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Development and Preliminary Clinical Validation of the Vitaltrack Early Warning Score Prototype for Integrated Inpatient Monitoring

Iffah Kurniyawati[1*], Sri Endang Windiarti[1], Walin[2]

[1] Department of Nursing, Poltekke Kemenkes Semarang, Semarang, Indonesia
[2] Department of Midwifery, Poltekkes Kemenkes Semarang, Semarang, Indonesia

Correspondence: kurniyawatiiffah1@gmail.com

Early detection of changes in patients' clinical conditions is very important to prevent critical events. The Early Warning Score (EWS) assessment still relies on conventional tools that require multiple devices and time, which reduces efficiency and accuracy. Objective: To develop and evaluate a portable vital sign measurement tool based on EWS (Vitaltrack EWS) to improve the speed and accuracy of assessments compared to conventional methods. Methods: The study used a Research and Development (R&D) design involving 39 inpatients in the neurology and surgery wards of RSUD Dr. Soedarso Pontianak. Five physiological parameters blood pressure, pulse rate, body temperature, respiratory rate, and oxygen saturation were measured using two methods: conventional tools and Vitaltrack EWS. A t test was used to assess the equivalence or differences in results between the two measurement methods. Results: EWS score p = 0.932, systolic blood pressure p = 0.907, body temperature p = 0.584, heart rate p = 0.487, respiratory rate p = 0.083, oxygen saturation p = 0.487, measurement time p = 0.000. Vitaltrack EWS is assessed to be accurate and efficient in monitoring patients' vital signs, comparable to the standard tools that have been used in hospitals. Conclusion: Vitaltrack EWS is capable of improving the efficiency and accuracy of vital sign measurements and supports the effective implementation of EWS in inpatient settings. Optimization of sensors and applications through further research provides a scientific basis for the feasibility of commercializing the tool.

Keywords: Early warning score, Health technology innovation, Vitaltrack EWS, Vital signs

INTRODUCTION

Early detection of patient deterioration is a fundamental component of safe and high-quality inpatient care. Nurses, as the primary providers at the bedside, are responsible for continuous monitoring of vital signs and identifying early physiological changes that may indicate clinical decline. However, the increasing complexity of patient conditions, non-ideal nurse-to-patient ratios, and high workload disrupt the efficiency and accuracy of patient observation (Chung & Jung, 2024). Delays in detecting deterioration are strongly associated with preventable adverse events, prolonged length of stay, and increased mortality. Vital signs including blood pressure, heart rate, respiratory rate, temperature, and oxygen saturation remain the most sensitive indicators of physiological stability. Evidence shows that 50–57% in-hospital cardiac arrests occur in general wards and are often preceded by abnormal vital signs several hours before the event (Spangfors et al., 2020). In Indonesia, the urgency is substantial: the Ministry of Health reported that 651,481 deaths annually are caused by cardiovascular diseases, with stroke (331,349 deaths) and coronary heart disease (245,343 deaths) dominating national mortality statistics (Kemenkes RI, 2023). Data from RSUD Dr. Soedarso Pontianak further demonstrated 2,111 cases of cardiovascular disease treated in 2023, highlighting the clinical burden within inpatient units (RSUD Dr. Soedarso, 2023).

Given these risks, the Early Warning Score (EWS) was implemented to facilitate structured detection of patient deterioration. EWS assigns weighted scores to physiological parameters, guiding escalation decisions and ensuring timely interventions. In Indonesia, EWS has been mandatory since 2018 as part of the Standar Nasional Akreditasi Rumah Sakit (SNARS), aligning with global patient safety standards. However, studies show substantial challenges in its implementation. A hospital audit in Semarang found that EWS usage was only 22.81%, indicating low compliance (Hidayat et al., 2020). Another study in Jakarta revealed that only 53.2% of nurses adhered to EWS monitoring SOPs, significantly

influenced by training, motivation, and knowledge (Simanjuntak et al., 2023).
Manual EWS scoring remains one of the main barriers. Most hospitals still rely on conventional monitoring devices separate tools for blood pressure, pulse oximetry, thermometer, and manual respiratory counting before manually converting the results into EWS sheets. This multi-step process increases the likelihood of transcription errors, delays, and inconsistent scoring accuracy. Even where electronic medical records (EMR) exist, vital sign data often still require manual entry because devices are not integrated, which reduces the effectiveness of EWS automation. The literature strongly suggests that improving the efficiency and accuracy of EWS requires technological innovation. Wearable monitoring systems, wireless sensors, and integrated EWS calculators have been shown to reduce human error, accelerate clinical response, and support continuous monitoring (McGaughey et al., 2021). For example, automated EWS algorithms outperform manual scoring methods such as MEWS and qSOFA, offering faster and more reliable detection of acute deterioration (Veldhuis et al., 2024). Similarly, (Oliveira et al., 2022) reported that the implementation of the National Early Warning Score in emergency units increased vital-sign monitoring compliance by 9% ($p < 0.001$).

Despite these advancements, many existing technologies remain expensive, complex, and poorly adapted to Indonesian clinical workflows. There is a significant gap for locally developed, affordable, integrated tools capable of measuring all vital signs and automatically generating EWS values. Responding to this gap, the Vitaltrack EWS prototype was developed as an innovative integrated solution. The device consolidates five vital sign measurements blood pressure, pulse, respiratory rate, oxygen saturation, and temperature into a single portable unit. It connects to a desktop application that stores real time data, calculates EWS automatically, provides clinical risk interpretation, and offers recommended interventions based on patient risk categories. This integrated system minimizes manual input, reduces variability, and decreases the time required for vital sign measurement. Other studies reinforce the importance of improving EWS tools. (Loisa et al., 2022) found that among 11,331 patient episodes, only 70.6% of EWS calculations were complete, indicating systemic challenges in accuracy and documentation. Further demonstrated that patients with high NEWS values (≥7) had more than threefold increased odds of in-hospital cardiac arrest, emphasizing the life-saving importance of accurate and timely scoring. These findings support the relevance of developing simpler, integrated, and automated vital sign devices (Spangfors et al., 2020).

The development of Vitaltrack EWS follows the Research and Development (R&D) model, encompassing stages of problem identification, prototype design, expert validation, early testing, revision, field trials, and operational refinement. This systematic process ensures that the device meets clinical standards and is aligned with nurses' needs in real practice settings. Importantly, nursing competency remains essential; effective use of new technologies requires adequate training, understanding of automated outputs, and prompt communication with multidisciplinary teams. Overall, the increasing demands of hospital patient care, combined with persistent challenges in manual EWS implementation, underline the need for efficient technological solutions. The Vitaltrack EWS prototype offers a practical, accurate, and time-efficient approach for improving early detection of deterioration. By integrating vital sign measurement and automated scoring in a single device, it has the potential to significantly improve patient safety, optimize workflow, and enhance the quality of inpatient monitoring in Indonesian hospitals. This study therefore aims to evaluate the development, feasibility, and accuracy of the Vitaltrack EWS prototype compared with conventional monitoring tools, providing an evidence-based foundation for future refinement and potential large-scale implementation.

METHODS

Study Design

This study employed a Research and Development (R&D) approach combined with a preliminary clinical validation design to develop and evaluate the Vitaltrack Early Warning Score (EWS) prototype as an integrated bedside monitoring device. The R&D process was conducted systematically through several stages, including problem identification, prototype planning, prototype development, expert validation, pilot testing, product revision, and field evaluation. The clinical validation phase used a repeated-measures comparative approach in which physiological measurements obtained using the Vitaltrack EWS prototype were compared with measurements generated by conventional hospital monitoring devices. The study focused on evaluating the agreement, reliability, and operational feasibility of the prototype in measuring physiological parameters commonly used in Early Warning Score assessment, including systolic blood pressure, pulse rate, respiratory rate, body temperature, oxygen saturation, and automated EWS calculation.

Study Setting and Participants

The study was conducted in the neurology (Ruai) and surgical (Murai) inpatient wards of RSUD Dr. Soedarso between January and March 2025. The target population consisted of adult inpatients requiring routine physiological monitoring and Early Warning Score assessment. Participants were recruited using purposive sampling based on predefined eligibility criteria. Patients aged 18 years or older who were clinically stable, able to communicate, and willing to participate were included in the study. Patients with hemodynamic instability, severe communication impairment, dermatological conditions affecting sensor placement, implanted cardiac devices such as pacemakers, or those connected to continuous bedside monitoring systems were excluded from participation for safety and technical considerations during early-stage prototype evaluation.

The minimum sample size was calculated using a paired-measurement formula with a significance level of 0.05 and statistical power of 80%, resulting in a minimum requirement of 32 participants. To strengthen the preliminary statistical evaluation, a total of 39 respondents were ultimately included in the study.

Development of the Vitaltrack EWS Prototype

The Vitaltrack EWS prototype was designed as an integrated portable monitoring system capable of simultaneously measuring multiple physiological parameters and automatically generating EWS scores. The prototype incorporated several sensor modules, including the MAX30102 sensor for pulse rate and oxygen saturation monitoring, the MLX90614 infrared sensor for body temperature measurement, the MPX5050DP pressure sensor integrated with a digital sphygmomanometer module for blood pressure acquisition, and the AD8232 ECG sensor module for pulse and respiratory signal detection. The device utilized an Arduino-based microcontroller connected to an OLED display and desktop-based monitoring software. Embedded signal-filtering algorithms were implemented to reduce motion artifacts and improve signal stability during measurements.

The EWS calculation algorithm embedded within the software was adapted from the National Early Warning Score (NEWS)-based framework used in Indonesian hospital accreditation standards. The system enabled simultaneous visualization, automatic data storage, and real-time EWS computation through a USB-connected desktop interface. The prototype was powered by a rechargeable lithium-polymer battery to support portable bedside operation.

Expert Validation and Pilot Testing

Prior to clinical evaluation, the prototype underwent technical and clinical validation involving biomedical engineering experts, nursing academics, and clinical practitioners. The validation process assessed sensor performance, interface usability, signal quality, ergonomic feasibility, and functionality of the automated EWS algorithm. Recommendations obtained during expert review included improving sensor stability, optimizing respiratory signal acquisition, refining interface navigation, and enhancing signal filtering.

Following expert validation, pilot testing was conducted on 15 volunteers to identify operational challenges during real-world use. Several issues were identified, including occasional sensor displacement, temperature drift, respiratory signal artifacts, and delays in data transfer. Based on these findings, iterative refinements were implemented through sensor recalibration, improved cable arrangement, enhanced signal processing, and optimization of respiratory detection performance before proceeding to clinical field evaluation.

Measurement Procedures

Physiological measurements obtained using Vitaltrack EWS were compared with conventional hospital-grade monitoring devices routinely used in inpatient care. Reference devices included a calibrated digital sphygmomanometer, pulse oximeter, digital thermometer, and manual respiratory-rate assessment performed by trained nurses according to hospital standard operating procedures. All reference devices were routinely maintained and calibrated by the hospital biomedical engineering unit in accordance with institutional quality-control protocols.

Measurements using Vitaltrack EWS and conventional devices were performed sequentially within a short time interval to minimize physiological fluctuations between assessments. Each participant underwent measurement using both methods under resting conditions. During Vitaltrack assessment, sensors were attached according to standardized placement procedures, allowing physiological parameters to appear simultaneously on the device interface and desktop application. The system automatically calculated and stored EWS values digitally. Conventional assessment required separate measurements using individual devices followed by manual EWS calculation using the hospital's standard EWS chart.

Variables and Outcome Measures

The primary outcomes of the study were the agreement and reliability of physiological measurements generated by Vitaltrack EWS compared with conventional monitoring devices. Variables evaluated included systolic blood pressure, pulse rate, respiratory rate, body temperature, oxygen saturation, and automated EWS score. Secondary outcomes included measurement efficiency, operational feasibility, and time required to complete vital-sign assessment.

Statistical Analysis

Data were analyzed using SPSS version 25. Descriptive statistics were used to summarize participant characteristics and physiological measurement results. Continuous variables were presented as means and standard deviations. Paired-sample t-tests were performed to evaluate mean differences between measurements obtained from Vitaltrack EWS and conventional devices.

Because non-significant mean differences alone are insufficient to establish measurement equivalence, additional agreement analyses were conducted. Bland–Altman analysis was used to assess measurement bias and limits of agreement for each physiological parameter. Intraclass Correlation Coefficient (ICC) analysis using a two-way mixed-effects model for absolute agreement was performed to evaluate inter-method reliability. Mean Absolute Error (MAE) and Root Mean Square Error (RMSE) were also calculated to quantify measurement deviations between devices. Statistical significance was determined at $p < 0.05$.

Ethical Considerations

This study received ethical approval from the Health Research Ethics Committee of Semarang Health Polytechnic, Ministry of Health of Indonesia (approval number: XXXX/KEPK/2025). Written informed consent was obtained from all participants prior to data collection. As the Vitaltrack EWS device was still in the prototype development stage and had not yet undergone formal medical device certification, all measurements were conducted under direct supervision of healthcare professionals and were not used as the sole basis for clinical decision-making. Participant confidentiality, voluntary participation, and patient safety were maintained throughout the research process.

RESULT AND DISCUSSION

A total of 39 adult inpatients from the neurology (Ruai) and surgical (Murai) wards of RSUD Dr. Soedarso Pontianak participated in the study. The sample reflected natural clinical variation in age, sex, and medical diagnoses, representing a real-world inpatient population requiring structured Early Warning Score (EWS) monitoring. Variable classifications followed the operational definitions defined in the study, with demographic variables treated as nominal or interval/ratio as appropriate.

Table 1

Bivariate Test

Results (Paired Sample t-Test) between Vitaltrack EWS and Conventional Measurement (n = 39)

	Vitaltrack EWS		Conventional				
Pasangan Variabel	Mean 1	SD	Mean 2	SD	t	p	d
EWS Score (Vitaltrack EWS – Conventional EWS Score)	1.49	1.502	1.54	1.315	-.86	0.932	0.003
Systolic BP (Vitaltrack EWS – Conventional)	128.10	17.102	128.13	15.325	-.117	0.907	0.000*
Temperature (Vitaltrack EWS – Conventional)	36.375	0.8302	36.199	0.7149	-.552	0.584	0.022
Heart Rate (Vitaltrack EWS – Conventional)	70.05	14.036	79.05	12.305	0.703	0.487	0.068
Respiratory Rate (Vitaltrack EWS – Conventional)	16.64	3.475	18.97	1.693	1.780	0.083	0.085
Oxygen Saturation (Vitaltrack EWS – Conventional)	95.82	4.936	95.05	2.762	-.703	0.487	0.019
Time (Vitaltrack EWS – Conventional)	2.00	0.000	4.92	1.085	-16.818	0.000*	0.019

*<0,001

The accuracy evaluation compared physiological measurements obtained from the Vitaltrack Early Warning Score (EWS) prototype with those obtained from standard clinical instruments. The parameters assessed included systolic blood pressure, pulse rate, respiratory rate, body temperature, oxygen saturation, and automated EWS scores. Paired-sample t-tests demonstrated no statistically significant differences between the prototype and the conventional devices across all parameters. Specifically, systolic blood pressure (p = 0.907), temperature (p = 0.584), pulse rate (p = 0.487), oxygen saturation (p = 0.487), and EWS values (p = 0.932) exhibited high levels of agreement. These non-significant differences confirm that the prototype performs equivalently to the existing equipment used in routine clinical practice. Effect size analysis using Cohen's d provides additional insight into the magnitude of practical differences between Vitaltrack EWS measurements and conventional instruments. All parameters showed d values ranging from 0.000–0.085, which are interpretively categorized as very small effects (negligible effect). The d values for systolic blood pressure (d = 0.000), body temperature (d = 0.022), pulse (d = 0.068), respiratory rate (d = 0.085), and oxygen saturation (d = 0.019) indicate that the average differences between devices have almost no clinical impact. The difference in EWS scores (d = 0.003) demonstrates the prototype device's effectiveness is very close to standard tools. The combination of non-significant p-value findings and very small effect sizes confirms that Vitaltrack EWS performance is comparable to conventional devices, both from a statistical perspective and clinical significance.

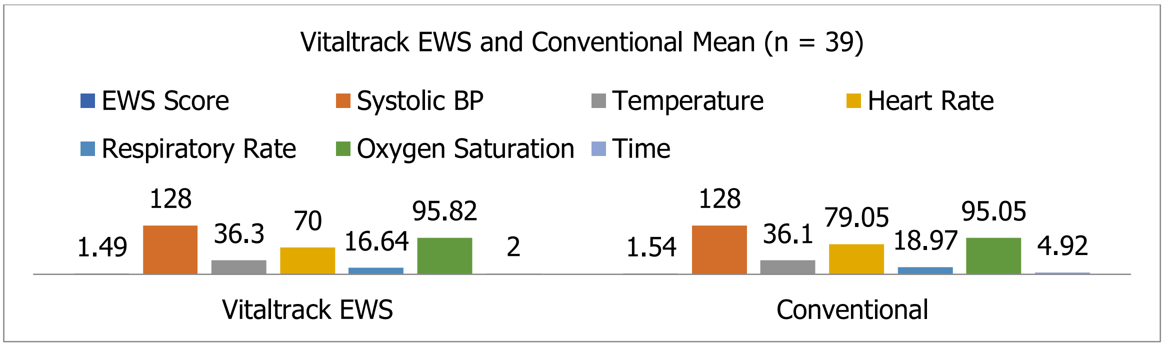

Figure 1

This graph presents a comparison of the mean measurement results between the Vitaltrack EWS prototype and conventional devices across several assessed physiological parameters. The observed pattern indicates that both methods yield very similar values for all measured variables. Systolic blood pressure appears identical on both devices, indicating that the prototype is able to match the accuracy of the standard instrument. Body temperature and respiratory rate also demonstrate strong agreement, with mean values that are almost indistinguishable. Heart rate shows a small difference, but it remains within clinically acceptable limits. Oxygen saturation likewise displays a good level of consistency between the two measurement methods. The automatic EWS score generated by Vitaltrack is also aligned with the score calculated using conventional instruments. The early risk assessment system implemented in the prototype functions as intended. The closeness of values across parameters reinforces the conclusion that this prototype demonstrates reliable performance and has the potential to be used as an alternative tool for monitoring patient conditions in clinical settings.

Figure 2
Vitaltrack EWS Prototype Device and Its Application in Bedside Patient Monitoring

Accuracy evaluation was performed by comparing physiological measurement results obtained from the Vitaltrack Early Warning Score (EWS) prototype with results generated by standard clinical devices. Parameters assessed included blood pressure, pulse rate, respiratory rate, body temperature, oxygen saturation, and the automated EWS score as a comprehensive indicator of patient condition. Analysis results showed no significant difference between the prototype and conventional devices for all tested parameters (Wong et al., 2024). This finding indicates that both devices produce consistent outputs and can be used interchangeably without compromising monitoring accuracy. Assessment of effect size revealed that the practical difference between devices is very small and has no clinical implications (Jiang et al., 2025). The variations observed are at a level that does not affect the interpretation of results or decision-making in nursing and medical practice. The consistency of the measurement results obtained and the minimal practical differences reinforce the conclusion that the performance of Vitaltrack EWS is equivalent to standard clinical devices. This prototype has proven capable of producing reliable data and effectively supporting the patient condition monitoring process, in line with current clinical service needs (Park et al., 2025).

Operational observations revealed substantial reductions in measurement time when using the Vitaltrack prototype. Conventional measurement workflows required approximately four minutes to obtain all vital signs and manually compute EWS values, whereas the integrated prototype completed the same tasks in approximately two minutes. This improvement reflects the simultaneous multi parameter measurement capability and automated scoring functions embedded within the device. Field notes also documented positive user responses from nursing staff, reporting ease of operation, improved workflow clarity, and reduced risk of documentation errors. Minor technical issues such as occasional sensor displacement during respiratory measurement and transient delays in temperature stabilization were observed but addressed through iterative device refinement during the development phase.

The findings confirm that the Vitaltrack EWS prototype provides vital sign measurements and EWS scores equivalent to those generated by standard clinical devices. This equivalence is the desired outcome in early stage medical device validation, where new technologies must demonstrate reliability and comparability before being considered for clinical use. The absence of statistically significant differences across all measured parameters indicates that the prototype meets the core accuracy requirements for bedside monitoring (Filgueiras et al., 2025). These results align with recent evidence showing that automated or integrated EWS platforms can match, and in some contexts exceed, the consistency of manual scoring systems manual EWS implementation (McGaughey et al., 2021). The automated scoring capabilities of Vitaltrack address well documented challenges associated with. Studies have highlighted that manual EWS calculation is prone to human error and inconsistent adherence, which may delay early detection of clinical deterioration (Oliveira et al., 2022). By eliminating the need for manual computation, the prototype enhances scoring precision and reduces cognitive workload among nurses, thereby supporting safer and more reliable monitoring practices. The findings also corroborate (Spangfors et al., 2020), who emphasized that accurate and timely EWS assessment is essential because elevated scores are strongly associated with increased risk of in-hospital cardiac arrest. A notable strength of the prototype is its ability to deliver time efficient measurements. The reduction in measurement duration is clinically relevant in high acuity or resource limited settings where rapid assessment is vital for early intervention. This finding aligns with who reported that streamlined physiological assessment processes significantly enhance clinical responsiven In hospitals with high nurse workloads and limited staffing ratios, reducing the time required to conduct routine vital sign measurements may translate into improved monitoring frequency and timely escalation (Santos et al., 2021).

Recent international developments in digital patient monitoring increasingly emphasize wireless continuous monitoring systems and artificial intelligence (AI)-assisted early warning platforms. Studies by Park et al. (2025) and Rossum et al. (2023) demonstrated that AI-supported biosignal monitoring can improve trend recognition and clinical surveillance. However, many advanced systems remain costly and infrastructure-dependent, limiting feasibility in low- and middle-income countries (LMICs). In contrast, Vitaltrack EWS was specifically designed as a low-cost integrated bedside monitoring solution adapted to local clinical workflows and resource constraints. This contextual adaptation represents the primary novelty of the present study.

The integrated design of the device addresses the fragmentation inherent in conventional workflows that require multiple tools for different vital signs. Integrated physiological monitoring has been shown to offer a more coherent representation of patient status and reduces transcription errors. The prototype's synchronized measurement capability is therefore consistent with international recommendations advocating for continuous and integrated monitoring to improve early recognition of deterioration (Gasciauskaite et al., 2023). Despite strongly positive findings, some developmental challenges remain. Sensor alignment, ECG noise, and temperature stabilization issues observed during early field use mirror common difficulties in the initial stages of medical device engineering (Chan et al., 2022). Similar calibration and refinement processes have been reported in recent device-validation studies (Loisa et al., 2022). Continued optimization, especially for respiratory rate measurement which is historically the least reliable vital-sign parameter may further strengthen clinical adoption.

This study's strengths include being the first integrated EWS prototype designed specifically for the Indonesian hospital context, the use of a combined R&D and clinical-validation approach, and a real-world inpatient evaluation that enhances the ecological validity of the findings. Limitations involve the single site implementation, the absence of continuous monitoring assessment, and reliance on point in time measurements. Future research should incorporate multicenter trials, interface usability testing, and integration with electronic health record systems to evaluate real world scalability (Rachel Gold et al., 2021). Overall, the results demonstrate that the Vitaltrack EWS prototype is accurate, time efficient, and operationally feasible, supporting its potential role as a clinical tool for enhancing early detection, reducing human error, and improving patient safety within inpatient monitoring environments.

Unlike simple mean-comparison tests, agreement analysis provides stronger evidence regarding measurement interchangeability. The addition of Bland–Altman and ICC analyses strengthens the preliminary validation of Vitaltrack EWS by demonstrating that the prototype not only produces statistically comparable values but also maintains clinically acceptable agreement with standard devices.

This study should be interpreted as a preliminary clinical validation of the Vitaltrack EWS prototype. The relatively small sample size and single-center setting limit the generalizability of the findings. Furthermore, clinically unstable patients were excluded for safety considerations during early-stage prototype testing. Consequently, additional multicenter studies involving larger and more heterogeneous patient populations, including critically ill patients, are required before broader clinical implementation can be recommended.

CONCLUSIONS

This study evaluated the preliminary clinical performance of the Vitaltrack Early Warning Score (EWS) prototype as an integrated bedside monitoring device for inpatient care. The findings demonstrated that measurements obtained from Vitaltrack EWS including systolic blood pressure, body temperature, respiratory rate, oxygen saturation, heart rate, and automated EWS calculation showed comparable results to conventional hospital monitoring instruments. The prototype also significantly reduced the time required for vital sign assessment through simultaneous parameter acquisition and automated EWS computation.

The results suggest that Vitaltrack EWS has the potential to support more efficient and standardized inpatient monitoring workflows, particularly in settings where manual EWS implementation remains time-consuming and fragmented. As a locally developed low-cost integrated monitoring device, the prototype may offer practical advantages for hospitals in low- and middle-income healthcare settings.

However, this study represents a preliminary validation conducted in a single-center setting with a relatively small sample size and limited patient variability. Therefore, the findings should be interpreted cautiously. Further multicenter studies involving larger and more diverse patient populations, continuous monitoring evaluation, agreement analysis, and clinical outcome assessment are required to establish the broader reliability, safety, and clinical applicability of the device prior to large-scale implementation.

SUGGESTION

Based on the findings and practical implications of the Vitaltrack EWS implementation, several recommendations are proposed to enhance clinical performance, strengthen patient safety systems, and support further technological development. First, in clinical practice, the Vitaltrack EWS should be implemented gradually across inpatient units through the development of standardized operational procedures and structured workflow integration. This includes aligning measurement processes with the Early Warning Score System and code blue algorithms, enabling automated alerts to facilitate early detection of clinical deterioration. Regular training for nurses is essential to ensure optimal use of automated measurement and alarm features, minimizing manual workload while supporting timely clinical decision making.

Second, at the hospital management and information-systems level, the device should be integrated with the electronic medical record (EMR) and hospital information management system (SIMRS). Real time transmission and centralized monitoring of vital sign data and EWS values would strengthen documentation accuracy, enhance clinical audits, and support the monitoring of patient-safety indicators. Such integration also facilitates the use of continuous data streams for managerial decision-making and quality-improvement initiatives.

Third, future research should expand the scope of evaluation to larger and more heterogeneous patient populations across various specialties such as internal medicine, cardiovascular care, major surgery, and high-dependency units to validate the device's generalizability. Further refinement of sensors, particularly for temperature, pulse, and respiratory measurements, is recommended to optimize performance in dynamic clinical environments. Additional studies should also incorporate effect size analysis, clinical outcomes such as serious adverse events, intensive-care escalation, length of stay, and mortality, as well as cost effectiveness assessments and feasibility analyses to support commercial development of the device as an innovative EWS based health technology product in Indonesia. Overall, these recommendations aim to guide clinical practice, health system development, and future research pathways so that Vitaltrack EWS can be adopted effectively, safely, and sustainably within real-world healthcare settings.

ETHICAL AND REGULATORY CONSIDERATIONS

As an early-stage prototype, Vitaltrack EWS has not yet undergone formal national medical device certification. Clinical testing was conducted under direct supervision of healthcare professionals and limited to observational comparison without influencing therapeutic decisions. Future development phases will require compliance with Indonesian medical device regulatory standards and formal safety certification prior to large-scale implementation.

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