What Is the Impact of Ambulatory Vital Sign Monitoring on Deterioration Detection and Related Clinical Outcomes in Hospitalised Patients: a Systematic Review and Meta-analysis.

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Research

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Abstract

Background: Timely recognition of the deteriorating inpatient remains challenging. Ambulatory monitoring systems (AMS) may augment current monitoring practices. However, there are many challenges to implementation in the hospital environment, and evidence describing the clinical impact of AMS on deterioration detection and patient outcome remains unclear.

Objective: To assess the impact of vital signs monitoring on detection of deterioration and related clinical outcomes in hospitalised patients using ambulatory monitoring systems, in comparison with standard care.

Methods: A systematic search was conducted in August 2020 using MEDLINE, Embase, CINAHL, Cochrane Database of Systematic Reviews, CENTRAL and Health Technology Assessment databases, as well as grey literature. Studies comparing the use of AMS against standard care for deterioration detection and related clinical outcomes in hospitalised patients were included. Deterioration related outcomes (primary) included unplanned intensive care admissions, rapid response team or cardiac arrest activation, total and major complications rate. Other clinical outcomes (secondary) included in-hospital mortality and hospital length of stay. Exploratory outcomes included alerting system parameters and clinical trial registry information.

Results: Of 8706 citations, 10 studies with different designs met the inclusion criteria, of which 7 were included in the meta-analyses. Overall study quality was moderate. The meta-analysis indicated that the AMS, when compared with standard care, was associated with a reduction in intensive care transfers (risk ratio, RR, 0.87; 95% confidence interval, CI, 0.66 to 1.15), rapid response or cardiac arrest team activation (RR, 0.84; 95% CI 0.69 to 1.01), total (RR, 0.77; 95% CI 0.44 to 1.32) and major (RR, 0.55; 95% CI 0.24 to 1.30) complications prevalence. There was also association with reduced mortality (RR, 0.48; 95% CI 0.18 to 1.29) and hospital length of stay (mean difference, MD, -0.09; 95% CI -0.43 to 0.44). However, none were statistically significant.

Conclusion: This systematic review indicates that implementation of AMS may have a positive impact on early deterioration detection and associated clinical outcomes, but differing design/quality of available studies and diversity of outcomes measures limits a definite conclusion. Our narrative findings suggested that alarms should be adjusted to minimise false alerts and promote rapid clinical action in response to deterioration.

PROSPERO Registration number: CRD42020188633

Background

In the United Kingdom, the use of physiological early warning scoring (EWS) systems (which measure "standard" vital signs such as pulse rate, respiratory rate, blood pressure, oxygen saturation, and temperature) is still common practice in general wards, together with a graded response such as referral for a senior review or increasing monitoring frequency [1]. This frequency of observations is generally guided by the clinical condition of the patient, and due to the requirement of manual physiological measurements, it can be time-consuming for healthcare professionals [2]. As a result, the optimal monitoring frequency is often not achieved [3], limiting the efficacy of intermittent monitoring systems dependent on the frequency of manual observations [4]. Furthermore, even when the ideal frequency is achieved, patients can deteriorate between observation sets [5]. Higher risk patients are often continuously monitored (for example in critical care), improving early detection of deterioration [2]. However, in the UK, continuous monitoring is not commonly used in the ward environment [6], although one study suggests it may be feasible and cost-effective in surgical wards [7], with the potential to improve patient outcomes when compared to intermittent monitoring [5].

Despite the potential to promote earlier detection of deterioration, limitations in continuous vital sign monitoring technology can pose a barrier to implementation [2], such as restriction of patient mobility and independence due to wires and static devices [6, 8]. In response to this need, commercially available wearable monitoring devices are evolving rapidly [9]. Wearable devices may provide an alternative to static wired continuous monitors and offer a bridge between bedside wired monitoring and intermittent manual measurements. This development has the potential to promote patients' mobility and comfort while reducing nursing time and improving the early detection of abnormal physiological parameters [10].

A recent meta-analysis assessed the impact of multi-parameter continuous non-invasive monitoring in hospital wards, including wired static devices, suggesting a 39% decreased mortality risk in monitored patients compared to those receiving standard care (intermittent manual observations), it also suggested a trend of reduced intensive care unit (ICU) transfer, rapid response team (RRT) activation and hospital length of stay (LoS) [11]. The validation, feasibility, costs and clinical outcomes of 13 different wearable devices were assessed in another systematic review, which demonstrated that the majority of studies were still at the validation and feasibility phases [12], emphasising the lack of evidence assessing the impact on economic and clinical outcomes as there is still uncertainty around the impact of ambulatory monitoring systems (AMS) in the hospital environment, hindering its implementation and clinical use [13]. Our review focused on these ambulatory monitoring devices and/or systems implemented inside the hospital (inclusive of all specialities, acuity and ages).

Objective

The objective of this systematic review and meta-analysis was to assess the impact of vital sign monitoring on the detection of physiological deterioration and related clinical outcomes of hospitalised patients using ambulatory monitoring systems in comparison with standard care.

Methods

This systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on the 10th July 2020, registration number CRD42020188633 [14]. This review was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

checklist (Appendix 1) [15]. The full systematic review protocol was published prospectively [16].

Outcomes

Primary Outcomes

This study aimed to compare the impact of ambulatory monitoring systems on deterioration detection and related clinical outcomes metrics, in comparison with standard care. A variety of outcomes related to deterioration detection were anticipated, and therefore searches were not limited by outcome. Any outcome related to the detection of deterioration was included as a primary outcome for this review. Specific outcomes reported in the included studies were: intensive care unit (ICU) transfers; and rapid response team activation or cardiac calls...

A variety of other complications related to clinical deterioration were reported and included in the meta-analysis, from minor (for example fainting, or shortness of breath) to major (such as life-threatening events). A separate analysis was then conducted for the studies separately reporting major complications; the Clavien-Dindo system [17] was applied to postoperative complications in the included studies. This system grades complications from I (deviation from usual recovery not requiring intervention) to V (patient death). To be included in our major complication meta-analysis we included complications defined by a Clavien-Dindo grade of > II (8,18). Patient death and ICU transfer were not included in this analysis and were assessed separately.

Outcomes reported in less than 3 studies were not included in the meta-analysis and were instead narratively described such as time to antibiotic administration in case of sepsis and number of the National Early Warning Score (NEWS) measurements.

Secondary Outcomes

Secondary outcomes in the meta-analysis included in-hospital mortality and hospital length of stay. Further secondary patient outcomes were reported in the narrative analysis, such as 30-day readmission rates and time to post-operative mobilisation

Exploratory Outcomes

Exploratory outcomes included the alerting systems used, implementation and iterations in clinical practice. This included type of early warning score, alert thresholds used for each vital sign or overall EWS and other relevant alert parameters/information, where available.

Clinical trial registry searches were also conducted. For included studies that were registered, a comparison was made between the details in registration and report of the study. Registered studies eligible for inclusion but without published results were also narratively reported.

Eligibility criteria

Population and interventions

Complete inclusion and exclusion criteria are available in the published protocol [16]. We included any studies conducted in hospitalised patients, excluding studies conducted in healthy volunteers or non-hospitalised patients.

Studies were eligible for inclusion if they used an ambulatory monitoring system (with or without standard care) in comparison with standard care. An ambulatory monitoring system was defined as a wearable system monitoring at least one vital sign (heart rate, respiratory rate, temperature, blood pressure or oxygen saturation) sampled continuously at a high rate (e.g. under a minute) or low rate (e.g. every 5 minutes) and where measurements did not require frequent manual input from clinical staff. For comparator we considered any type of standard care for vital sign monitoring, as defined in the protocol [16].

Study types

Studies with the following designs were considered for inclusion: randomised controlled trials (RCTs), cluster RCTs, interventional studies, observational studies (including case-control and before-after studies), and pilot studies. Retrospective studies that complied with the proposed outcomes and eligibility criteria, and unpublished (grey) literature, were also considered.

Literature Search and Selection of Studies

Search terms were designed by a medical librarian with field expertise (NT). Relevant articles up to 27th August 2020 were identified through electronic searches on MEDLINE Ovid (including Epub Ahead of Print and In-Process & Other Non-Indexed Citations), Embase (Ovid), CINAHL (EBSCO) and Cochrane Database of Systematic Reviews (Cochrane Library, Wiley), Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library, Wiley) and Health Technology Assessment (HTA) database via <https://www.crd.york.ac.uk/CRDWeb/>. Full search strategy and terms/combinations used in each database can be found in Appendix 2.

Clinical trials and prospective studies registered up to 10th September 2020 in ClinicalTrials.gov via <https://clinicaltrials.gov/> and ISRCTN via <https://www.isrctn.com/> were also identified. Search details in Appendix 3.

Search of unpublished grey literature and pre-print servers was also conducted manually (search details in Appendix 4) and additional studies published in these servers up to 16th December 2020 were identified.

Titles and abstracts of all potentially relevant articles were independently reviewed for possible inclusion by two authors (CA, CB). The full text of any citation considered potentially relevant by any reviewer was retrieved. The degree of interrater agreement for study selection was determined by using kappa, with standard definitions for poor (< 0.20), fair (0.21 to 0.40), moderate (0.41 to 0.60), good (0.61 to 0.80), and very good (0.81 to 1.00) agreement [18, 19]. The

included abstracts full-texts were assessed for eligibility and disagreements resolved by discussion between the 2 review authors; if no agreement could be reached, a third author was consulted (SV). The full selection process is outlined in the published protocol [16].

Data collection and extraction

Two reviewers (CA and CB) extracted the data independently from the included studies. Disagreements were resolved by discussion between the 2 review authors. When required, this was also discussed with a third author (MS) and a statistician (SG).

The following data were extracted for each study, where available: author list, country, date published, registration number, aim, design, setting and population, recruitment start and end dates, ethical approval and informed consent information, eligibility criteria, intervention description, included devices, period of device wear, vital signs measured by devices, frequency of ambulatory data availability, comparator type, EWS and frequency of manual measurements, sample size, demographics (e.g. age, gender, BMI, etc.), other clinical characteristics (e.g. type of admission, American Society of Anaesthesiologists, ASA, score, etc.), deterioration detection and related clinical outcomes summary data, total/median monitoring hours, alerting system information (e.g. thresholds and alarms description), study limitations, device FDA/CE mark information, funding and conflict of interest information.

Risk of Bias of Individual Studies

Four tools, selected based on study design, were used to assess risk of bias. For randomised controlled trials the Cochrane risk of bias tool (RoB2) was used [20]; for non-randomised studies, the Newcastle Ottawa Scale (NOS) [21] and the "Risk Of Bias In Non-randomised Studies - of Interventions" (ROBINS-I) were applied [22]; and, in addition, the Mixed Methods Appraisal tool (MMAT) [23] was used for all studies. This was a change from the original protocol [16] as the Jadad scale was replaced by the ROBINS-I for assessment of non-randomised studies, as we found it more comparable with the ROB2 tool used for included RCTs. Two reviewers (CA and CB) independently appraised each study and disagreements were solved by discussion until consensus was reached with a third reviewer (SV).

Data Analysis

All outcomes with results from at least three studies were considered for the meta-analysis. Outcomes with data from less than three studies were not included in the meta-analysis but reported in a narrative synthesis.

Data preparation and meta-analysis

Review Manager 5.4.1 (The Cochrane Collaboration, Oxford, England [24]) was used to calculate pooled risk ratios (RRs) for dichotomous outcomes and pooled weighted mean differences (WMDs) for continuous outcomes, and respective 95% confidence intervals (CIs). Continuous variables are expressed as mean (SD). Due to differences in design between included studies, we used random-effects meta-analysis and the TAU2 statistic, and respective significance level was calculated [25]. We assessed heterogeneity among trials by using I^2 (the percentage of total variability across studies attributable to heterogeneity rather than to chance) and used published guidelines for interpretation [24].

One before-and-after study compared the AMS group with a before period in the same unit and a different unit (both before and during) [26]. For the meta-analysis, we limited data to that reported from the same unit to minimising confounding. Outcomes for this study were also presented per 1000 discharges. As the authors provided the total number of discharges, the actual event numbers were calculated for inclusion in our analysis [26]. Similarly, another included study presented the hospital length of stay (LoS) in hours [27], this was converted to days for the analysis. In a further study, the authors presented LoS in median (Interquartile range, IQR), which was converted to mean (standard deviation, SD). A normal distribution of the values was assumed to make this conversion, as per Cochrane guidance [28].

Finally, in one study complication data was presented as the number of events rather than the number of patients suffering a complication [29, 30]. A formal data request to the principal investigator was made to acquire the data in the correct format, and this was used in the meta-analysis.

Narrative analysis

Alerting thresholds, methods and other alarm information was extracted from the included studies, where available, and narratively reported. For analysis of study registration, the proportion of registered studies that were published, and both the dates of trial registration and publication of results were reported. We also explored registered versus published primary and secondary outcomes. Principal Investigators for the included and registered studies were contacted for further information, as required.

Body of evidence summary

A body of evidence summary is provided in Appendix 5, using the GRADEpro software [31].

Results

Study selection

After removal of duplicates, 8706 studies were identified. Following title and abstract review 51 full texts remained, of which 10 met the inclusion criteria (Fig. 1). Four studies appeared to meet the inclusion criteria but were excluded at full-text review: two studies were excluded for not reporting a subset of their analysis for the patients using the AMS [32, 33]; one was excluded after confirming with the author that the device was not ambulatory at the time of the study [34], and another did not have a comparator group [35]. A total of 4433 patients were included in these studies.

Study Characteristics

Devices

A variety of devices were used in the studies included in this review: four studies used the VisiMobile (Sotera Visi Mobile, San Diego, California) [26, 36–38], with two studies also adding the HealthPatch (Vital Connect, Campbell, CA, USA) [37, 38]; two studies used Sensium Vitals (Sensium, Abingdon, United Kingdom) [29, 30]. The remaining four studies used different devices, including the Patient Status Engine (Isansys Lifecare Ltd.) [27], the Auricall monitoring system [39], the Avant-4100 (Nonin) [40] and the Monica Novii wireless patch system (General Electric Company, Milwaukee, WI) [41].

Included studies and outcomes

Table 1

Characteristics of the included studies. AMS: ambulatory monitoring system, BP: blood pressure, CEWS: centile-based early warning score, ESS: efficacy score, EWS: early warning score, HR: heart rate, NEWS: national early warning score, PSE: Patient Status Engine, RR: respiratory rate, SpO2: peripheral oxygen saturation, T: temperature. *Same patients. Weenk et al. 2020 added 30 controls. ** Both maternal and fetal heart rate

Source	Country	Population	Sample size	Interventions		Vital signs measured by AMS					Age (years)		Sex (% male)		
			Total	Control (EWS)	AMS	HR	RR	SpO2	BP	T	Control	AMS	Control	A	
Meta-analysis															
Skraastad et al. 2019	Norway	General surgery	195	Intermittent vital signs (NEWS)	PSE (NEWS) + ESS	x	x	x	x	x	62	61	63%	6	
Downey et al. 2020	UK	General surgery	135	Intermittent vital signs (NEWS)	SensiumVitals + NEWS	x	x			x	62	65	54%	5	
Downey et al. 2018	UK	General surgery	226	Intermittent vital signs (NEWS)	SensiumVitals + NEWS	x	x			x	63.7	65.2	45%	5	
Kisner et al. 2009	Switzerland	General surgery	357	Intermittent vital signs (Unknown)	Auricall	x		x			62.7	65	75%	7	
Weller et al. 2018	USA	Neurology and neurosurgery	1958	Intermittent vital signs (Unknown)	VisiMobile	x	x	x	x	x	59.3	60.5	58%	5	
Verrillo et al. 2018	USA	Orthopaedic, spinal and trauma general care	849	Intermittent vital signs (Unknown)	VisiMobile	x	x	x	x	x	51.4	54.5	58%	5	
Watkinson et al. 2020	UK	Gastro intestinal surgery	407	Intermittent vital signs (CEWS)	Avant-4100	x		x			63	63	56%	5	
Narrative															
Weenk et al. 2019	Netherlands	Surgical and internal medicine ward	60*	Intermittent measurement (MEWS)	VisiMobile	x	x	x	x	x	N/A	63	N/A	6	
					HealthPatch	x	x		x	N/A	56	N/A	7		
Weenk et al. 2020	Netherlands	Surgical and internal medicine ward	90*	Intermittent measurement (MEWS)	VisiMobile	x	x	x	x	x	62	63	67%	6	
					HealthPatch	x	x		x		56		7		
Monson et al. 2020	USA	Labour and delivery ward	216	Standard external monitoring	Monica Novii	x**					28.6	29.2	0%	0	

Of the ten studies identified, seven were included in the meta-analysis with a total of 4127 patients. These included two RCTs [27, 30], one cluster RCT [29], and four before-and-after observational studies [26, 36, 39, 40]. Three further studies (RCTs) were included in the narrative synthesis [37, 38, 41], including a total of 306 further patients. Details of the included studies are presented in Tables 1 and 2.

The majority of the included studies implemented the AMS in post-surgical patients. Four studies also reported the patient American Society of Anaesthesiologists (ASA) score for preoperative functional status [42], with a median ASA score of 2 ("Patient has mild systemic disease") in three studies [29, 30, 43] and 3 ("Patient has severe systemic disease that is not incapacitating.") in one [27].

Reviewers achieved a fair level of agreement (kappa: 0.348; 95% CI 0.285 to 0.482) for study inclusion. There were no major disagreements between reviewers regarding data extraction, study quality or bias assessments.

Table 2
Included studies primary outcomes and outcomes included in the meta-analysis.

Included studies primary outcomes and outcomes included in the meta-analysis.								
Source	Design	Primary outcome	Deterioration detection outcomes				Clinical Outcomes	
			ICU transfer	RRT activation or cardiac arrest team call	All complications	Major complications	Mortality	Length of stay
Meta-analysis								
Skraastad et al. 2019	RCT	Time to mobilisation			X	X	X	X
Downey et al. 2020	Pilot RCT	Progression criteria to full RCT	X		X	X	X	X
Downey et al. 2018	Cluster RCT	Time to antibiotics in patients with sepsis	X		X	X	X	X
Kisner et al. 2009	Before-after	Incidence of postoperative atrial fibrillation			X			
Weller et al. 2018	Before-after	Rate of patient deterioration events	X	X			X	X
Verrillo et al. 2018	Before-after	Early deterioration detection	X	X	X		X	
Watkinson et al. 2020	Before-after	Length of stay	X	X			X	X
Narrative								
Weenk et al. 2019	RCT	Experiences of patients and care givers						
Weenk et al. 2020								
Monson et al. 2020	RCT	Amount of time with the interpretable fetal HR tracing during of labour						

Studies not included in the meta-analysis were narratively explored (Tables 1 and 2). Two papers reported results from one RCT, comparing two devices (HealthPatch and VisiMobile) with nurse measurements [37, 38]. However, they have not included the third group (control) in the analysis and not assessed any clinical outcomes, mostly exploring factors related to deterioration detection, failing to provide sufficient data to include in the meta-analysis. In the first paper from this RCT, the authors report that both HealthPatch and VisiMobile modified early warning scores (MEWS) were higher than the nurse measured MEWS, mostly due to RR measurements differences [38]. In the second paper (the full RCT) the authors identified positive and negative effects as well as barriers and facilitators for the use of these devices, such as the impact of AMS in a shorter length of stay and prevention of ICU admissions, additionally, a total of 17 patients, 2 relatives and 17 healthcare professionals reported to be expecting earlier deterioration detection using these wearables [37].

Another RCT evaluated wireless external fetal electrocardiography versus standard external monitoring [41]. We were unable to include this study in the meta-analysis as (1) the primary outcome of the study was the percentage of interpretable fetal HR data, (2) the population of interest is very different from the remaining studies and (3) the clinical outcomes analysed also differed (eg. length of labour, fetal Apgar score, etc.). Considering this, their results demonstrated no differences in maternal or neonatal clinical outcomes between groups. However, results did suggest an increased acceptance by patients and staff, with satisfaction scores significantly higher when compared to the standard monitor [41].

Included studies registration

Details of the clinical trials search are shown in Appendix 6. Of the ten included studies in this review, only seven were registered (most retrospectively, as per Appendix 7). Within these, all primary outcomes stated in the registration were reported in the main paper, as well as most of the secondary outcomes.

Study quality and risk of bias

The overall quality of included studies was moderate with some bias to take into account, as per Figs. 2 and 3. For the included RCTs, using the ROB2, two were identified as at "low risk" of bias [30, 41] and a further three were assessed as raising "some concerns" [27, 37], including the cluster RCT [29]. The risk of bias, assessed by the ROBINS-I was "moderate" for all before-and-after studies [26, 36, 39, 40]. See Appendix 8 for further details. The results of the bias assessment did not influence inclusion in the meta-analyses.

Primary outcomes

In total, data from seven studies were included in the meta-analysis of primary outcomes related to deterioration detection, analysed separately according to the three reported deterioration outcomes – ICU transfers, rapid response or cardiac arrest activation, and complications.

ICU transfers

A total of five studies reported ICU transfers and were included in this meta-analysis (data from 3565 patients, 1898 in the AMS group) [26, 29, 30, 36, 40]. Pooling of data indicated that use of AMS did reduce ICU transfer (RR, 0.87; 95% CI 0.66 to 1.15), but not statistically significantly ($p = 0.32$) (Fig. 4).

Rapid response or cardiac arrest activation

For this outcome, two before-and-after studies reporting rapid response team activation and another study reporting cardiac arrest calls were included (with data from 3214 patients, 1698 in the AMS group, Fig. 5) [26, 36, 40]. Pooled data for this outcome indicated AMS reduced RRT or cardiac arrest calls (RR, 0.84; 95% CI 0.69 to 1.01) with a p -value near statistical significance ($p = 0.07$).

All clinical complications

A total of five studies reported data on complication outcomes classed by the Clavien-Dindo system as grade I or II (with data from 1752 patients, 837 in the AMS group, Fig. 6), indicating the AMS group had a reduced risk of complications (RR, 0.77; 95% CI 0.44 to 1.32) however without statistical significance ($p = 0.34$) and with high heterogeneity between studies ($I^2 = 93\%$).

For the major complications (Fig. 7), we included 3 studies (with data from 546 patients, 296 in the AMS group) indicating the AMS group had reduced risk of major complications (RR, 0.55; 95% CI 0.24 to 1.30) however, with no statistical significance ($p = 0.17$).

Other deterioration detection outcomes not included in the meta-analysis

A few of the included studies also explored other deterioration detection outcomes, but in insufficient numbers to allow a meta-analysis. One cluster RCT [29] and one RCT [30] from the same research group compared the time to antibiotic administration in case of sepsis in the AMS group against the control group, finding this statistically insignificant in both studies (656.0 (95% CI 431.7–820.3) vs 1012.8 (95% CI 425.0–1600.6) minutes [29] and 551 (95% CI 296–805) vs 527 (95% CI 199–856)) [30].

Secondary outcomes

The two secondary outcomes of in-hospital mortality and hospital length of stay were also meta-analysed.

In-hospital mortality

For the outcome of in-hospital mortality, we included six studies (with data from 3760 patients, 1994 in the AMS group, Fig. 8) [26, 27, 29, 30, 36, 40], with one study reporting no deaths in either group (no estimates to be analysed in the meta-analysis) [27]. Our results indicated the AMS group had a reduced risk of mortality (RR, 0.48; 95% CI 0.18 to 1.29) but this reduction was not statistically significant ($p = 0.15$).

Hospital length of stay

A total of five studies were included for the outcome of hospital LoS (with data from 2911 patients, 1994 in the AMS group, Fig. 9) indicating a non-significant reduction in hospital length of stay for patients monitored using AMS (MD, -0.09; 95% CI -0.43 to 0.44, $p = 0.63$).

Other clinical outcomes not included in the meta-analysis

Studies also included other clinical outcomes, for example, two studies explored 30-day hospital readmission rates and showed mixed results, with one showing lower readmission rates in the AMS group [29] and the other slightly higher [30] in comparison with standard care.

Skraastad and colleagues indicated reduced time to post-operative mobilisation in the AMS group, 10.1 (95% CI 8.1–12.2) against 14.2 (95% CI 12.0–16.3) in the control group [27]. They also compared the number of NEWS measurements in their RCT, with 8.2 (95% CI 4.7–9.0) in the AMS group versus 3.4 (95% CI 3.1–3.6) in the standard care group. Additionally, there was a higher mean in opioid dose given in the AMS group, 25.5 (95% CI 20.9–30.0) vs 15.2 (95% CI 11.1–19.3) in the control arm; and more supplementary oxygen was given to 57/96 in the AMS group against 32/99 in the control group [27], that the authors defend being a result of the increased monitoring in the AMS group, facilitating pain and oxygen management of those patients, and promoting earlier mobilisation [27]. This study also

Exploratory outcomes

Alerting systems (Central station and mobile devices for alerts)

Some information about the alerting system was available in nine out of the ten included studies [26, 27, 29, 30, 36, 38–40, 44]. Five studies reported their development in reducing the number of alarms per patient per day (APDs). One reported having started with 11.41 APDs and conducted iterations down to 2.01 APDs, reducing the non-actionable alarms and modifying their vital sign limits and thresholds to reduce the rate of false alarms [26]. The authors focused on monitoring optimisation, reviewing and modelling the alarm data every few days and discussing with clinical managers whether widening vital sign parameters would create a significant reduction in alarm rates while still being clinically acceptable and sensible to deterioration detection [26]. In Downey and colleagues' first study there was an unacceptable number of alerts sent to the nursing staff. After adjustments in the vital sign thresholds, the false alerts were reduced by 90% (30). This was addressed in their second RCT where a clinical fellow was visiting the wards daily to check the rate of false alarms and adjust thresholds and/or delays of the alerts as per clinical need (18,48). Despite this, two patients withdrew from the study due to "too many false alerts" (18). In two other studies, the authors just discussed the intention was to improve the rate of true positives and reduce false negatives/false alarms [37, 38].

Most alerting thresholds were pre-set and individualised as required, alerted through the central station and/or nurse mobile/pager/PDA, with the majority using audio alerts (Table 4). In one study the authors used a single risk score calculated from all vital signs (VSI) and based on modelling from a previous patient dataset, creating an alert when the VSI score was above the threshold for more than 4 out of 5 minutes [40]. Alerting parameters from the included studies are explored in Table 4.

In one study's final version of the alerting system, hypotension, bradycardia and hypoxemia were tolerated for shorter periods than tachycardia or hypertension, unless the tachycardia resulted in hypotension. Additionally, the majority of the alerts in this final iteration were due to SpO₂ (0.97 APDs) [26]. Another study found that the most accurate vital sign parameter was systolic blood pressure, which had a positive predictive value (PPV) of 97%, followed by high respiratory rate (PPV of 85%) and low SpO₂ (PPV of 76%), indicating high sensitivity and reliability and a low false alarm rate. [36]

Table 3

Vital sign thresholds summary table. BP: blood pressure, DBP: diastolic blood pressure, HR: heart rate, MAP: mean arterial pressure, PDA: personal digital assistant, PR: pulse rate, RR: respiratory rate, SBP: systolic blood pressure, SMS: short message service, SpO₂: peripheral oxygen saturation, T: temperature, VSI: Visensia Safety Index.

Vital sign thresholds (delay before alert in seconds)									Alert method
Study	HR/PR		RR		SpO2	BP		MAP	T
	High	Low	High	Low	Low	High SBP	Low DBP	Low	
Weller et al. 2018	HR: 150 (15) PR: 150 (60)	HR: 39 (15) PR: 39 (60)	35 (120)	4 (120)	85 (90)	200 (240)		58 (60)	Sound Central station + nurse phone
Kisner et al. 2009	Individualised (immediate)				Pre-set individualised (immediate)				Sound Pager or SMS to doctor and nurse
Verrilo et al. 2018	Pre-set (5)		Pre-set (120)		Pre-set (60)	Pre-set (120)			Sound Central monitor + nurse mobile
Downey et al. 2018	Pre-set, individualised if required (immediate)		Pre-set, individualised if required (immediate)					Pre-set, individualised if required (immediate)	Sound Mobile device to nurse
Downey et al. 2020	Pre-set, individualised if required (immediate)		Pre-set, individualised if required (immediate)					Pre-set, individualised if required (immediate)	Sound Mobile device to nurse
Weenk et al. 2019 & 2020	Individualised (immediate)		Individualised (immediate)		Individualised (immediate)	Individualised (immediate)		Individualised (immediate)	Sound Nurse station
Skraastad et al. 2020	As per NEWS score		As per NEWS score		As per NEWS score	As per NEWS score		As per NEWS score	Visual only Warnings at patient bedside
Alerting score thresholds									
	Score name	Vital signs included in score	Range	Threshold	Time to alert				
Watkinson et al. 2020	VSI	All	0 to 5	> 3.0 for more than 4 out of 5 minutes	On the fifth minute				
					Sound Bedside + central station + nurse PDA				

Clinical trial registries (other potentially eligible studies to be included)

A total of sixteen registrations were identified in the search and screened for eligibility. Six were excluded and six registrations refer to the included studies. A further four registrations were deemed potentially eligible to be included in our review and meta-analysis (Table 3). A registered cluster RCT [45] aimed to develop a two-tiered monitoring system to improve the care of patients at risk of clinical deterioration in general hospital wards. This registered study also included a subset of patients using wireless devices [45]. However, although the main results are published [32], no data were reported on the impact of wireless devices on the subset population and we were unable to make contact with the Principal Investigator to clarify publication status and request this subset of the AMS group data. A further registration [46] before-and-after study was potentially eligible and although the main results are published [33] a subset of patients (278) used at least one cableless sensor, but the author confirmed there were no data available on outcomes for this sub-set of wirelessly monitored patients [33]. The other two registrations did not publish their results at the time of our systematic literature search. The Principal Investigator of

one prospective, observational cohort study confirmed the study results have been submitted and is under peer review [47]. We were unable to contact the Principal Investigator to clarify the status of the other study [48].

Table 4
Studies with potential for inclusion.

Year registered	Registration ID	Date start recruitment	Recruitment status	Reason for non-publication
2011	NCT01280942 [45]	January 2011	Completed	Main results published but not sub-group analysis with the wireless device. [32]
2012	NCT01692847 [46]	October 2012	Completed	Main results published but not sub-group analysis with the cableless device. [33]
2015	NCT02427828 [48]	March 2013	Completed	Unknown
2017	NCT03179267 [47]	September 2017	Completed	Under peer review

Discussion

Main results

In this systematic review and meta-analysis, we identified 10 eligible studies of various designs comparing the impact of AMS on deterioration detection and clinical outcomes with standard care, including a total of 4433 patients. Our main findings indicate that AMS may have the potential to reduce ICU admissions, RRT/cardiac arrest calls and complications in hospitalised patients, although without significant significance. The strength of these findings is limited by the small number of studies, limited sample sizes, and moderate risk of bias, failing to provide a generalisable answer to our research question (GradePro summary in Appendix 5). This review also provides some limited indication that AMS may reduce in-hospital mortality and length of stay, but again without strong statistical significance supporting these findings.

Although our review focused specifically on ambulatory monitoring devices, our results are in accordance with a previous systematic review with a focus on the clinical impact of a broader range of multi-parameter continuous non-invasive monitoring of vital signs in non-intensive care unit patients. In this previous review, the authors included all non-invasive devices (including wired and static bed monitors such as EarlySense) and also found a trend towards reduced ICU transfers, RRT activations and hospital length of stay. It also suggested reduced hospital mortality in patients using these devices [11]. Our study also updates their review with the inclusion of an additional four more recent studies.

All the studies included in this review were conducted in a non-ICU environment (mostly in surgical patients) and most comparators were standard intermittent vital sign monitoring with the use of local EWS. Previous evidence suggests that focus on non-critical care settings is due to AMS being unable to replace the continuous monitoring commonly used for high dependency patients. Instead, AMS offers an intermediate level of monitoring between continuous high dependency monitoring and intermittent manual measurements, with the potential to facilitate early deterioration detection in high-risk patients (e.g. post-ICU) [2]. In addition, a recent study in the paediatric population concluded that wireless monitoring is feasible and can identify more deteriorations. The authors suggest that by using this in combination with a paediatrics early warning (PEW), some life-threatening events may be prevented [35].

One study included in this review reported patients', relatives' and healthcare professionals' perceptions of the use of AMS in the general ward, and found agreement between all interviewed groups that AMS could facilitate earlier deterioration detection and improve patient safety without posing a barrier to mobility, as well as reduce staff workload and hospital costs [37], agreeing with previous evidence [49–51] and reinforcing the direction of our findings.

To better understand the used AMS, we have aggregated available information, of the alerting methods and thresholds of the included studies. As most studies used audio alerts, system iterations seemed to focus on reducing the rate of false alerts by adjusting/individualising each vital sign and/or overall score to avoid alarm fatigue from clinical staff. This has been previously discussed as an important factor for the successful deployment of monitoring technology [52–55]. The exception was one study that used visual warnings alone, resulting in increased NEWS measurements in patients using AMS without clinical staff being aware of the potential deterioration. They identified three patients for whom AMS alarmed between two intermittent measurements and who were later diagnosed with a pneumonia, atrial fibrillation and an anastomotic leakage [38]; in the same study, the authors also explored the delay between high MEWS measured by a device and next regular MEWS measurement by a nurse, ranging from 0 up to 10 hours, and varying between day and night [38].

Finally, a review of known registries was conducted to address the issue of publication bias, finding that the majority of the included studies were registered either in ClinicalTrials.gov or ISRCTN databases and all registered primary outcomes were reported as well as most of the secondary (Appendix 7). However, most studies were registered retrospectively, rather than prospectively. We did, however, identify four studies that might have contributed to this systematic review by either performing a subgroup analysis for patients using ambulatory devices [33, 45] and by publishing their results as registered in another two [47, 48]. Our registry search allowed to highlight this under-reported and non-published evidence that could have potentially impacted our results and contributed to the meta-analysis and overall body of evidence in this field.

Study limitations

There were some limitations to this review. The number of studies included was limited and used a variety of designs, populations, outcomes, medical devices/systems, EWS and alerting thresholds. Our meta-analysis only included two RCTs (one being a pilot) and one pilot cluster RCT, all of which had small

sample sizes which reduced the probability of significant difference in outcomes, despite large effect sizes. In contrast, the included before-and-after studies had larger sample sizes but increased bias and quality limitations, again posing a barrier to any significant conclusion. This reflects the emerging nature of this area of research and highlights the need for a large, multicentre RCT that tests whether AMS may be beneficial for early deterioration detection and related clinical outcomes in hospitalised patients.

One of the studies [29] had an extra non-randomised bay in their exploratory analysis. We did not include these data in our meta-analysis in accordance with Cochrane guidelines, so only the randomised groups were considered [56]. Similarly, another study compared the AMS group with a period before in the same unit and a period during and before in an alternative unit. In this case, we only used the data comparing the before period in the same unit, to minimise selection bias [56]. For RRT and cardiac team call analysis, it is important to note that Weller and colleagues study accounted for 96.7% of the weight on these results [26]. In addition, studies exploring RRT and cardiac team calls were combined in the meta-analysis, and therefore results might differ if analysed separately.

As previously reported, bias may be present as clinical staff is aware of the AMS use in their patients. However, the practicalities of blinding in AMS studies may not be feasible and may potentially have a counterproductive impact on clinical outcomes [11].

Future research

The results of this systematic review suggest the use of AMS might promote early deterioration detection and improve clinical outcomes. However, these findings are limited by the reduced sample size of the included RCTs and reduced methodological quality of the before-and-after studies. One of the included studies [30] conducted a subgroup analysis exploring clinical outcomes in high-risk participants. This further highlighted the impact of the AMS use in patients at higher risk of deterioration and further RCTs should consider including a similar analysis of their results.

Remote monitoring systems are only beneficial to the clinical staff if they are easy to use and clinicians understand the potential benefit for patient clinical outcomes [57]. This review is part of a wider phased project, the virtual High Dependency Unit (vHDU) study. So far, we have selected [58] and tested AMDs [59] to be integrated in a final AMS, that will be tested in a pilot and then a full multicentre RCT in the near future.

Conclusions

Our systematic review suggests that AMS may have a positive impact on early deterioration detection and associated clinical outcomes. Although no results were significant, we did find a trend towards fewer ICU admissions, RRT/cardiac arrest team calls, major and overall complications, in-hospital mortality and hospital length of stay in patients using the AMS against standard care. The included studies were limited by a reduced number of RCTs with a small sample size and before-and-after studies with moderate bias. This review highlights the need for bigger and more rigorous RCTs to support our meta-analysis findings. Additionally, our narrative findings suggest that alarms should be adjusted to minimise false alerts and thus support prompt clinical action to deterioration events.

Abbreviations

ADLs: activities of daily living

AMD: ambulatory monitoring device

AMS: ambulatory monitoring system

APD: alarm per patient per day

ASA: American Society of Anaesthesiologists

CEWS: centile-based early warning score

BP: blood pressure

CI: confidence interval

CRS: comfort rating scale

ECG: electrocardiogram

EWS: early warning score

HR: heart rate

ICJME: international committee of medical journal editors

ICU: intensive care unit

IQR: interquartile range

LoS: length of stay

MD: mean difference

MEWS: modified early warning score

NEWS: national early warning score

NIHR: National Institute for Health Research

NOS: Newcastle Ottawa scale

PEW: pediatric early warning

PPV: positive predictive value PR: pulse rate

RCT: Randomised Controlled Trial

RoB2: Cochrane risk of bias tool

ROBINS-I: Risk Of Bias In Non-randomised Studies - of Interventions

RR: respiratory rate

RR: risk ratio

RRT: rapid response team

SBP: systolic blood pressure

SpO₂: peripheral capillary oxygen saturation

UK: United Kingdom

vHCU: virtual High Dependency Unit

WMD: weighted mean difference

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable

Data availability statement

All data generated or analysed during this study are included in this published article and its supplementary information files

Conflicts of interest

PW and LT report significant grants from the National Institute of Health Research (NIHR), UK and the NIHR Biomedical Research Centre, Oxford, during the conduct of the study. PW and LT report modest grants and personal fees from Sensyne Health, outside the submitted work. LT works part-time for Sensyne Health and has share options in the company. PW holds shares in the company.

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Authors' contributions

CA designed the study. NT conducted databases search. PW and LT made final approval of the study protocol. CA and CB selected studies for inclusion, SV resolved any disagreements. CA and CB extracted the data from studies, SG and MS reviewed data extraction. CA and CB conducted quality assessment, SV resolved disagreements. CA conducted statistical analysis with SG supervision. CA wrote the first draft of the manuscript with SV support. All authors contributed and approved the final manuscript.

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Figures

Figure 1

Figure 2

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 3

Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 4

Meta-analysis forest plots comparing AMS and standard care ICU transfer risk ratio. AMS: ambulatory monitoring systems, CI: confidence intervals, M-H: Mantel-Haenszel, RCT: randomised controlled trial.

Figure 5

Meta-analysis forest plots comparing AMS and standard care rapid response or cardiac arrest team activation risk ratio. AMS: ambulatory monitoring systems, CI: confidence intervals, M-H: Mantel-Haenszel.

Figure 6

Meta-analysis forest plots comparing AMS and standard care all complications risk ratio. AMS: ambulatory monitoring systems, CI: confidence intervals, M-H: Mantel-Haenszel, RCT: randomised controlled trial

Figure 7

Meta-analysis forest plots comparing AMS and standard care major complications risk ratio. AMS: ambulatory monitoring systems, CI: confidence intervals, M-H: Mantel-Haenszel, RCT: randomised controlled trial

Figure 8

Meta-analysis forest plots comparing AMS and standard care in-hospital mortality risk ratio. AMS: ambulatory monitoring systems, CI: confidence intervals, M-H: Mantel-Haenszel, RCT: randomised controlled trial.

Figure 9

Meta-analysis forest plots comparing AMS and standard care hospital length of stay mean difference. AMS: ambulatory monitoring systems, CI: confidence intervals, IV: inverse variance, RCT: randomised controlled trial

Supplementary Files

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