity, RRT calls, unplanned ICU admissions or mortality. All the proactive nursing activities

collectively may contribute to the prevention of more serious complications and prolonged hospitalization times.

As an alternative to proactive trend assessment, machine-learning algorithms may be developed that provide reliable personalized clinical decision support tools to facilitate correct and timely interpretation of vital signs trends. This may contribute to development of highly efficient alarm strategies. This will prevent unnecessary diagnostic procedures and overtreatment by reducing the number of irrelevant and false-positive alarms and may improve workflow efficiency on the ward.[50,51,69,70]

In addition, future availability of advanced and validated multi-parameter CMVS wireless sensors, which are sufficiently accurate, patient friendly and comprehensive, may allow the discontinuation of standard manual vital sign measurements by nurses. This may not only improve clinical outcomes but also reduce nursing workload and increase efficiency of inpatient care.

Considering that inpatient hospital stays are becoming increasingly shorter, postoperative complications and clinical deterioration will inevitably occur more frequently at home.[71,72] Therefore, continuing CMVS after discharge–which is possible with the sensor used in the study- may be considered to allow monitoring and timely detection at home. This may further lower barriers for safe early discharge. In addition, functionality of providing patients with insight into their own vital signs via an app may generate more patient involvement in their own health and benefit recovery.

Conclusion

In conclusion, we found that CMVS using wearable wireless sensors and proactive trend assessments was associated with a significant decrease in length of stay for CR surgery patients but not for HPB surgery patients. Although all other clinical outcomes were similar in both groups, a non-significant trend towards less severe complications and reduced ICU LOS were noted in the CMVS-group. CMVS with the sensor used in this study was highly accepted by patients. It is important to note that CMVS triggered additional nursing activities such as patient assessments and therapeutic interventions, which may eventually result in attenuation of the severity of postoperative complications. Future studies should focus on additional interventions prompted by CMVS and its consequences in carefully selected patient groups with a relatively high risk of deterioration to establish the causal effects of CMVS and enhance the quality and safety of postoperative care.

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Conflict of interest statement

None of the authors has conflicting interests. The manufacturer of the CMVS system (Philips Healthcare, Eindhoven, the Netherlands) did not play a role in the design, implementation, interpretation, and reporting of the study. Sensors were provided at a reduced price for the study.

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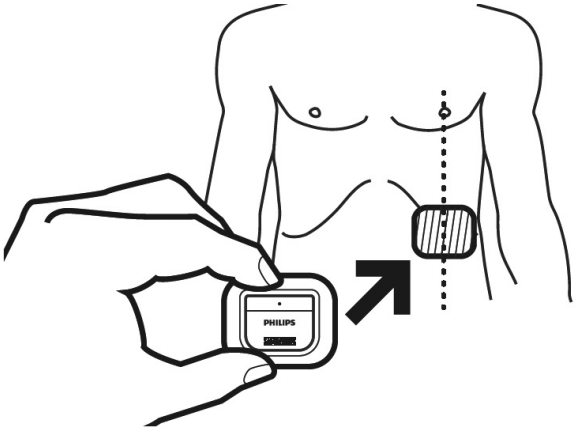
APPENDICES

Appendix 1: The Philips Healthdot wearable sensor



Appendix 2: Multivariate analysis of log transformed Length of Stay

	Total (n=908)			CR surgery (n=651)			HPB surgery (n=257)		
	Unstandardized coefficients (95% CI)	**SD**	**p-value**	**Unstandardized coefficients (95% CI)**	**SD**	**p-value**	**Unstandardized coefficients (95% CI)**	**SD**	**p-value**
Constant	.322 (.238 - .406)	.043	.004	.422 (.330 - .514)	.047	.000	1.062 (.868 – 1.257)	.099	.000
Gender	.141 (.105 - .177)	.018	.000	.091 (.055 - .126)	.018	.000	-.276 (-.338 - -.214)	.031	.000
Procedure	.202 (.166 - .238)	.019	.000	.177 (.131 - .223)	.024	.000	.125 (.070 - .180)	.028	.000
CCI score	.005 (.000 - .010)	.003	.063	.009 (.003 - .015)	.003	.003	.018 (.008 - .028)	.005	.001
Complications	.484 (.437 - .530)	.024	.000	.542 (.489 - .596)	.027	.000	.309 (.232 - .386)	.039	.000
Group	-.043 (-.077 - -.009)	.017	.012	-.058 (-.095 - -.021)	.019	.002	-.014 (-.078 - .050)	.033	.675

*statistically significant

Abbreviations: CR: colorectal, HPB: hepato-pancreaticobiliary, n: frequency, CI: Confidence Interval, SD: standard deviation, CCI: Charlson Comorbidity Index

Appendix 3: Modified Early Warning Score (MEWS) protocol

The MEWS consist of the following elements; heartrate, systolic blood pressure (BP), respiratory rate, temperature, the level of consciousness is scored by the AVPU A = Alert V= Voice P= Pain U= Unresponsiveness (AVPU), saturation, urine production and a worry indicator. For all items cut off points are predetermined which will lead to an EWS score.

Score	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	MEWS						
Heartrate		<40	40-50	51-100	101-110	111-130	>130
Systolic BP	<70	70-80	81-100	101-200		>200	
Respiratory rate		<9		9-14	15-20	21-30	>30
Temperature		<35,1	35,1-36,5	36,6-37,5	>37,5		
AVPU				A	V	P	U
	CMVS (D-EWS scores)						
Heartrate		<40	40-50	51-100	101-110	111-130	>130
Respiratory rate		<9		9-14	15-20	21-30	>30

- Saturation is not mandatory. It is only measured when needed according to agreements or own clinical judgement.
- If the patient uses oxygen the following parameter needs to be taken into account; saturation < 90% or > 90%. When <90%: add 3 points
- If urine production is < 75ml in past 4 hours: add 1 point
- If worried (nurses worry indicator) about patient condition: add 1 point

Response protocol to EWS score

Score of 0-1:	Repeat EWS once a day
Score of 2:	Repeat EWS 3 times a day according EWS for the upcoming 24h (a 8 hours) (*monitoring frequency)*
Score ≥ 3:	Contact physician, apply SBARR (communication model), within 30 minutes define treatment policy and evaluated status after 1 hour *(Clinical response)*

Appendix 4: Patients remarks on the questionnaire (translated and adapted from Dutch)

Desire to have more insight own vital signs (n=10)

1. *I don't know how the intervention interacted with nurses and what it provides for them. However, a few days later it did show that signaling was done by nurses by the device. So definitely an asset for the future.*
2. *As a patient, I don't have any insight into the action or effect of this intervention. So I also have no opinion: neither positive nor negative.*
3. *I do understand the functionality and possible benefits of the intervention, but where have the patient insight in it?*
4. *I think it is important, that there is also communication from nurses to the patient about the monitoring . Now it felt like I wore the patch without purpose.*
5. *The most important function in my eyes is the intervention. However, this has not been necessary, is therefore difficult to assess for me.*
6. *It does not bother me, but also does not benefit me. I do not have insight in any results.*
7. *I think the sensor can help, but haven't actually noticed anything (probably because my vital signs were okay). (…)*
8. *I think it is important to provide feedback of the results to the patients. Otherwise it certainly does not match the patient's needs. On the last day upon discharge from the hospital, I was able to review my vital signs. Then you also understand the functionality of the system.*
9. *I would like to gain more insight in the relationship between interventions and the intervention. After application of the sensor, no feedback was provided to me.*
10. *No insight in the measurements and what the nurse assessed, it is difficult to assign a value judgment.*

Comfort of the sensor (n=19)

1. *I did not notice anything.*
2. *The intervention did not give any objections.*
3. *(…). At least it wears comfortably.*
4. *The intervention didn't bother me.*
5. *I haven't noticed much, but think it's a great innovation.*
6. *The nice thing about the sensor is, you don't notice anything.*
7. *I have not been bothered in any way by the sensor.*
8. *The sensor is a too hard product. It was good to try once though.*
9. *It was fine, but I had to get used to it.*
10. *I did notice wearing it, super convenient!*
11. *The sensor is difficult to sleep with.*
12. *The sensor felt awkward on the stomach, but didn't notice anything else.*
13. *I don't feel anything of the senor.*
14. *I have not noticed much of the sensor.*
15. *Totally uncomfortable sensor, but actually felt safer with it.*
16. *It doesn't make me more happier, but it is useful.*
17. *The intervention is useful. I don't notice it much. It gives a kind of assurance that you are being watched.*
18. *Not bothered at all. (…)*
19. *I did not notice a lot of it (…)*

Appendix 4: (Continued)

Feeling more safe (n=5)
1. *It is a good thing there is proper control of patients.*
2. *I provided me an excellent reassured feeling.*
3. *In this case no negative development in the recovery process, so you don't notice anything. Still reassuring that the first signals are picked up.*
4. *(…) Actually felt safer with it.*
5. *(…) It gives a kind of assurance that you are being watched.*
Benefits for healthcare professionals (n=4)
1. *I hope it will help in the future of health care.*
2. *I think the intervention can be of good service to nurses and patients.*
3. *It provides peace of mind for healthcare professionals.*
4. *It is important that healthcare professionals can monitor remotely.*
Incompatible with diagnostics (n=2)
1. *The sensor had to be removed before going for a scan.*
2. *It was odd the sensor had to be removed before an electrocardiogram.*
General positive comments (n=7)
1. I *always like new innovations.*
2. *It think it went well.*
3. *Great invention!*
4. *A very good initiative which provides new possibilities for the future.*
5. *Any initiative to improve care I think is fantastic!*
6. *Nice initiative to continue.*
7. *Research is always fine, a study is good for everyone.*

9

GENERAL DISCUSSION

Healthcare systems are facing considerable challenges globally. The number of older patients with complex problems is increasing,[1,2] and healthcare expenditures will rise considerably.[2,3] In addition, healthcare faces a growing shortage of staff to properly care for existing patients in the system.[4,5] This calls for innovative, smarter solutions to deliver safe and effective care.

One possible solution is the adoption of patient monitoring systems using wearable wireless sensors that enable continuous vital signs monitoring (CVSM) by providing automated, high-frequency measurements. When properly implemented, they could improve timely detection of clinical deterioration caused by adverse events, help trigger early therapeutic interventions, and reduce failure or delays in recognizing and responding to complications as well as unplanned transfers to intensive care units (ICUs).[6–8] In addition, CVSM can have a positive impact on the efficiency of the clinical nursing workflow. A potential future scenario is described in Box 1.

Box 1: Wearable continuous vital signs monitoring in 2040: a possible scenario

Mr. Bakker, a 75-year old male scheduled for colorectal surgery, receives a wearable sensor in the mail several weeks before his planned procedure. Besides measuring his vital signs, this small device is also able to measure biochemical and physical activity parameters. Following the instructions provided, Mr. Bakker can independently attach the sensor and install the corresponding application on his own smartphone.

Throughout the process, the patient's status is observed remotely by a nurse working in a dedicated remote patient observation center. Mr. Bakker has already viewed instructional videos and materials on his upcoming procedure, identifying clinical deterioration and rehabilitation advice. During a remote video consultation, the nurse can answer any additional questions and provide further personalized counseling.

In the weeks before the surgery, the sensor determines the patient's normal values. By using data from the electronic health record, the remote monitoring system can provide him with individual performance feedback as well as everyday advice on how to optimally prepare for the surgery, for instance by daily moderate exercise.

After two weeks, Mr. Bakker is admitted to the hospital for surgery. The sensor remains in situ and is used for surveillance during the procedure and in the post-anesthesia care unit. Advanced alarm strategies, which combine the sensor data with relevant information from the patient record, advise the anesthesiologist. When Mr. Bakker returns to the surgical ward, the data from the wearable sensor can be used by the nurses, reducing or eliminating the need for them to perform manual vital sign measurements.

During his stay at the ward, Mr. Bakker can also record any subjective symptoms using the application, providing further insights and trends to the data. The system suggests personalized rehabilitation exercises and dietary goals to help speed recovery. A clinical deterioration index predicts the risk of complications and advises nurses and physicians on how and when to perform proactive nursing interventions or additional diagnostic tests. Based on this index, the system also recommends a day and time for Mr. Bakker's discharge, which nowadays typically occurs on or soon after the day of surgery.

When Mr. Bakker is discharged home, the sensor remains in place. Mr. Bakker can enter concerns and/or symptoms into the app and is again presented with preliminary information and rehabilitation goals in the app. The nurses are guided in their clinical decision-making by advanced artificial intelligence (AI) technology that pre-processes the large amount of data. If necessary, the nurse will contact Mr. Bakker for a remote consultation or may visit him at home.

The aim of this thesis is to gain a better understanding of the core elements of a CVSM system (consisting of CVSM technology and corresponding workflow processes) in a hospital ward setting, focusing on critical aspects of the implementation process, and the potential positive impact of this technology on patient. Through a systematic review of available CVSM technologies, exploratory qualitative studies with nurses and physicians, and feasibility studies in clinical practice, we have developed, tested, and refined a CVSM system and implementation strategy. This preliminary work formed the foundation for a larger prospective implementation-effectiveness hybrid study to evaluate implementation of a CVSM system at scale in two general wards.

Given the complex nature of CVSM system and the wide variety of outcomes addressed by this thesis, we first provide an overview of the key findings (section 9.1). In the sections that follow, we discuss the characteristics of a CVSM system (9.2), user perspectives (9.3) and evaluation of CVSM systems (9.4). This is followed by a

discussion of the methodology of this thesis (9.5), its implications (9.6), and a final conclusion.

KEY FINDINGS

Overall, we find that existing wearable CVSM technologies – wearable sensors and their associated software platforms – are suboptimal for integration into clinical workflows. As a result, they deliver limited benefits for clinicians, who typically do not fully adopt them. This is an especially important point, as we also find that nurses can play a critical role in the development of a CVSM system and facilitate its successful implementation on general wards. This may explain why the CVSM system still has only limited impact on major patient outcomes. Ultimately, when the technology matures and successful implementation is achieved, substantial patient benefits may be identified.

The key findings are summarised below:

- Wearable CVSM devices can be broadly divided into two types: patch sensors that are able to measure heart rate (HR) and respiratory rate (RR) as well as temperature; and devices that can measure a larger range of vital parameters (often bulkier and more complex to use) Chapter 2)
- New wearable devices for CVSM are mainly evaluated based on validation and feasibility results, while evidence for effectiveness and cost-effectiveness is lacking. (Chapter 2)
- Most nurses would consider implementing a CVSM system in their departments. (Chapter 3)
- A CVSM system using alarms is feasible in practice, but when tested resulted in many false alarms, which hindered its acceptability to nurses. (Chapter 4)
- Nurses need a combination of education and on-the-job learning and coaching to use a CVSM system effectively. (Chapter 5)
- Nurses consider adequate management alerts and integration of the CVMS technology into their existing IT systems to be important prerequisites. (Chapters 5 and 6)
- Nurses feel that clinical decision support is necessary for appropriate assessment of vital-sign trends and follow-up interventions. (Chapters 5 and 6)
- Nurses feel that gaining hands-on experience with a CVSM system, particularly with clinically deteriorating patients, is necessary for their successful use, as interpretation of vital sign trends is a relatively new concept for them. (Chapters 5 and 6)

- We were able to adequately implement a CVSM system based on proactive trend assessment without the use of alarms; this approach was more acceptable to nurses. (Chapter 6)
- Healthcare professionals remain critical about the impact of a CVSM system on patient care and believe that it will only be beneficial for certain categories of patients. (Chapters 3, 5, 6 and 7)
- Nurses deem their clinical assessment to be more important than measurements of the CVSM system. (Chapter 7)
- Nurses prioritise the use of a CVSM system less when they are experiencing a high workload. (Chapter 7)
- When tested, the performance of a CVSM system was better on a surgical ward than on an internal medicine ward. Performance declined over time on both wards despite the use of a comprehensive implementation strategy. (Chapter 7)
- Patient acceptance of CVSM systems is high. (Chapters 4, 6 and 8)
- The use of CVSM systems did not result in direct benefits for the majority of patients, but in some cases it did lead to additional nurse observations and interventions. (Chapters 7 and 8)
- Compared with conventional, intermittent monitoring of vital signs, a CVSM system is associated with a reduced length of stay in colorectal surgical patients, but not in hepatobiliary patients. (Chapter 8)

CVSM SYSTEM CHARACTERISTICS

First, we discuss the main characteristics of a CVSM system, consisting of CVSM technology and the corresponding workflow processes, for optimal use in clinical practice.

Description of CVSM systems

The CVSM system used in these studies was developed, redesigned, and refined for this thesis based on a combination of wearable sensors, the software platform and work process. We selected three different potentially eligible wearable sensors, which all recorded HR and RR, some also recorded skin temperature, but the sensors used could not measure blood pressure (BP) and blood oxygen saturation (SpO2). The measurement frequency used for measuring vital signs ranged from once/min to every five minutes. In addition, the clinical decision support software used varied from a single-parameter, threshold-based alarm strategy to proactive trend assessments of aggregated scores. Lastly, the type of assessment in the work process varied from purely reactive, with the use of alarms, to proactive monitoring on a regular basis

with a time frame that varied from 14 minutes to four hours. Eventually, we selected a sensor measuring HR and RR (*Philips Healthdot*) with measurement frequency of 5 minutes on which nurses proactively performed trend assessments guided by the aggregated scores.

The heterogeneity of CVSM systems is not exclusive to our own studies, but common across the research literature.[9] The features and purposes of wearable CVSM systems on general wards may be very different from those intended for high-care units, for example. However, while it is logical to redesign and tailor the components of CVSM systems for each phase of development and testing,[10] this also underlines the need for clarity and consensus on how wearable CVSM systems are intended to be used on general wards.

This improved understanding can guide manufacturers in the further development of CVSM technologies that are more appropriate to the context of a general ward and thus to the needs of nurses and physicians. Here it is of critical importance that introducing the new CVSM technology is already aligned with the dynamic, complex work processes on the ward to avoid an increase in workload and cognitive burden on nurses.[11] This should enable healthcare professionals to implement clear and well-integrated protocols for CVSM systems. Although some variation may be appropriate to optimise CVSM systems for specific patient populations, without this 'random' variation in implementation will remain due to lack of consensus and insufficient dissemination of lessons learned from clinical implementation, which also makes proper evaluation difficult.

Wearable sensors

Data quality and validation

In our studies, we focused on patch sensor devices because we expected these to be the most comfortable for patients to wear as well as easier to use for nurses. More importantly, they also have the potential to be applied with relative ease in the patient's home situation in the future.

We established several criteria for selecting and using wearable sensors for CVSM systems. As a rigorous prerequisite for use in practice, a sensor should have consistent accuracy. Based on a systematic review of the available evidence (Chapter 2), our selection of a device for the sequential feasibility study, the Sensium® patch wearable sensor, was primarily based on documented accuracy (Chapter 4).[12,13] For the selected sensors used in the other studies that were not included in this systematic review, we performed validation tests at our centre (not published) in preparation for the study in

Chapter 6 (*Biosensor BX100, Philips Healthcare, Eindhoven, The Netherlands*), and there was evidence to demonstrate sufficient accuracy for the sensor in Chapter 7 (*Healthdot, Philips Healthcare, Eindhoven, The Netherlands*).[14,15]

Several issues remain regarding validation of accuracy in a clinical setting, however. First, the lack of a standard validation protocol for novel sensors results in a wide variety of practices, from the use of medical devices as clinical references (e.g. ICU monitoring, other wearable CVSM sensors or spot-check measurements), to the study of patients and measuring vital signs, to establishing which differences are acceptable for results to be clinically permissible. Notably, attention should be paid to validating the accuracy of data in mobilizing and deteriorating general ward patients and ensuring artefacts in the data occur less frequently. Signals contaminated with many artefacts may result in vital-sign trends that are not reliably assessable by healthcare professionals and should be minimized.

Second, RR is the most important parameter for early detection of clinical deterioration, followed by HR, systolic BP, and SpO2.[16,17] Evidence shows that manual intermittent measurement RR by nurses is still frequently "guesstimated" to be 16 or 20 per minute rather than carefully counted for 30 seconds by nurses[18,19] and is often sub-optimally documented.[20] For wearable wireless sensors, it has been recommended that special attention be paid to adequate validation of the RR measurement, because current studies have shown disappointing results.[21–23]

Finally, studies of CVSM technologies are not always conducted as independent clinical studies.[24] Manufacturers play a role in the funding, data collection, analysis and reporting of data in many studies, and this industry involvement can lead to conflicts of interest and overly optimistic results.[25,26]

Usability

Besides accuracy, we found the usability of wearable sensors to be highly important. This aspect should be improved if such devices are to be used successfully on the ward by nurses.

Several obstacles to usability were experienced by nurses during the studies, notably the need to replace the sensor every five days (Chapters 4 and 6), as well as issues regarding the activation and wireless pairing of the sensor (Chapter 7). Previous research indicates many nurses have little technological affinity[27,28] and therefore wearable sensors should be made easier to use (plug-and-play), for instance when installing the sensor. After installation of the sensor on the patient, any maintenance of

the technology should be minimized by ensuring a sufficiently long battery life. Other aspects of patient wearability such as proper adhesion of the device should also be considered, to ensure patients and are not hindered in their daily living.

Moreover, nurses express a need to extend the range of validated vital signs that can be measured by wearable wireless sensors (Chapters 4, 6 and 7). Currently, only HR can be monitored accurately by such devices, while RR accuracy can be further improved (Chapter 2). By contrast, skin or axillary temperature remains a difficult parameter in clinical practice. Periods with poor skin-sensor contact result in frequent false-positive 'under temperature' alarms (Chapter 4). Few other vital sign parameters are measured by most wireless devices.[29,30]

Although continuous measurement of all vital signs is not required for early detection of clinical deterioration caused by major events,[31] a deviation of a single vital sign is often sufficient to alert practitioners to the timely administration of medications, fluid therapy, or oxygen therapy, for example.[32] Such deviation may also trigger additional nursing interventions, such as mobilization and respiratory techniques (Chapter 7 and 8).

It is important to consider ease of use for nurses, and wearability for patients, when considering which parameters are most important to be measured and which can possibly be determined in derivation. For example, there is a growing body of research showing that BP can be measured by wrist or upper arm photo plethysmography alone, without the use of a cuff.[33–35] Ultimately, a sensor should be minimally invasive, be extremely easy to use and maintain, and there should be no limitations in what vital signs can be measured. Ultimately, the aim of this technology is to eliminate the need for intermittent manual vital signs measurements.

Software platforms

General considerations

For this thesis, two different software platforms were used to present vital sign measurements to healthcare professionals: the Sensium® software (Sensium Healthcare, Abingdon, UK) and the IntelliVue Guardian Software (IGS) (Philips Healthcare, Eindhoven, The Netherlands). Both software platforms present the continuous data as trend graphics. Interpretation of the data was further aided either by single parameter threshold-based alarms (Sensium® software) or thresholds resulting in early warning scores (EWS) without alarms (Philips IGS).

Although we selected the Philips IGS software as part of the CVSM system for evaluation on a larger scale, the current software platforms available for CVSM systems

are still too limited for optimal use in clinical practice. This is due to two related issues: poor integration with the hospital's information technology (IT) systems, and the lack of high-level clinical decision support to help interpret changes in vital sign trends.

Integration with hospital IT systems

In our studies, both systems had only limited integration into the hospital electronic Health Record (HER) and other hospital information systems, such as the wireless connectivity and mobile applications for nurses. Interoperability standards for CVSM systems are necessary and a prerequisite for adequate usability by nurses. Once in place, this could dramatically increase their successful implementation in clinical practice. A key aspect of this is the visual presentation of trends and integration of individual vital sign measurements into the EHR (including portable devices for nurses).

In our early studies, connectivity from sensors to software used radiofrequency signals, which required additional Wi-Fi access points (Chapters 4 and 6) and meant that connections were limited in range and integratability. The long-range wide area network (LoRaWAN) connection used in Chapters 7 and 8 allowed us to perform location-independent monitoring without the need for additional infrastructure. We believe that this type of connection, which allows freer movement and makes minimal use of internal systems, is the most promising due to its scalability, including seamless continuation of monitoring in the home setting after hospital discharge.

Clinical decision support: reactive and proactive alarm strategies

For timely notice of clinical deterioration, most wearable CVSM systems come with conventional threshold-based alarm strategies, as used in ICUs.[9,36] In our studies, we tested the CVSM system both with (Chapter 4) and without alarms (Chapter 6).

In the first feasibility study, we found that the alarms were a major deterrent for nurses. Lacking a suitable alternative strategy, we switched to testing a proactive trend assessment strategy to prevent interrupting or adding a further burden to the nursing work.[37,38] We had several other reasons for this. First, 'acute' clinical deterioration from adverse events is extremely rare at the ward and clinical deterioration in the nursing ward usually occurs gradually (for example, the onset of a systemic inflammatory response after major abdominal surgery). Second, given the relatively low nurse-to-patient ratio in general wards (one nurse per 15 patients at night is not uncommon), any system that generates unnecessary or unreliable alarms will disrupt nurse workflows easily and hinder successful implementation.[39] Third, trend assessments were relatively new to nurses and therefore may have been difficult to perform. In fact,

it may be necessary for them to use CVSM systems more often, in order to perform better assessments by learning to recognize normal and abnormal trend patterns.

Eventually the last method (regular trend observation without alarms) showed better rates of adoption and acceptability by professionals, although maintaining long-term adherence to proactive trend assessments was still a challenge (Chapter 7). One likely explanation is that the majority of the assessments did not result in new insights for nurses regarding a patient's status, nor did they result in any additional care interventions, which causes a reduction in vigilance. Therefore, the optimal strategy has not yet been achieved.

Clinical decision support: data analytics

We found that the aggregated threshold-based EWS of the Philips software (Chapters 6 and 7) was more useful for nurses in assessing trends and making clinical decisions, because of familiarity with this scoring system. Given the limits in sensitivity of these EWS and the availability of continuous data, an important next step is advancing clinical decision support through the use of artificial intelligence such as machine learning and predictive algorithms.[40,41] These analytics may detect specific patterns or 'signatures' of clinical deterioration before it becomes overt, resulting in a shift from being reactive (by detection) to becoming proactive (by predictive care).[42]

Initial development could focus on clinical parameter values that, individually, may still be within 'normal' limits, but collectively suggest a developing adverse event.[43] In addition, it is important to integrate contextual factors such as signs/symptoms, the patient's circadian rhythm and level of physical activity, including activities of daily living (ADLs).

Overall, it is probably important to establish high-quality preoperative baseline values and assess when there is relative deviation from established trends for specific vital signs over a certain time interval.[44] For example, a mild but gradual increase in resting HR over several hours may be indicative of a developing complication. Furthermore, patient characteristics such as age and co-morbidity, as well as information such as admission indication or surgical procedure, can also play an important role. Lastly, unexpected changes in laboratory values (obtained from the EHR) could further enhance prediction models for clinical deterioration.[45]

While, in theory, machine learning and predictive analytics, together with better alarm strategies, might enable the advance from descriptive to prescriptive models, they are not magic bullets.[46,47] If an algorithm takes incorrect or inaccurate information from a

wearable sensor or the EHR, the prediction will be incorrect.[47] In addition, given the highly dynamic nature of some contextual data, such as in-between interventions, the algorithm will always need accurate and up-to-date information to be able to provide correct recommendations.[48] Although it may seem only a matter of time before algorithms can predict deterioration better than healthcare professionals, we must remain cognizant that the ability to correctly asses and react to vital signs trend deviations will remain a key competency for the nursing profession.

Considerations regarding CVSM systems in relation to clinical work flow

In this thesis, we designed and evaluated a CVSM system as an addition to the current intermittent manual measurements of vital signs guided by EWS. This design is in line with other CVSM systems developed for wearable patch sensors, and is probably the most suitable method given its ability to collect the most relevant vital signs continuously and the familiarity of nurses with the EWS system.[49,50]

However, this CVMS system design also has several drawbacks. First, the existing system of intermittent manual measurements guided by EWS already has several shortcomings. These include inadequate detection of clinical deterioration due to the intermittent nature of checks, time constraints for performing measurements, understaffing, low confidence among nurses, and the large number of mildly elevated EWS scores that can result in desensitization and less sensitivity to detect deterioration early.[51–55] Second, the routine method of monitoring vital signs manually was maintained during tests. This may explain why successful implementation of the CVSM system was more challenging over time, because old habits were sustained and nurses were more likely to lapse into prior patterns of behaviour.[56]

For successful implementation of CVSM systems, therefore, it seems necessary to abandon old methods of monitoring. Once the CVSM technology is sufficiently improved to reliably provide all nurse-measured vital signs (HR, RR, BP, SpO2 and temperature), it may become possible to safely implement such systems without continuing the intermittent manual measurements guided by EWS.[57] At the bedside the nurse can then focus on observing and documenting symptoms/signs and mental status or even psychosocial care.

USER PERSPECTIVES

The 'technology push' to implement new CVSM systems on general wards remains.[58] However, although technology plays an important role in such interventions, it is important to consider early on the perspective of users, especially that of nurses, to ensure optimal integration and successful implementation.

Nurse perspectives

Acceptability to nurses

Our studies demonstrate that professionals do not yet fully embrace wearable CVSM systems. We observed this in our initial observations as well as finding different attitudes between nurses and surgeons (Chapter 3). These attitudes were in line with the moderate acceptability scores and qualitative themes uncovered in the subsequent pilot tests. Although we observed a short-term increase in acceptability between the two feasibility studies (Chapters 4 and 6), in the longer term we observed a decrease in both acceptability and intervention fidelity when CVSM system was used for a longer period of time (Chapter 7).

In comparison with other recent studies, there also remain challenges to the successful implementation of CVSM systems, particularly with regard to the trustworthiness of vital sign data, the added value of continuous measurement versus intermittent vital sign measurement, and the importance of nursing assessment at the bedside.[59,60] Until the technology fully meets the needs of healthcare professionals and proper integration into workflows becomes possible, substantial time savings are unlikely and perceived benefits will be limited.

The crucial role of the nurse in the implementation process

We have identified three key elements that are important for successful implementation of CVSM systems. In all elements, the nurse plays a crucial role.

Involving nurses from the beginning of the process is the most important element. This means that they should be involved in selecting the technology, deciding how it will be integrated into the workflow, choosing how it will be piloted, and assessing what the evaluation criteria will be. In particular, designating nurses as role models in this area can also have a positive impact on the attitudes and beliefs of their colleagues and thereby promote successful implementation.[27,61–63]

The second important requirement is a firm focus on nurse education and bedside training. Reliable assessment of vital sign trends is particularly important. This became

clear during the pilot studies and interviews with nurses, and accordingly, we gave this a prominent place in our implementation strategy. Indeed, current practice is based on interpretation of vital signs using absolute values based on EWS, so assessing trends is a new concept for nurses in the nursing ward.

We found that hands-on training and coaching was particularly important during the first phase of implementation.[27,64,65] The actual experience of using the hardware and software in practice seemed important for successful adoption of the technology. Appointment of key users and a project manager who is available for guidance appeared to be crucial. We found a lack of experience in assessing vital sign trends and clinical deterioration trends. This may mean that nurses felt less confident in their ability to use the CVSM system and were less motivated to persist using it when technological challenges arose.[66]

Monitoring progress, regular evaluation, and reflection on the part of nurses is the third crucial element. This provides insights into nurses' performance and ensures that adjustments in the implementation strategy or CVSM system can be made promptly and appropriately. In addition, these moments can also provide an opportunity to share experiences of success as well as relevant cases of acute clinical deterioration, which is also highly beneficial to developers.

Entanglement of nursing work

Wearable CVSM technology is often depicted as timesaving and easy to use, but nursing work is not a simple composite of individual tasks, so CVSM technology cannot provide the ultimate solution. We found that there are two important aspects to consider in relation to nursing work when implementing CVSM systems. The first is the importance of the nurse's clinical perspective; the second is the entanglement of the technology with nursing work. Both aspects are embedded in the morning rounds on the general ward, including the nurses' manual measurement of vital signs.

In terms of nurses' clinical perspective, they are able to interpret vital signs, whether measured intermittently or continuously, and place them directly in the patient's clinical context. In addition to the values themselves, subjective assessments such as breathing patterns (e.g., shortness of breath) can be assessed or placed alongside subjective patient complaints. Furthermore, important patient characteristics can be part of this manual assessment and, if necessary, medication can be administered immediately. Having said this, experience and expertise of the individual nurse also plays an important role. These observations are in line with previous research

showing that an experienced nurse's 'gut feeling' is often more sensitive for detecting deterioration than conventional measurements.[67,68]

It is also important to consider the entangled nature of nursing work. Automating a nursing activity may appear to be an improvement, but it may also lead to a less clear overview of the status of the patient, resulting in important information being overlooked.[69,70] For example, besides measuring BP during the morning rounds, nursing care also includes simultaneous assessment of other aspects such as a patient's nutritional status, ADL needs, and the need for follow-up care.[70] In addition, bedside rounds can encourage patients to become more involved in sharing information about their condition and making decisions about their care.[71]

The introduction of automated monitoring of vital signs, such as wearable CVSM systems, has great potential to improve the safety and quality of patient care. However, it also threatens to increase the frequency of 'missed care' by reducing the frequency or even eliminating these vital nursing observations and accessible patient interactions. As CVSM systems reduce the need to be present at the bedside at regular intervals to collect routine vital signs measurements, the opportunity for nurse-patient dialogue may be reduced.[72–75] On the other hand, there is potentially more time for nurses to be genuinely in touch by (comfort) talking with their patients providing emotional and physiological support, which is often mentioned as 'missed care' by nurses.[76–78]

Patient perspectives

Besides nurses, it also important when implementing CVSM systems to consider the perspective of the patients themselves. Several considerations regarding selection, acceptability, and engagement are particularly relevant to patients and may improve future implementation.

In terms of patient selection, it seems important to apply CVSM systems to patients with a significant risk of clinical deterioration, as mentioned by physicians and nurses (Chapters 3, 5 and 6). Therefore, we focused in our studies on high-risk patients, to increase the likelihood of detecting early deterioration while they were wearing a CVSM sensor. Nevertheless, clear cases of clinical deterioration were still rare in our studies. Eventually, however, as the technology matures and associated costs are reduced, consideration should be given to using CVSM systems routinely for all patients, creating a single workflow for nurses and enabling its successful use.

In all our studies where we evaluated the CVSM system at the patient level, we found high patient acceptability, regardless of the technology used. These results are

consistent with other studies of wearable patches, as well as research into more bulky CVSM devices.[50,79] However, with the bulkier multi-parameter devices, the connection cables from the sensors cause more inconvenience for patients, increasing the risk of premature discontinuation of CVSM, and should therefore be considered carefully before use.[80] In particular, high patient acceptability may positively influence nurses to use a CVSM system appropriately and therefore implement it successfully.[81,82] Moreover, it is important to consider that both patients and nurses share the opinion that CVSM technologies cannot and should not replace direct nurse-patient contact.[59]

Engagement, which is considered important by patients (Chapter 8), remains a missing aspect of current CVSM systems. Some of the patients are interested in their own vital sign trends, and while the patient may not be able to influence the management of clinical deterioration, there are other parameters such as body position and activity that can be displayed from the wearable sensor data, and which can encourage the patient to regain post-operative mobility.[83] In particular, digital health applications are well suited to promoting self-management,[84,85] patient activation and autonomy.[86] Especially when accounted for limited digital health literacy,[87] this can further promote successful implementation of CVSM systems for all patients.

EVALUATION

As the technology within the CVSM system is further developed to better fit into clinical workflows, user perspectives will increase and eventually the impact can be more adequately evaluated. Two key issues in this regard are described below.

Maximising the impact of CVSM systems on health outcomes

Our studies found no overt positive effects of a CVSM system on major clinical outcomes such as the incidence of adverse events, severity of complications, length of stay, or readmissions (Chapter 8). These results are consistent with the majority of studies that have evaluated the impact of this technology.[9,36] This raises the question whether CVSM technology – in its current state of maturity – offers sufficient benefit in clinical practice to warrant widespread implementation. However, our experience strongly suggests that outcome benefits do exist; adequate evaluation of major outcomes in large prospective clinical trials will not be possible until the technology has matured, work processes have been optimised, and acceptance of such interventions has improved.

In the meantime, it is important to consider other relevant outcome measures when evaluating and expanding the use of CVSM systems in order to maximise their impact. An important impact we observed in the last two studies (Chapters 7 and 8) was that the use of a CVSM system led to the delivery of additional nursing interventions, potentially resulting in more proactive care. These include the administration of pain medication, for example, or breathing exercises, which are known to promote patient recovery.[88,89] This could potentially have a significant impact on patient care that could ultimately be reflected in the major endpoints, such as a shift from severe to less severe complications and a reduction in overall length of hospital stay. However, some might argue that CVSM systems could lead to overtreatment, as these additional interventions may have limited impact on clinically relevant endpoints.

There is also the potential to extend CVSM systems beyond in-hospital postoperative monitoring. However, this usage was out of scope for this thesis. To date, the evaluation of CVSM systems has been fragmented and limited to either preoperative, perioperative, or postoperative in-hospital or home use.[90,91]

The objectives of the CVSM systems will vary depending on the stages of a patient's care pathway. Extending the application throughout the surgical care pathway beyond the hospital could increase the impact on patient outcomes. For example, there is still much to be gained in the area of prehabilitation in the weeks before surgery, and continuous post-hospital monitoring has the potential to improve patient outcomes by capturing any post-discharge adverse events early.[83,92,93] In addition, CVSM systems could also provide an incentive to promote early discharge, enabling intensified follow-up at home.[94] This would also potentially reduce the number of readmissions and shorten their duration by allowing more timely interventions.

For this reason, we conducted a first study to determine the feasibility of a remote home monitoring intervention for patients discharged after colorectal surgery.[95] This intervention consisted of continuous vital sign measurements (with the CVSM technology used in Chapter 7) and teleconsultations for five consecutive days after discharge. Monitoring was provided by nurses in a dedicated remote patient monitoring department. Ultimately, we found the intervention to be feasible, given its high performance and high patient acceptability. However, the intervention design needs further optimisation before the true value for early discharge protocols, prevention of readmissions and overall patient outcomes can be adequately determined.

Evaluation of CVSM systems in a real-world context

A proper evaluation of the impact of a CVSM system can only be carried out once its design has been optimised, nurse acceptability has been improved, and the nature of its impact has been redefined. Traditionally, a randomised controlled trial is an appropriate method to investigate this. Published studies evaluating the impact of CVSM systems were limited to evaluating the effects on patient outcomes, predominantly in non-controlled designs, without insights into implementation.[9,36,80] However, at the moment, a RCT may not be appropriate, given the complexity of a CVSM system, the lack of insight into how the various components of the system work,[96,97] and how it is influenced by context.[98–100] RCTs are also costly and time-consuming, so not ideal for rapidly developing eHealth technologies such as CVSM systems.[40,101,102] This could potentially lead to the failure of effective technology due to poor implementation.[103]

A suitable alternative may be to use implementation-effectiveness hybrid design studies to evaluate CVSM systems.[98,104,105] Such an approach can provide us with extensive insights into the implementation process and the delivery of the intervention, and are able to relate them to clinical outcomes (Chapters 8 and 9). The outcomes can be linked to provide information on the timing of the evaluation of patient outcomes.

To evaluate effectiveness, a cluster randomised controlled trial with wards as the cluster would be most appropriate, as the CVSM system would be delivered by the group of nurses.[106] Ultimately, this should increase the likelihood of successful implementation and thus speed up the translation of research findings into routine practice.

Cost-effectiveness of CVSM systems

Cost is one of the inevitable questions asked by decision makers.[107] As long as a CVSM system is not fully optimised for clinical practice, however, it is hard to carry out a proper analysis of effectiveness and therefore cost-effectiveness. Moreover, once a CVSM system is utilized at scale, cost is likely to come down from improved technology, mass production and competition between vendors. For these reasons, cost-effectiveness evaluation was outside the scope of this thesis.

On the other hand, it is important to perform an early health technology assessment (HTA) for the development of CVSM systems, particularly as there has been no evaluation yet of current outcomes (Chapter 2). Nurses and doctors also indicated that it is important that costs are in proportion to benefits (Chapters 3 and 5).

The current evidence on cost evaluations indicates that CVSM systems may only be cost-effective when implemented on a large scale. However, it is important to realize that this prediction is based on numerous assumptions that may lead to an inaccurate forecast. Case evidence and types of CVSM systems vary widely while the underlying data on clinical outcomes and range of cost models used are still limited.[108–113] In addition, the costs of the implementation strategy were often not included in these analyses.[108,111–113]

At least in theory, CVSM systems could improve the efficiency of hospital workflow, thereby increasing annual patient capacity, yet this factor is often not part of these calculations. Furthermore, it would also be interesting to explore the potential benefits of hybrid designs from this perspective, as the relative speed of translation from research to clinical practice is not usually considered in traditional cost-effectiveness analyses. Nevertheless, it should be possible to accurately assess cost-effectiveness once the aspects mentioned above have been optimised and realised.

METHODOLOGICAL CONSIDERATIONS

Our studies are among the first to investigate the development and testing of a CVSM system, including nurses' perspectives on CVSM system and its implementation, as well as evaluating this process in parallel with its possible impact on clinical outcomes. However, these studies have several limitations that should be considered when interpreting the results.

First, this thesis was born out of a 'technology push' that culminated in the first feasibility study (Chapter 4). Because we had poor understanding of the impact of a CVSM system, the design of the first study may have been suboptimal, while the negative experiences of nurses in this early study possibly hindered their acceptance and implementation of CVSM systems in subsequent studies.

Second, although this work has generated valuable insights into the implementation process, there is a lack of an overarching, systematic approach to implementing a CVSM system. For example, we have used the COM-B model, but have not systematically translated it into other elements of the Behaviour Change Wheel for selecting appropriate implementation interventions.[114] In particular, there are other appropriate systematic approaches, such as the Consolidated Framework of Implementation Research, which also captures contextual factors. [57]

Third, despite extensive education, training, and protocols, we did not fully capture nurses' knowledge, skills, and expertise when using CVSM systems or properly record how they use them to assess vital sign trends. As a result, there may be variability in their assessments and role in clinical decision-making. In addition, we did not fully examine the influence of CVSM systems on the entire Rapid Response System (RRS) within the hospital.

Fourth, our evaluation of the implementation and impact of the CVSM system may be suboptimal. Despite the strengths and advantages of a hybrid design, the before-and-after study design used to assess the impact on patient outcomes resulted in less valid results for causality between the intervention and outcomes.[115] Instead of historical controls, a cluster randomised controlled trial may be more appropriate, but because of the high costs involved this was not feasible.

Last, while a detailed assessment of cost-effectiveness is not yet possible, we could have included an early HTA analysis in the studies, so that an early cost estimate was available.

IMPLICATIONS

Implications for future research

The results of this thesis have several implications for future research. Increased collaboration between manufacturers and researchers in the development of CVSM technologies is a key recommendation. This cooperation is essential to ensure validation of novel sensors and associated software platforms in real clinical patients.

In addition, the needs of end-users such as nurses can be inventoried during the early stages of development. New variants of wearable wireless sensors should be further investigated so that a greater range of vital signs can be measured, in particular BP and SpO2. Once these added modalities are shown to be reliable, they could eventually replace manual measurements and bring significant benefits to clinical workflows.

Given the immense quantity of vital sign data generated from these studies, this information could be used to further develop predictive algorithms of vital sign trends using artificial intelligence such as Bayesian statistics and machine learning. These algorithms could aid clinical decision-making and may provide an alternative to the conventional EWS scores.[31] This may ultimately lead to prediction of adverse outcomes and thereby prevention of such events.

It would also be useful to explore how professionals can use and integrate vital sign trends – and possibly new prediction models – in their clinical decision-making. This should not be limited to RRT calls but also focus on process outcomes such as performed nursing observations, interventions, and patient-nurse interactions. These activities, which together may prevent patients from developing complications and adverse events, include administering analgesics, promoting mobilization, and providing instructions and repeated encouragement on optimal breathing techniques.[68,116]

Further (qualitative) research is also needed to generate more insights into patient acceptability, especially because nurse-patient interaction may be negatively affected by CVSM systems. In relation to this, CVSM systems also have the potential to improve the physicians' work, which we have only briefly explored in this thesis. The impact of a CVSM system on the physicians role, nurse-physician interaction and communication, particularly with regard to clinical decision-making and RSSs, should also be further examined, as this is known to influence effective escalation of care.[117,118] Eventually, when reaching a large scale, centralizing remote assessment of CVSM trends may be an efficient way to monitor patients remotely during and after their hospitalization.[102,119]

In addition, future research should focus on the integration of continuous vital sign monitoring throughout the patient care pathway, before and after surgery. By establishing a role in the prehabilitation and rehabilitation of hospitalised patients, both clinical impact and cost-effectiveness of the technology might improve. In this respect, it is important to properly investigate the benefit of continuous versus intermittent measurements from the perspective of patients and professionals, as well as the potential role of continuous vital sign monitoring in supporting self-management.

Lastly, evaluation of cost outcomes should be integrated as standard in any evaluation of CVSM systems. During the development and testing phases, these are extremely important to demonstrate early on the potential value in terms of cost-benefits. This is especially important given the fact that new technological interventions are associated with high investment costs for hospitals.

Implications for education

Several implications for the education and training of (future) nurses arise from the results of our thesis. First, previous research as well as our present studies reveal a need for improved knowledge and 'hands-on' experience with continuous vital signs monitoring and associated escalation processes.[120] Even when that knowledge improves, deficits in identification of deteriorating patients can remain.[121–123] Incorporating

CVSM systems into simulation training, preferably using an interdisciplinary approach, as well as training (student) nurses to be observant when using the assessment tool, could not only close this gap, but also improve shared situational awareness.[124,125]

Second, education on the potential benefits of CVSM systems, the use of wearable sensors, related software systems, and assessment of vital sign data trends, should be part of the nursing curriculum. An affinity for technology can be fostered in this way, preventing a lack of skills and negative attitudes towards telemedicine.[126] In addition, nurses may ultimately feel more secure taking a leading role in the development and evaluation of these interventions in practice.[127]

Third, educational opportunities for nurses at both undergraduate and graduate levels in informatics, digital health, co-design, and implementation science should be created to enhance future implementation of CVSM technologies.[127] A growing number of nurses will be needed who understand how to use data science to inform the creation of clinically relevant support tools for monitoring vital signs.[128]

Implications for practice

The following practical implications are considered for stakeholder groups including nurses, healthcare organizations, and the manufacturers of CVSM technologies.

For nurses and healthcare organizations

Nurses should take a leading role in implementing any new CVSM system, as they are most familiar with its clinical context. In doing so, they should keep in mind the entanglement of their work when integrating the technology into the clinical process. One possible approach for nurses could be to combine their work as clinicians with dedicated time to implement the CVSM system and encourage early engagement. Similarly, in order to integrate the technology into a hospital's complex IT system, it is important to involve the hospital's IT and medical technology departments at an early stage.

During the selection process of a CVSM technology for local implementation, organizations should be critical of manufacturers' statements and claims about the benefits of the technology. It is important to assess the availability of peer-reviewed articles on the hardware and systems available. For present-day use on the general ward, we recommend choosing an off-the-shelf CVSM technology such as the 'ICU-grade' bulkier wearable devices that are able to completely replace manual vital sign measurements on all relevant parameters. This will then have an immediate benefit in the workflow process, making a successful implementation more likely. Integration

with patient records is thereby essential. If minimally invasive patch sensors can also validly measure the relevant parameters, they will be preferred. Obviously, for pre-hospital and post-discharge CVSM, only small unobtrusive sensors are acceptable.

When introducing such systems, the use of a theoretical approach can be useful for successful development, evaluation and implementation. Relevant frameworks include the Medical Research Council (MRC) framework for intervention development and evaluation, and both the Behaviour Change Wheel – to guide the design and evaluation of behaviour change interventions – and the constructs of the Consolidated Framework for Implementation Research (CFIR) can support the implementation strategy for effective implementation. These can help to determine the degree of fit between the CVSM system and its context. In addition, the use of a short-term, cyclical approach commonly used in action research, such as Agile or Plan-Do-Study-Act (PDSA) cycles,[129–132] is advisable, as close collaboration between clinicians, the technology manufacturer and the IT department is essential. Finally, it is important to define clear criteria for evaluating the implementation process. The 'Quadruple Aim' (parallel evaluation of health outcomes, patient experience, staff satisfaction, and cost of care) can guide these criteria through the use of qualitative and quantitative research methods, which are mutually reinforcing and ultimately provide a broad analysis of the use of digital care.[133,134]

For manufacturers of CVSM technologies

Wearable sensors should be developed further to measure the full range of vital signs. There should also be a focus on reusable sensors (with simple wireless recharging) rather than disposable wearable sensors, potentially reducing costs and increasing sustainability. Compatibility with current electronic health record systems should also be improved, so that efficiency and usefulness are more apparent to healthcare professionals from the outset. This is a joint responsibility between CVSM manufacturers and EHR vendors. Greater compatibility will also facilitate the implementation of advanced analytics such as artificial intelligence to clinical decision support, based on vital signs data combined with critical contextual and patient-related factors.

Finally, ubiquitous connectivity is needed to expand the scope of use inside and outside the hospital. Prehabilitation and home-based rehabilitation can also benefit from CVSM technologies. Special attention is needed in these areas with regard to patient engagement with the technology, to make sure that every patient – also those with limited (digital) health literacy – can benefit from the new technology.[87]

FINAL CONCLUSION

In order to maintain high quality care with scarce staff capacity in the future, the widespread introduction of CVSM systems on the general ward and potentially also outside the hospital seems inevitable. Despite the theoretical benefits of CVSM systems in improving clinical outcomes, such as reducing unplanned ICU admissions, mortality from Failure-to-Rescue, and supporting nursing care by optimising clinical workflows, we have not yet been able to successfully demonstrate these benefits in clinical practice. Nevertheless, it seems safe to conclude that CVSM systems – provided that it is properly implemented – could be one promising option for ensuring the future quality and safety of care for patients in and out of hospital and for the advancement of the nursing profession.

In conclusion, our results highlight the complexity of implementing CVSM systems on hospital wards, and highlight the need for further research and development to realize a substantial contribution to improved patient care. Nurses play a pivotal role in implementing CVSM systems on the general ward and thereby ensuring their success. However, given the current state of technology, its actual implementation in clinical practice is still a challenge and requires additional time and energy from nurses to be implemented properly. With poor implementation CVSM systems can only have a very limited impact on patient care. The technology is expected to mature further, so that it can be optimally integrated in healthcare IT systems and make a significant contribution to efficiency in nursing and to the early detection of clinical deterioration. Only then can the clinical effectiveness and cost-effectiveness of CVSM systems be adequately determined and provide substantial benefits for nurses and their work.

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A

APPENDICES

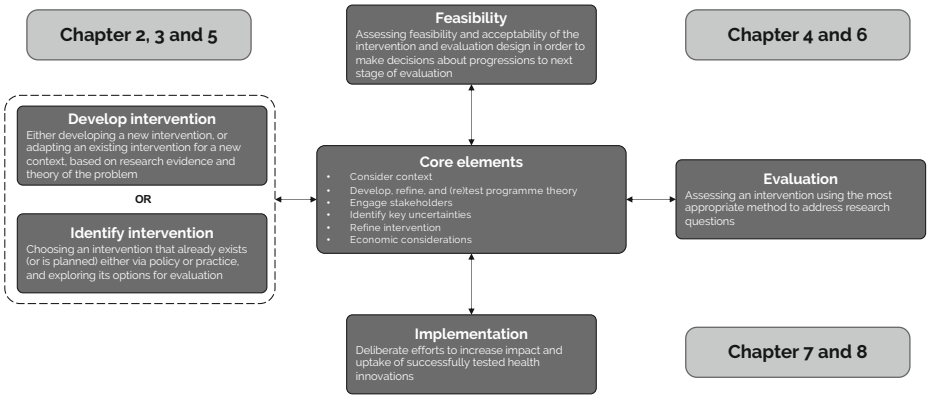
SUMMARY

Hospitalised patients, including patients undergoing major abdominal surgery, are at risk of complications and adverse events. Serious adverse events, such as infections and myocardial infarction, are often preceded by changes in physiological signs (e.g. tachycardia and tachypnoe) before becoming clinically evident. Lack of recognition and subsequent delay in interventions may lead to inferior clinical outcomes (e.g. ICU admissions or mortality). Monitoring and early detection of these deviations in vital signs is therefore important. In current practice, nurses perform intermittent manual measurements (once every 8-24 hours). However, due to the intermittent nature, suboptimal protocol compliance, and low accuracy of measurements (especially respiratory rate), early signs of deterioration may be missed. Increasing the frequency of patient observation and vital signs measurements by nurses seems a logical step to improve safety, but this is not feasible in practice due to the growing shortage of nurses and overall rising healthcare demand.

One possible solution to improve safety on hospital wards in the face of increasing nursing shortages is the implementation of innovative technological solutions. Wearable wireless continuous vital signs monitoring (CVSM) could contribute to earlier detection of deteriorating patients, especially in 'low-care' environments such as general wards, and perhaps even after discharge to home. Although the technical validity of current CVSM technology seems acceptable, rigorous evaluation and successful large-scale integration and implementation of these devices in clinical practice is still lacking. Initial studies of these CVSM systems have shown variable results and have proven that it is quite challenging to adequately implement them in nursing practice.

The overall aim of this thesis was to gain a better understanding of core elements of CVSM systems, critical aspects of the implementation process and potential benefit of CVSM systems for patient care, with a focus on the nurse's professional perspective in the prelude to further development and future implementations. The studies in this thesis followed the phases of development, feasibility, evaluation and implementation as described by the Medical Research Council (MRC) Framework (Figure 1).

Figure 1: Chapters of this thesis arranged according to the phases of the Medical Research Council (MRC) Framework



In **chapter 1**, a general introduction on the topic and outline of the thesis is presented. In **chapter 2**, a systematic literature review gives an overview of the current evidence for wearable CVSM technology on the outcomes: validation, feasibility, clinical outcomes and costs. A total of 27 studies were included, evaluating 13 different wearable devices. The results showed that most wearable CVSM devices were still in the clinical validation and feasibility phase. There were no high-quality, large, well-controlled trials of wearable CVSM that showed a significant clinical benefit or cost-effectiveness.

In **chapter 3** we explored nurses' and surgeons' expectations of the potential effectiveness and impact of CVSM in patients after esophagectomy. We performed 12 semi-structured interviews at three oesophageal cancer centres in the Netherlands. Our results showed the majority of nurses and surgeons expected that CVSM could contribute to the earlier recognition of deterioration and result in earlier treatment for postoperative complications, although the effective time gain would depend on patient and situational factors. Their expectations regarding the impact of potential earlier detection on clinical outcomes varied. Nevertheless, most caregivers would consider implementing continuous monitoring in the surgical ward to support patient monitoring after esophagectomy.

Based on the studies in chapter 2 and 3, an observational cohort study was initiated to determine the feasibility, in terms of acceptability and technical fidelity, of CVSM on a general surgical ward (**chapter 4)**. Patients were continuously monitored until discharge, using the SensiumVitals patch, which was the best evaluated device according to our systematic review (Chapter 3). Heart rate, respiratory rate and

axillary temperature were measured every 2 minutes. Vital sign values and trends were visualised and alerts sent to the nurses. In total, 30 patients were monitored and patient acceptability was high. However, nurses' ratings were highly variable on usefulness, ease of use and satisfaction, resulting in an on average neutral attitude towards the intervention. These varying scores were mostly related to the perceived limited fidelity of the CVSM technology. We found a median alert rate of 4.5 per patient per day, of which the majority were system alarms. Of the vital sign alarms, 35% were true positives. Subsequently, artefact rates were between 9% -51% of measurements. The results suggest that CVSM in general wards is feasible, but improvements in the intervention are needed to increase nurse acceptance.

Subsequently, in **chapter 5**, we further explored nurses' experiences with CVSM during the feasibility study as nurses play a major role in the conduct of CVSM and eventually the success of the implementation. We performed 12 semi-structured interviews and used the Capability, Opportunity, Motivation – Behaviour (COM-B) model of the Behaviour Change Wheel to organise the results. We identified five key themes about what was important to nurses in relation to the use of CMVS systems: learning and coaching on the job (capability), interpretation of vital sign trends (capability), management of alarms (opportunity), integration and compatibility with clinical workflow (opportunity) and added value for nursing care (motivation). We found that when the topics in Capability and Opportunity are not properly addressed by selecting interventions and policy categories, this may negatively influence the Motivation and may compromise successful implementation.

Next, the findings from Chapters 4 and 5 were integrated and evaluated in a sequential mixed methods study in **Chapter 6** to determine the feasibility of CVSM without the use of alarms, relying solely on interval trend assessments over a three-month period. We selected another CVSM technology which measured patients' heart rate and respiratory rate using the Philips Biosensor BX100 with Intellivue Guardian Solution (IGS) software. The vital signs trends were visualised for regular assessments six times a day by nurses and once a day by physicians without using alarms. The implementation strategy consisted of weekly information bulletins and group education prior to implementation, followed by on-the-job coaching and fortnightly email feedback. We showed that this CVSM system was acceptable to nurses, physicians and patients. For the majority of nursing shifts (81%), trend assessments were documented without missing deviating trends, thereby avoiding unnecessary alarms and preventing alarm fatigue. Professionals in the focus groups found the intervention useful and were willing to use the technology. Although insight into vital sign trends allowed faster anticipation and response to changes in patient status, professionals were neutral

about its usefulness. They also found CVSM easy to use and learn but indicated the need to gain more practical experience. Nurses felt that the use of alarms for abnormal vital signs was unnecessary if trends were regularly assessed and reported.

These promising results provided sufficient reason to evaluate the CMVS system on a larger scale and over a longer period of time, both on the surgical ward and internal medicine ward with an implementation-effectiveness hybrid design study. In **Chapter 7**, a process evaluation was conducted to evaluate the fidelity of the intervention, technology and implementation together with the nurse perspectives by surveys and interviews over a six month period. The CMVS system consisted of the Philips Healthdot sensor and with the similar IGS software with proactive trend assessments. The key elements of the implementation strategy were 1) extensive e-learning training before the start of the study, 2) bedside training and coaching during the first few months of the study, and 3) monthly evaluations with the ward project teams.

We successfully implemented the CVSM system at scale on two hospital wards. Our results show that intervention fidelity decreased over time on the medical ward, but only minimally on the surgical ward. This decrease appeared to be dependent on several medical ward specific factors: almost 70% of patients did not require any intervention based on observed vital sign trends, and nurses' explanations were: the relatively low priority of CVSM in their work, the importance of bedside nursing assessment, the relatively limited perceived benefits to patient care, and the perceived mediocre usability of the technology.

To assess effectiveness, **Chapter 8** describes the results of a before-after study designed to examine the effects of the CVSM system on 20 in-hospital and post-discharge outcomes in patients undergoing major abdominal surgery on the general ward, with length of stay as primary outcome measure. After analysis of 908 patients, we found the median length of stay was significantly lower in the CVSM group (5.0 vs 5.5 days). In the subgroup analysis, the reduced length of stay was only observed in colorectal surgery patients and not in hepatopancreatobiliary surgery patients. Furthermore, all secondary clinical outcome measures were similar in the CVSM and control groups, with the exception of a reduction in nurse-to-house-officer calls in the CVSM group. In addition, a non-significant trend towards fewer major complications and shorter ICU stay was observed in the CVSM group. In 35% of CMVS-patients 109 additional nursing activities were performed, and 83% of patients indicated CMVS was acceptable.

Chapter 9, the general discussion, describes the implications of our findings in a practical and scientific context, including methodological considerations, implications for future research, education and clinical practice and final conclusion. In order to maintain high quality care with scarce healthcare staff capacity in the future, the widespread introduction of CVSM systems on the general ward and potentially also outside the hospital seems very likely. Despite the theoretical benefits of CVSM systems in improving clinical outcomes, such as reducing unplanned ICU admissions, preventing mortality from failure to rescue, and supporting nursing care by optimizing clinical workflows, larger controlled studies will be needed to successfully demonstrate these benefits in clinical practice.

In conclusion, our results highlight the complexity of implementing CVSM systems on hospital wards and the need for further research and development to assess the true clinical value and cost effectiveness. Given the current state of the technology, its proper implementation in clinical practice remains challenging. Nurses play a pivotal role in implementing CVSM systems on the general ward and thereby ensuring their success. It is expected that CVSM technology will continue to mature over the next few years, so that it can be seamlessly integrated into healthcare EMR systems and provide wireless multi-parameter monitoring with personalized alarm decision support tools. If properly implemented, such evolving CVSM systems hold great promise for improving the future quality and safety of patient care in (and out of) the hospital and for the advancement of nursing work.

Scan the QR-code to watch a video about the thesis:

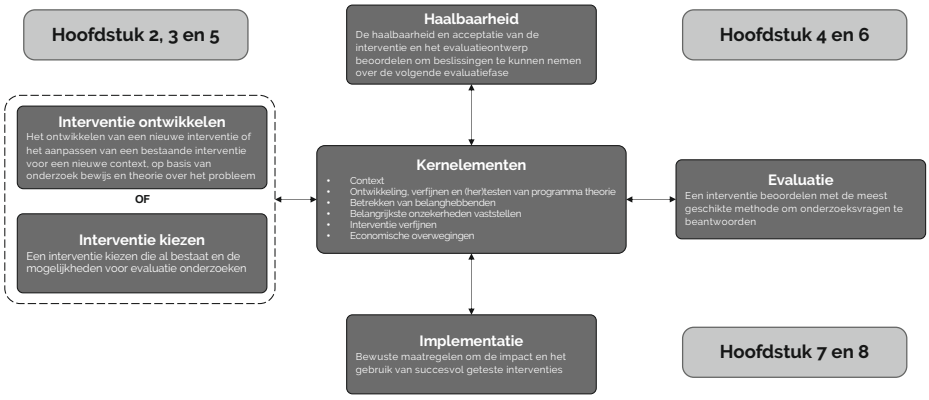
SAMENVATTING

Patiënten in het ziekenhuis lopen risico op complicaties en 'adverse events'. Ernstige adverse events, zoals infecties en myocardinfarcten, worden vaak voorafgegaan door veranderingen in vitale functies (bijv. een verhoogde hartslag en ademhaling) voordat ze klinisch duidelijk worden. Gebrek aan tijdige herkenning en de daaropvolgende vertraging in interventies kan leiden tot slechtere klinische resultaten (bijv. IC-opnames of sterfte). Monitoring en vroegtijdige detectie van deze afwijkingen in de vitale functies is daarom belangrijk. In de huidige praktijk voeren verpleegkundigen intermitterende handmatige metingen uit (eens in de 8-24 uur). Echter, door het intermitterende karakter, de suboptimale naleving van het protocol en de lage nauwkeurigheid van de metingen (vooral ademhalingsfrequentie), kunnen vroege tekenen van verslechtering gemist worden. Het verhogen van de frequentie van patiënten observatie en het meten van vitale functies door verpleegkundigen lijkt een logische stap om de veiligheid te verbeteren, maar dit is in de praktijk niet haalbaar vanwege het groeiende tekort aan verpleegkundigen en de alsmaar stijgende zorgvraag door de dubbele vergrijzing.

Een mogelijke oplossing om de veiligheid op verpleegafdelingen te verbeteren in het licht van toenemende verpleegkundige tekorten is de implementatie van innovatieve, slimme technologie. Draagbare, draadloze continue monitoring van vitale functies (CMVF), ook wel bekend als een 'slimme pleister', zou kunnen bijdragen tot een vroegere detectie van verslechterde patiënten, vooral op algemene verpleegafdelingen en na ontslag in de thuissituatie. Hoewel de technische validiteit van de huidige CMVF-technologie acceptabel lijkt, ontbreekt het nog steeds aan een grondige evaluatie en een succesvolle grootschalige integratie en implementatie van deze technologie in de dagelijkse klinische praktijk. De eerste onderzoeken naar deze CMVF-systemen hebben wisselende resultaten laten zien en hebben aangetoond dat het een hele uitdaging is om ze adequaat te implementeren in de verpleegkundige praktijk.

Het algemene doel van dit proefschrift was om een beter begrip te krijgen van de kernelementen van CMVF-systemen, kritische aspecten van het implementatieproces en potentiële voordelen van CMVF-systemen voor de patiëntenzorg, met een focus op het professionele perspectief van de verpleegkundige als opmaat voor verdere ontwikkeling en toekomstige implementaties. De studies in dit proefschrift volgden de fasen van ontwikkeling, haalbaarheid, evaluatie en implementatie zoals beschreven in het Medical Research Council (MRC) Framework (Figuur 1).

Figuur 1: Hoofdstukken van dit proefschrift van dit proefschrift geordend volgens de fasen van het Medical Research Council (MRC)-raamwerk



In **hoofdstuk 1** wordt een algemene inleiding van het onderwerp en de opzet van het proefschrift gepresenteerd. **Hoofdstuk 2** geeft een systematisch literatuuronderzoek een overzicht van het huidige bewijs voor draagbare CMVF-technologie op de uitkomsten: validatie, haalbaarheid, klinische eindpunten en kosten. In totaal werden 27 studies geïncludeerd waarin 13 verschillende draagbare apparaten werden geëvalueerd. Uit de resultaten bleek dat de CMVF-apparaten zich hoofdzakelijk in de klinische validerings- en haalbaarheidsfase bevonden. Daarnaast waren er geen grote onderzoeken die verbeterde klinische eindpunten of kosteneffectiviteit lieten zien.

In **hoofdstuk 3** onderzochten we de verwachtingen van verpleegkundigen en chirurgen over de mogelijke impact van CMVF bij patiënten na een slokdarmresectie. Wij voerden 12 semigestructureerd interviews uit in drie slokdarmkankercentra in Nederland. Uit onze resultaten bleek dat de meerderheid van de verpleegkundigen en chirurgen verwachtte dat CMVF zou kunnen bijdragen aan eerdere herkenning van klinische achteruitgang en zo eerdere behandeling voor postoperatieve complicaties. Hun verwachtingen liepen uiteen en de effectieve tijdwinst zou echter wel afhangen van patiënt- en situationele factoren. Niettemin overwegen de meeste zorgverleners de invoering van CMVF op hun afdeling.

Op basis van de studies in hoofdstuk 2 en 3 werd een observationele studie opgezet om de haalbaarheid, in termen van acceptatie en technische werking, van CMVF op een algemene chirurgische verpleegafdeling te bepalen (**hoofdstuk 4**). De patiënten werden tot hun ontslag uit het ziekenhuis continu gemonitord met de SensiumVitals-sensor, die volgens onze systematische review (hoofdstuk 3) het meest geschikte apparaat was. Hartslag, ademhalingsfrequentie en okseltemperatuur werden elke 2

minuten gemeten. Vitale functies en trends werden gevisualiseerd en alarmen werden naar de verpleegkundigen gestuurd. Uiteindelijk werden 30 patiënten gemonitord en de acceptatie van patiënten was hoog. De acceptatie van de verpleegkundigen verschilde veel wat betreft nut, gebruiksgemak en tevredenheid. Dit resulteerde in een neutrale houding ten opzichte van de interventie. Deze uiteenlopende scores hielden vooral verband met de beperkte technische werking van de CMVF-technologie. Wij vonden een mediane alarmfrequentie van 4,5 per patiënt per dag, waarvan de meerderheid systeemalarmen waren en maar 35% terechte vitale-functie alarmen. Tevens lag het artefactpercentage tussen 9%-51%. Deze resultaten suggereren dat CMVF op de verpleegafdelingen haalbaar kan zijn, maar dat verbeteringen in de interventie nodig zijn om de acceptatie door verpleegkundigen te vergroten.

Vervolgens onderzochten we de ervaringen van verpleegkundigen met CMVF tijdens de haalbaarheidsstudie in **hoofdstuk 5**, aangezien verpleegkundigen een belangrijke rol spelen bij de uitvoering van CMVF en uiteindelijk het succes van de implementatie. We voerden 12 semigestructureerde interviews uit en gebruikten een gedragsveranderingsmodel (bestaande uit kennis en vaardigheden, mogelijkheid en motivatie) om de resultaten te ordenen. Wij identificeerden vijf hoofdthema's over wat belangrijk was voor verpleegkundigen met betrekking tot het gebruik van CMVF-systemen: leren en coachen tijdens het werk (kennis en vaardigheden), interpretatie van vitale functies trends (kennis en vaardigheden), management van alarmen (mogelijkheid), integratie en compatibiliteit met de klinische workflow (mogelijkheid) en toegevoegde waarde voor de verpleegkundige zorg (motivatie). Wij vonden dat wanneer de thema's in 'kennis en vaardigheden' en 'mogelijkheid' niet goed worden aangepakt, dit de motivatie negatief kan beïnvloeden en een succesvolle implementatie kan belemmeren.

Hierna werden de bevindingen uit de hoofdstukken 4 en 5 geïntegreerd en geëvalueerd in een vervolgonderzoek (**hoofdstuk 6**) waarbij de haalbaarheid van een CMVF-systeem zónder het gebruik van alarmen werd bepaald. Voor dit CMVF-systeem kozen we een andere CMVF-technologie: de Philips Biosensor BX100 met Intellivue Guardian Solution (IGS) software. De sensor meet de hartslag en ademhaling van patiënten. De vitale functie trends werden zes keer per dag beoordeeld door verpleegkundigen en één keer per dag door artsen. De implementatiestrategie bestond uit wekelijkse informatiebulletins en groepsonderwijs voorafgaand aan de implementatie, gevolgd door coaching op de werkplek en tweewekelijkse feedback per e-mail. Wij toonden aan dat dit CMVF-systeem acceptabel was voor verpleegkundigen, artsen en patiënten. In de meerderheid van de verpleegkundige diensten (81%) werden trendbeoordelingen gedocumenteerd zonder afwijkende trends te missen, waardoor onnodige alarmen werden voorkomen en alarmmoeheid werd vermeden. Professionals in de focusgroepen vonden de interventie

nuttig en waren bereid de technologie te gebruiken. Hoewel inzicht in trends in vitale functies het mogelijk maakte sneller te anticiperen en te reageren op veranderingen in de status van de patiënt, waren professionals neutraal over het nut ervan. Zij vonden het CMVF systeem ook gemakkelijk te gebruiken en te leren, maar gaven aan behoefte te hebben aan meer praktijkervaring. Verpleegkundigen vonden het gebruik van alarmen voor abnormale vitale functies overbodig als trends regelmatig werden beoordeeld en gerapporteerd.

Deze veelbelovende resultaten gaven voldoende aanleiding om het CMVF-systeem op grotere schaal en over een langere periode te evalueren, op twee verpleegafdelingen (chirurgie en interne geneeskunde) met een implementatie-effectiviteit hybride studie. In **hoofdstuk 7** werd de procesevaluatie beschreven om de uitvoering van de implementatie en interventie en werking van de CMVF-technologie samen met de verpleegkundige perspectieven te evalueren door middel van enquêtes en interviews. Het CMVS-systeem bestond uit de Philips Healthdot sensor en de IGS-software met proactieve trendbeoordelingen. De belangrijkste elementen van de implementatiestrategie waren 1) uitgebreide e-learning training, 2) bedside training en coaching tijdens de eerste paar maanden van de studie, en 3) maandelijkse evaluaties met de projectteams van de afdeling.

We hebben het CMVF-systeem met succes op schaal geïmplementeerd op de twee afdelingen. Onze resultaten laten echter zien dat de uitvoering van de interventie in de loop van de tijd afnam, op de verpleegafdeling interne geneeskunde in sterkere mate dan op de chirurgische verpleegafdeling. Deze afname bleek afhankelijk te zijn van verschillende afdelingsspecifieke factoren: bijna 70% van de patiënten had geen interventie nodig op basis van trendbeoordelingen, en de verklaringen van de verpleegkundigen waren: de relatief lage prioriteit van CMVF in hun werk, het belang van verpleegkundige beoordeling aan het bed, de beperkte voordelen voor de patiëntenzorg, en de matige gebruiksvriendelijkheid van de technologie.

In **hoofdstuk 8** evalueerden we de effecten van het CMVF-systeem op 20 klinische uitkomsten van buik chirurgische patiënten. Hierbij was ziekenhuisopnameduur primaire uitkomst. Na analyse van 908 patiënten bleek dat de mediane opnameduur significant lager was in de CMVF-groep (5,0 vs. 5,5 dagen). In de subgroep analyse werd de kortere opnameduur echter alleen waargenomen bij de colorectale chirurgie patiënten, maar niet bij de lever en alvleesklier chirurgische patiënten. Verder waren alle secundaire klinische uitkomsten vergelijkbaar tussen de groepen, met uitzondering van een vermindering van het aantal telefonische oproepen van de verpleegkundige naar dienstdoende arts. Ook werd in de CMVF-groep een niet-significante trend

waargenomen naar minder grote complicaties en een kortere opnameduur op de IC. Verder werden bij 35% van de patiënten 109 extra verpleegkundige handelingen verricht, en de meerderheid (83%) van de patiënten vond de CMVF acceptabel.

Hoofdstuk 9, de algemene discussie, beschrijft de implicaties van onze bevindingen in een praktische en wetenschappelijke context, methodologische overwegingen, implicaties voor toekomstig onderzoek, onderwijs en de klinische praktijk en een slotconclusie. Om in de toekomst zorg van hoge kwaliteit te kunnen blijven leveren met een beperkte capaciteit aan zorgpersoneel, lijkt de grootschalige invoering van CMVF-systemen op de verpleegafdeling en mogelijk ook buiten het ziekenhuis zeer waarschijnlijk. Ondanks de theoretische voordelen van CMVF-systemen voor het verbeteren van de patiëntenzorg, zoals het verminderen van ongeplande IC-opnames, het voorkomen van sterfte en het ondersteunen van verpleegkundige zorg door het optimaliseren van klinische werkprocessen, zijn er grotere gecontroleerde onderzoeken nodig om deze voordelen met succes aan te tonen in de klinische praktijk.

Concluderend benadrukken onze resultaten de complexiteit van de implementatie van CMVF-systemen op ziekenhuisafdelingen en de noodzaak van verder onderzoek en ontwikkeling om de werkelijke toevoegende klinische waarde en kosteneffectiviteit te beoordelen. Gezien de huidige stand van de technologie blijft de juiste implementatie in de klinische praktijk een uitdaging. Verpleegkundigen spelen een cruciale rol bij de implementatie van CMVF-systemen op de algemene afdeling en zorgen zo voor het succes ervan. Verwacht wordt dat de CMVF-technologie de komende jaren verder volwassen zal worden, zodat deze alle vitale functies continu kunnen worden gemeten, software naadloos kan worden geïntegreerd in ICT-systemen en gepersonaliseerde klinische besluitvorming adviezen kan worden geven. Indien op de juiste manier geïmplementeerd, houden dergelijke evoluerende CMVF-systemen een grote belofte in voor het verbeteren van de toekomstige kwaliteit en veiligheid van patiëntenzorg in (en buiten) het ziekenhuis en voor het bevorderen van verpleegkundig werk.

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LIST OF PUBLICATIONS AND PRESENTATIONS

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A

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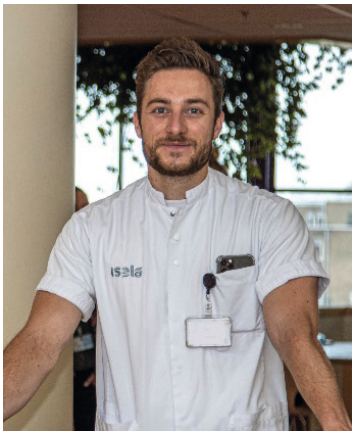
Zwolle, juli 2023

CURRICULUM VITAE



Job Leenen was born in Zwolle on 8 July 1993. After completing his pre-university degree (VWO) at the Carolus Clusius College, he started a BSc in Biology at the University of Groningen in 2011. After discovering that biology was not quite the right direction, he turned towards a more clinical discipline and started a Bachelor's degree in Nursing at the Windesheim University of Applied Sciences in Zwolle in 2012. As a minor in his third year, he completed the Pre-Master in Nursing Science at the University of Utrecht. In 2016 he obtained his Bachelor's degree in Nursing. After graduation, he started working as a nurse at the surgical department of Isala in Zwolle, while simultaneously starting the Master in Nursing Science at the University of Utrecht. During this study he participated in several departmental and hospital-wide quality improvement projects. Job obtained his Master's degree in 2018 with his thesis at the Emergency Department of the University Medical Centre Utrecht.

After graduating, Job continued to work as a nurse on the surgical ward at Isala. As a member of the Surgical Ward Quality Improvement Team, the idea of a feasibility study with wearable continuous ward vital signs monitoring emerged in 2019. After receiving a grant from the Isala Innovation & Science Fund and support from the Isala Connected Care Centre, the study was prepared and conducted. During the preparation of the first study, he explored the possibility of a PhD trajectory on this technological innovation, obtained a second grant from the Isala Innovation & Science Fund and finally formed a PhD team with Dr Gijs Patijn, surgeon at Isala, and Professor Cor Kalkman and Professor Lisette Schoonhoven from the University Medical Centre Utrecht in 2020. At the end of 2020, a follow-up grant was received for the actual implementation and evaluation of the developed continuous vital signs monitoring intervention. During the course of the research, Job started as a policy advisor in the field of nursing science at the Isala Academy in 2019 and as a project manager at the Isala Connected Care Centre in 2020.

Job intends to continue to work on his passion and ambition to improve care with a focus on technological innovation by linking clinical practice, policy, research and education through his work at Isala Academy, Isala Connected Care Centre and in his new position as a scientist in the IT Innovations in Health Care research group at the Windesheim University of Applied Sciences.

Albus Dumbledore: *"I think, if you so desired, you'd be able to board a train."*
Harry Potter: *"And where would it take me?"*
Albus Dumbledore: *"On."*