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Comparison of Two Pediatric Early Warning Systems: A Randomized Trial

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ABSTRACT

Purpose: Pediatric early warning systems (PEWS) are used to detect clinical deterioration in hospitalized children. Few PEWSs have been validated in multicenter studies and the performance in many single-center studies varies. We wanted to compare two PEWS in a multicenter study.
Design and Methods: Randomized multicenter unblinded trial conducted at all pediatric departments in the Central Denmark Region. A random sample of 16,213 pediatric patients (31,337 admissions) were enrolled from November 2014 to March 2017. Patients were randomized to The Bedside PEWS or CDR PEWS. The primary outcome was the sum of hospitalized children experiencing in-hospital clinical deterioration requiring transfer to a higher level of care.
Results: Of the 21,077 pediatric patients who met the inclusion criteria, 16,213 (from 31,337 admissions) were enrolled. 22 unplanned transfers to a higher level of care were identified: 14 in The Bedside PEWS group and 8 in the CDR PEWS group, a non-statistical difference ($P = 0.20$). No significant difference in predicting unplanned transfer to a higher level of care ($P = 0.78$) were detected and no significant difference was observed in the secondary outcomes.
Conclusions: The CDR PEWS prevents as many critical events as The Bedside PEWS. Shorter median time to PEWS reassessment when CDR PEWS was used and fewer reassessments being done to late could reflect that the CDR PEWS was more acceptable to staff.
Practice Implications: The results from this study should be interpreted with caution as very few patients experiencing clinical deterioration and further studies should also focus on challenges trying to evaluate PEWS.

Introduction

A mortality review panel suggested that some deaths in children are either avoidable or potentially avoidable (Pearson, 2008). The clinical deterioration of children is often preceded by worsening vital signs (Chapman et al., 2017; McLellan, Gauvreau, & Connor, 2017; Robson, Cooper, Medicus, Quinyero, & Zuniga, 2013). Pediatric early warning system (PEWS) have been developed to help detect critical deterioration in hospitalized children and to trigger activation of appropriate and timely response from staff (Lambert, Matthews, MacDonell, & Fitzsimons, 2017). Several studies have evaluated the performance of different PEWS (Chapman et al., 2017; Chapman, Wray, Oulton, & Peters, 2016; Lambert et al., 2017; Seiger, 2013). Internationally, the most intensively evaluated PEWS is The Bedside PEWS (Parshuram, 2009, 2011, 2018; Parshuram et al., 2015).

The Bedside PEWS has been shown to be among the best performing PEWS at predicting a critical event (Chapman et al., 2017). However, The Bedside PEWS involves some challenges and limitations. The measurement of blood pressure is a particular challenge when it comes to children. Firstly, blood pressure measurement is unpleasant and crying infants or toddlers might either have an increased blood pressure (not necessarily a sign of the clinical exacerbation of disease) or result in a

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failure to obtain blood pressure measurements (Jensen, Nielsen, Olesen, Kirkegaard, & Aagaard, 2018; Tume, 2007). Secondly, acutely ill children should be identified before they become hypotensive because this is a preterminal sign (Lundstrøm, 2010; Nygaard & Schmiegelow, 2010). Thirdly, measuring blood pressure is time consuming (Monaghan, 2005; Seiger, 2013). Furthermore, the assessment of children's level of consciousness is not included in The Bedside PEWS tool, even though it is important when assessing whether critical illness is evolving (Resuscitation Council (UK), 2016). Thus, a modified version of The Bedside PEWS, titled, the Central Denmark Region (CDR) PEWS, was developed. The CDR PEWS include assessment of the consciousness level and exclude mandatory measurement of blood pressure.

We aimed to compare the two PEWSs, and hypothesized that CDR PEWS is superior to The Bedside PEWS in terms of reducing the number of patients experiencing in-hospital clinical deterioration requiring transfer to a higher level of care (including unplanned transfers to PICU and transfers from regional hospitals to the university hospital to ensure proximity to PICU).

Trial Design

This multicenter randomized investigator-initiated, parallel, pragmatic clinical trial was conducted in nine units in four hospitals in the CDR. The study was approved by the CDR Committee on Biomedical and Research Ethics and The Danish Data Agency. An independent data and safety monitoring committee performed predefined blinded interim safety analyses when 7000 patients had been included, analyzing only on the primary outcome. A detailed description of the study rationale, design, interventions, and outcomes was described in a protocol article (Jensen, Aagaard, Olesen, & Kirkegaard, 2017).

Eligibility and Recruitment

All patients (0–19 years) admitted at the participating hospitals (Supplement 1, Table 1) were screened for eligibility. The patients were randomized when the referral from the general practitioner was received or upon admission; subsequently, written consent was obtained. All children admitted or examined at the acute pediatric assessment units in the CDR were eligible for inclusion in the trial. Exclusion criteria were: (i) children admitted directly to neonatal wards, (ii) children admitted directly to PICUs, (iii) children who were dead upon arrival at the hospitals, (iv) children admitted because of social interaction problems, (v) children receiving palliative care, and (vi) children whose parents' informed consent was not obtained. Recruitment occurred from November 2014 to March 2017.

Randomization and Blinding

Patients were randomly assigned in a 1:1 ratio to one of the two arms by using a web-based randomization procedure delivered by the Department of Clinical Medicine, Aarhus University, Denmark (Fig. 1). Patients readmitted >24 h after discharge during the enrolment period were kept to the initial assigned research arm and included in the analysis and counted as a new admission. If they were readmitted within 24 h from discharge that specific admission was excluded as the readmission was considered related to the previous admission. Staff at the

Table 1
Demographic and clinical characteristics among patients at randomization.

Characteristic	Bedside PEWS n (%)	CDR PEWS n (%)
Number of randomized patients	8107	8106
Total no. of admissions	15,635	15,702
Age in years, m (sd)	4.68 (4.98)	4.69 (5.01)
<1 years, n (%)	3724 (23.82)	3722 (23.70)
1–4 years, n (%)	5821 (37.23)	5914 (37,66)
5–12 years, n (%)	3790 (24.24)	3800 (24.20)
>12 years, n (%)	2300 (14.71)	2266 (14.43)
Gender, n (%)		
Boy	8609 (55.06)	8523 (54.28)
Girl	7026 (44.94)	7179 (45.72)
ICD-10 diagnosis, n (%)		
I. Certain infectious and parasitic diseases	1381 (8.45)	1379 (8.80)
II. Neoplasms	231 (1.48)	246 (1.57)
III. Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	191 (1.22)	168 (1.07)
IV. Endocrine, nutritional and metabolic diseases	542 (3.48)	494 (3.15)
V. Mental and behavioural disorders	102 (0.65)	110 (0.70)
VI. Diseases of the nervous system	532 (3.41)	535 (3.41)
VII. Diseases of the eye and adnexa	34 (0.24)	37 (0.24)
VIII. Diseases of the ear and mastoid process	248 (1.59)	193 (1.23)
IX. Diseases of the circulatory system	146 (0.93)	127 (0.81)
X. Diseases of the respiratory system	3322 (21.25)	3425 (21.81)
XI. Diseases of the digestive system	831 (5.31)	752 (4.79)
XII. Diseases of the skin and subcutaneous tissue	230 (1.47)	261 (1.66)
XIII. Diseases of the musculoskeletal system and connective tissue	417 (2.67)	424 (2.70)
XIV. Diseases of the genitourinary system	572 (3.66)	511 (3.25)
XV. Pregnancy, childbirth and the puerperium	3 (0.02)	3 (0.02)
XVI. Certain conditions originating in the perinatal period	184 (1.18)	152 (0.97)
XVII. Congenital malformations, deformations and chromosomal abnormalities	634 (4.06)	693 (4.41)
XVIII. Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	2820 (18.04)	2901 (18.48)
XIX. Injury, poisoning and certain other consequences of external causes	1934 (12.37)	1958 (12.47)
XXI. Factors influencing health status and contact with health services	1301 (8.32)	1301 (8.29)
Missing	43 (0.28)	32 (0.20)
Minutes from admission to transfer, median (IQR)[a]	1670 (0, 4139)	412 (0, 3964)
Time for transfer, n (%)[a]		
00:00–07:59 am	4 (28.6)	3 (37.5)
08:00 am–03:59 pm	5 (35.7)	2 (25.0)
04:00 pm–00:00	5 (35.7)	3 (37.5)

[a] Only patients transferred to a higher level of care owing to clinical deterioration: bedside PEWS, n = 14, and CDR PEWS, n = 8., IQR = interquartile range.

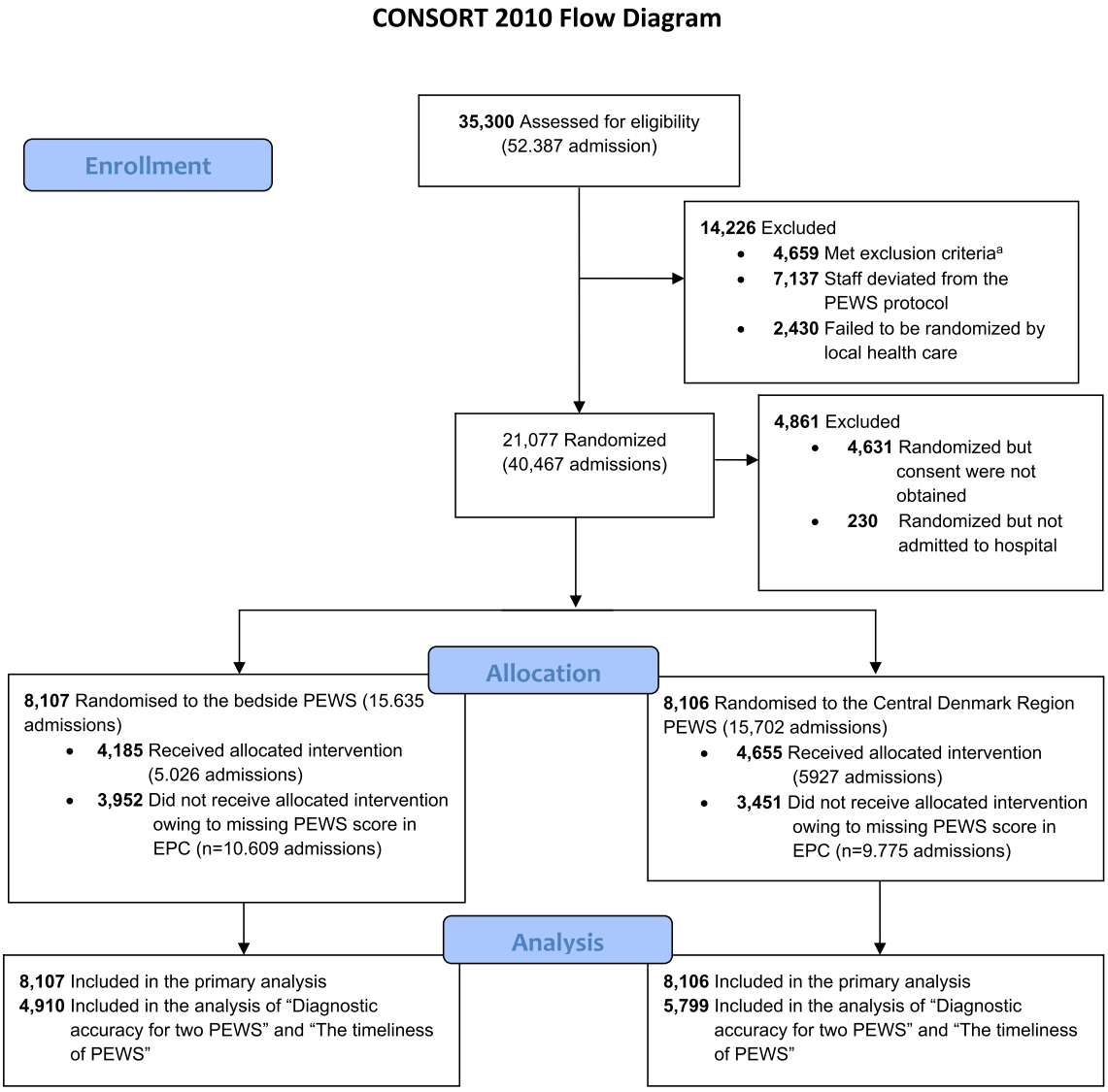

Fig. 1. Consort flow diagram [a]The Reasons for meeting the exclusion criteria were as follows: Neonatal patients (n = 4554), admitted due to social interaction problems (n = 105) EPC: Electronic Patient Chart.

participating units performed randomization and enrollment. Blinding of the staff, patients and their parents was not possible.

All transfers in the two randomized groups were reviewed by the principal investigator (PI) to identify unplanned transfers. In this particular process, the PI was blinded to the two PEWS. A co-researcher who was blinded to the primary coding reviewed 10% of the transfers to ensure validity.

Intervention

The patients were randomized to either The Bedside PEWS or the CDR PEWS. Both PEWS consisted of seven parameters (Supplement 1 Fig. 1). Each parameter can be assigned between 0, 1, 2, or 4 points (oxygen: 0–2 points, capillary refill: 0 or 4 points), depending on the deviation from a predefined age-specific threshold (Supplement 1, Fig. 1). The different points from each measurement were aggregated in a score from 0 to 24, with higher scores indicating more severe condition. This aggregated PEWS score gives directions to the level of observation (Supplement 1, Fig. 2). PEWS were measured on admission; actions and re-scoring/PEWS assessment then followed the PEWS decision algorithm (Supplement 1, Fig. 2) as a minimum patients were re-assessed with a full set of PEWS observations every 12 h. If a child's clinical condition is deteriorating, the 'score' for the observations will increase and the reassessment periods will be shorter; a higher or increasing PEWS score gives an early indication that intervention may be required. Based on the results of the clinical assessment and PEWS value, nurses could find the corresponding action(s) on the PEWS action algorithm (Supplement 1, Fig. 3). The corresponding action could, for example, be more frequent reassessment or notifying the charge nurse or pediatrician. The medical doctor has the option to assign modified PEWS scores for individual vital signs in patients with chronically impaired physiology due to chronic disease, e.g. patients with cystic fibrosis. It was not within the scope of the present study to validate if staff were scoring patients accurately, however this was done in another study (Jensen, Aagaard, Olesen, & Kirkegaard, 2018).

The introduction of the two PEWS was followed by these initiatives aimed at promoting the implementation; as no PEWS were used prior to the study: 1) A designated registration module in the electronic patient chart - providing age-specific sub-score for each of the seven observations, an aggregated PEWS score and an overview of time and trends for the PEWS scores and other vital parameters, 2) A mini-pamphlet containing the decision algorithm outlining the minimum time slots for re-PEWS observation; when nurses were to call a physician; the educational level of the physician who was to assess the patient and when

the physician was to assess the patient at bedside and make an escalated plan for care and treatment (Supplement 1, Fig. 2); 3) Clinical decision support sheet (Supplement 1, Fig. 3), Identification Situation Background Assessment Recommendation (ISBAR) communication tool (Supplement 1, Fig. 4); Cardiopulmonary resuscitation guidelines, the content of the two PEWS models, a tool for respiratory effort assessment, a clinical PEWS guideline, and an educational program for health care professionals - a 2-hour teaching session prior to implementing the PEWS.

Implementation

The implementation was multifaceted, and actively engaged clinicians throughout the process as recommended by Cochrane Effective Practice and Organisation of Care Group (2017). Prior to the implementation of the PEWS, all nurses and physicians went through the teaching programme and the PI met with the management of each participating department. All nurses employed in the participating departments attended a 2-hour teaching session prior to implementing the PEWS. The educational programme was inspired by the work of Tume, Sefton, and Arrowsmith (2014). The nurses were introduced to the rationale for working with a PEWS, the clinical guidelines and were taught how to measure vital signs. Hence, some of the PEWS measurements are based on individual assessment, for example, of respiratory effort. The nurses were shown five movies featuring children with respiratory problems and were asked to rate them. The aim of this exercise was to familiarise the nurses with children with mild, moderate and severe respiratory distress. To facilitate communication the ISBAR communication tool was introduced (Duggan, Lane, & Hill, 2009). Physicians attended a 30-minute teaching session in which they were introduced to the background for the PEWS, the ISBAR communication tool, their role related to PEWS and the possibility to modified PEWS score and individual vital parameters in patients with chronic disease. Champions, both nurses and physicians, were selected and their role was to functions as liaisons between the healthcare professionals and the PI. They were also to motivate the health care professionals and promote the project. The participating departments were enrolled in the project at different time points so that the PI could be present when beginning the PEWS project.

Throughout the PEWS project, the PI visited the departments, undertaking small teaching sessions and brush-up sessions. A webpage was developed (www.pews.dk) where information about the project and materials was available. To promote inclusion of patients and the use of PEWS, posters were developed and distributed for the patients' hospital rooms.

Outcome Measures

The primary outcome was the sum of patients experiencing in-hospital clinical deterioration requiring transfer to a higher level of care. Unplanned transfers were defined as transfers that were not elective or planned in advance, or transfers directly from the operating room. The secondary outcomes were (i) pediatric index of mortality score 3 (PIM3) (Straney, 2013), (ii) severity of illness during the PICU stay based on invasive ventilation and inotropes, length of hospital stay, length of PICU stay, Continuous Positive Airway Pressure (CPAP) and Extra Corporal Membrane Oxygenation (ECMO).

Statistical Analysis

A power calculation was made based on accessible preliminary data from 2013. These data showed 154 unplanned transfers out of 10,000 admissions. With a power of 80%, a 5% significance level, and an expected 30% reduction in the number of transfers, we would have to include 7112 admissions in each group. The total available study population was 26,800 admissions annually.

The statistical analyses followed the modified intention-to-treat principle. The patients randomly allocated to one of the PEWS were consecutively evaluated with the allocated PEWS during the initial hospitalization and any succeeding hospitalizations. In accordance with the modified intention-to-treat principle, admission for patients who were randomized but not assessed by the allocated PEWS model were included in the analyses but excluded in analysis of the timeliness of PEWS.

Descriptive statistics for baseline characteristics, outcomes, and timeliness of assessments were performed using percentages and medians 25th and 75th percentiles. As hospitalized patients are not continually and simultaneously monitored, we incorporated grace periods of 12.5% beyond the time intervals described in the algorithm (Supplement 1, Fig. 2) in the timeliness analysis, as done by Bunkenborg, Poulsen, Samuelson, Ladelund, and Åkeson (2016). For patients with a PEWS score of 9 or above requiring re-assessment every 15 min, no grace periods were allowed. The effect of the PEWS on unplanned transfers was analyzed using Pearson's chi-squared test. Non-normal distributed of data was analyzed with the Wilcoxon rank-sum test. The analyses of illness severity were performed with Fisher's exact test. The performance of the two PEWS models on the number of unplanned transfers was evaluated with sensitivity, specificity, and receiver operating characteristic (ROC) curve. The area under the ROC curve (AUROC) for the two PEWS models was compared using nonparametric estimation of the ROC curves for independent samples. The analysis did not include data from the final hour before the transfer, as a PEWS must be able to identify children at risk of clinical deterioration and provide a window for intervention. All analyses were performed in Stata 15, with a p-value <0.05 considered statistically significant.

Results

Recruitment and Baseline Characteristics

Of the 21,077 patients who met the inclusion criteria, 16,213 (from 31,337 admissions) were enrolled, as 4861 were excluded after randomization: 4631 were randomized, but their consent was not obtained, and 230 were randomized but were never admitted to the hospital. In the modified intention-to-treat primary outcome analysis, 4910 admissions were included in The Bedside PEWS group and 5799 in the CDR PEWS group (Fig. 1). There were no significant difference in the proportion of missing scores between the two arms. Baseline characteristics are presented in Table 1.

Primary Outcome

We identified 719 transfers, but of these only 22 unplanned transfers owing to clinical deterioration were identified. Of the 719 transfers; 371 patients were excluded, as they were transferred directly from surgery, 116 were transferred to a highly specialized ward (e.g. renal unit), 61 needed sedation, 76 needed telemetry, and 74 were transferred for other reasons. Of the 22 patients 14 patients were in The Bedside PEWS group, and 8 in the CDR PEWS group ($P = 0.20$) (Table 2). Of the 22 patients, 8 and 4 patients in The Bedside PEWS and CDR PEWS groups, respectively, did not have any PEWS score registered. Additionally, 1 patient in The Bedside PEWS group and 2 in the CDR PEWS group only had PEWS scores registered within the final hour before transfer. We found a difference in time from admission to transfer, with a median of 1670 min for The Bedside PEWS group and 412 min for the CDR PEWS group (Table 1).

The sensitivity and specificity for the two PEWS tools are presented in (Supplement 1, Table 2). In the comparison of the two ROC curves, no significant difference in accuracy of predicting unplanned transfer due to clinical deterioration (AUROC 0.91 The Bedside PEWS vs 0.88 CDR PEWS, $p = 0.78$) was found (Fig. 2).

Table 2
Outcomes for patients experiencing transfers to a higher level of care owing to clinical deterioration.

	Bedside PEWS, n = 15,635 admissions	CDR PEWS, n = 15,702 admissions	P-value
Primary outcome			
Unplanned transfers, n (%)	14 (0.09)	8 (0.05)	0.20
Secondary outcome			
Length of stay in hospital - hours, median (25, 75 pc)	163.5 (103, 346)	62 (24, 171)	0.09
Length of PICU stay - hours, median (25, 75 pc)	38 (19, 42)	19 (7, 231.5)	0.69
Pediatric Index of Mortality score, median (25, 75 pc)	0.034 (0.017, 0.047)	0.029 (0.012, 0.084)	1.00
Illness severity			
Invasive ventilation, n (%)	7 (53.9)	3 (37.5)	0.66
Median length of ventilation, days (25, 75 pc)	1 (1, 5)	10 (5, 30)	–
Use of inotropes, n (%)	2 (15.4)	1 (12.5)	1.00
Median length of inotropes, days (25, 75 pc)	2 (1, 3)	5	–
ECMO, n (%)	1 (7.7)	0 (0)	1.00
Median length of ECMO, days (25, 75 pc)	4	–	–
CPAP, n (%)	2 (15.4)	1 (12.5)	1.00
Median length of CPAP, days (25, 75 pc)	1.5 (1, 2)	1	–

Abbreviations: PEWS-Pediatric Early Warning System; PICU-Pediatric Intensive Care Unit; ECMO-Extracorporeal membrane oxygenation; CPAP- Continuous positive airway pressure; CDR- Central Denmark Region.

The timeliness of PEWS usage showed that the re-assessment time periods were not always followed, resulting in a longer-than-recommended PEWS re-scoring time for some patients. 54% and 66% were re-assessed early or on time in The Bedside PEWS and CDR PEWS, respectively. Interestingly, the percentage of patients with late re-assessments increased as the PEWS score increased, indicating a worsening of the child's condition (Table 3). The mean time between PEWS scores were longer compared to the measurement of individual vital parameters indicating that individual vital parameters were obtained more often than the complete PEWS score (Table 4).

Secondary Outcomes

No significant difference was observed in the secondary outcomes (Table 2).

Discussion

To date, this is the first study to compare two PEWS in a randomized controlled trial. No significant difference was found between the two PEWS in terms of the total number of unplanned transfers to a higher level of care as a result of clinical deterioration. We did not identify any significant difference in the ROC curves for the two PEWS. The results indicate that CDR PEWS is not superior, but at least equal to The Bedside PEWS. In a comparison of 18 pediatric track and trigger systems The Bedside PEWS was one of the best-performing tools (Chapman et al., 2017). The equally good performance of CDR PEWS indicates that we might focus on implementing CDR PEWS, as it includes level of consciousness and excludes mandatory blood pressure measurements. Blood pressure measurements can be unpleasant for children and has been identified as a major challenge for healthcare professionals (Jensen, Aagaard, et al., 2018; Jensen, Kirkegaard, Aagaard, & Olesen, 2018; Jensen, Nielsen, et al., 2018; Tume, 2007). Furthermore the CDR PEWS was considered more feasible in clinical practice by the nurses (Jensen, Aagaard, et al., 2018, Jensen, Kirkegaard, et al., 2018, Jensen, Nielsen, et al., 2018, Tume, 2007) which is supported by the findings in the present study with shorter median time to PEWS reassessment when CDR PEWS was used and fewer reassessments being done too late in the CDR PEWS group compared to The Bedside PEWS. The introduction of a PEWS and thus the focus on bedside observations was associated with a reduction in the number of annual transfers to a higher level of care as a result of clinical deterioration when compared with retrospective baseline. Prior to the implementation of the two PEWS, we identified 92 annual transfers (Jensen, Kirkegaard, et al., 2018) these were significantly reduced to 22 with PEWS in place. This result could indicate that implementing PEWS increases the focus on early warning signs.

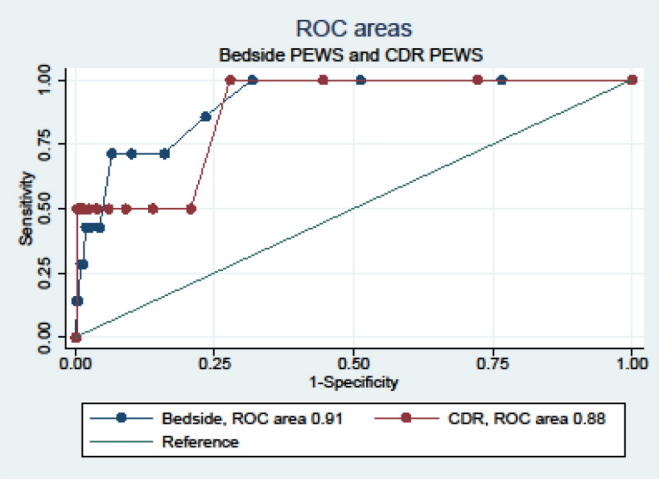

Fig. 2. Comparison of the receiver operating characteristics curves for The Bedside PEWS 0.91 (CI: 0.83–0.99) and CDR PEWS 0.88 (CI: 0.64–1.00). Analysis did not identify significant difference between the two PEWS (P = 0.78). Abbreviations: CI = Confidence intervals.

Table 3
The timeliness of the PEWS.

	Total hospital stay (no. of PEWS scores = 49,705)		
	Early	At time	Late
Bedside PEWS Timeliness, n (%)			
Score 0 (12*h*)	2530 (44.4)	1299 (22.8)	1867 (32.8)
Score 1–2 (6 h)	2761 (30.5)	1966 (21.7)	4321 (47.8)
Score 3–5 (4 h)	1433 (29.7)	1180 (24.5)	2212 (45.8)
Score 6 (2 h)	112 (17.7)	126 (19.9)	394 (62.3)
Score 7–8 (1 h)	61 (9.3)	102 (15.5)	495 (75.2)
Score 9+ (15 min)	13 (3.2)	2 (0.5)	390 (96.3)
CDR PEWS Timeliness, n (%)			
Score 0 (12 h)	4971 (52.4)	1946 (20.5)	2577 (27.1)
Score 1–2 (6 h)	4664 (41.9)	2490 (22.4)	3986 (35.8)
Score 3–5 (4 h)	2581 (43.4)	1478 (24.9)	1888 (31.8)
Score 6 (2 h)	232 (30.7)	201 (26.6)	324 (42.8)
Score 7–8 (1 h)	109 (15.1)	141 (19.6)	470 (65.3)
Score 9+ (15 min)	15 (3.9)	12 (3.1)	356 (93.0)

Abbreviations: PEWS-Pediatric Early Warning Systems; CDR-Central Denmark Region.

Table 4
Time between clinical assessments (PEWS score and vital parameters).

	Bedside PEWS	CDR PEWS
Minutes between PEWS, median (25,75pc)	375 (225, 723)	333 (185, 639)
Minutes between assessment, median (25,75 pc)		
Respiration rate	214 (115, 420)	215 (113, 416)
Work of breathing	354 (199, 683)	329 (180, 626)
Systolic blood pressure	351 (179, 706)	419 (148, 1146)[a]
Pulse rate	194 (100, 390)	192 (97, 386)
Capillary response	317 (169, 630)	299 (158, 576)
Saturation	315 (166, 630)	297 (156, 571)
Conscious state	247 (131, 948)[b]	257 (133, 1002)

Abbreviations: PEWS-Pediatric Early Warning System; CDR-Central Denmark Region.
[a] Even though blood pressure was not part of the CDR PEWS some patients in that group did have blood pressure measured e.g. patients with heart- or kidney disease.
[b] Even though assessment of conscious state was not part of The Bedside PEWS some patients in this group did have their conscious state observed e.g. patients with concussion.

Implementing a PEWS is complex and involves the entire organization, and it can be difficult to balance study design with PEWS that is practical enough to be applied to everyday practice (Lambert et al., 2017). Not many studies on PEWS have included an assessment of the degree of implementation, and in a PEWS review by Lambert et al. (2017), no conclusion could be drawn in regard to the optimal implementation strategy. Having a multifaceted implementation approach, and actively engaged clinicians throughout the process seemed to work positively. However, several obstacles were encountered along the way which is reported in details in (Jensen, Aagaard, et al., 2018; Jensen, Kirkegaard, et al., 2018; Jensen, Nielsen, et al., 2018). Lambert et al. (2017) highlight some elements that seem to have a positive impact on the implementation. We have failed to address some of these elements such as using a multi-professional approach to PEWS training and education as well as finding a way to integrate situation awareness into PEWS (Lambert et al., 2017). Interestingly, was it not only the randomization process and gaining informed consent that was a challenge as many patients were randomized but not assessed using PEWS.

The present study, Jensen, Aagaard, et al. (2018), Jensen, Kirkegaard, et al. (2018), and Jensen, Nielsen, et al. (2018) highlight some of the areas of complexity in both the PEWS intervention and in the settings in which it was evaluated. Many of the randomized patients in both groups did not obtain a PEWS score. This finding corresponds with the results of Jensen, Aagaard, et al. (2018), Jensen, Kirkegaard, et al. (2018), and Jensen, Nielsen, et al. (2018) where the nurses expressed how they not always found PEWS to be meaningful and that the lack of cooperation with the medical doctors made them reluctance to use the PEWS.

Missing vital parameters were also documented by Fuhrmann, Lippert, Perner, and Ostergaard (2008), who found that the staff had only documented vital parameters in 66%–77% of patients where the investigator had collected deviating vital parameters. Another reason for not documenting vital parameters was poor observational chart design (Niegsch, Fabritius, & Anhøj, 2013); however, in our study the electronic documentation system was highlighted as a positive feature that supported the nurses' overview (Jensen, Aagaard, et al., 2018, Jensen, Kirkegaard, et al., 2018, Jensen, Nielsen, et al., 2018).To ensure complete PEWS data, we designed both PEWS registration modules in such a way that completing all seven items was mandatory. However, we still encountered missing data, as many of the randomized patients did not have any PEWS observation registered.

Despite having included 31,337 admissions in the study, we still found very few unplanned transfers to a higher level of care as a result of clinical deterioration. The staff did not adhere to the recommended timeframe for re-scoring. Prolonging the timeframes may prove to have negative consequences on patient outcomes. Bunkenborg et al. (2016) documented a lower adherence to re-scoring in some EWS groups for adult patients. This could be due to nurses using their clinical judgment and assess the patient to be less severely ill than the score indicates. These are supported by Jensen, Aagaard, et al. (2018), Jensen, Kirkegaard, et al. (2018), and Jensen, Nielsen, et al. (2018) where nurses argued that they in some cases did not comply with the PEWS algorithm as they used their clinical judgment. Interestingly, the nurses did not comply with the timeframes for a high PEWS score which is in contrast to the finding in Bunkenborg et al. (2016). Not adhering to the re-assessment timeframe for patients' with a PEWS score above 9 (should be re-assessed every 15 min) indicating that a child's illness is critical, could be due to the nurses trying to optimize care and treatment, and thus not documenting PEWS scores. So, it seems as if the problem lies both within the recording of vital parameters, but also in the process of seeing the potential with PEWS.

In our study, unplanned transfer to a higher level of care was used as proxy for the measurement of clinical deterioration but in our population this was also a rare event, and other indicators for clinical deterioration might be useful to test in future research projects. This could be physiology dynamics such as progression to extreme physiology or unexpected deviation from planned care as discussed in Pedersen, Oestergaard, and Lippert (2016).

Limitations

Blinding the staff to the PEWS was not possible, which may have had an impact on the results. Although the data were collected prospectively and the designated PEWS registration module in the electronic patient system was developed in such a way that all seven items were mandatory to complete, we still had many missing PEWS observations. Of the 16,210 patients included in the study only 10,709 had PEWS registrations in the electronic patient chart. Furthermore the rate of unplanned transfers was lower than estimated (Jensen et al., 2017). The protocol was, however, written before the publication of a study describing unplanned transfer to a higher level of care in the study population (Jensen, Aagaard, et al., 2018, Jensen, Kirkegaard, et al., 2018, Jensen, Nielsen, et al., 2018). These results would require a much larger study with approximately 26.000 patients in each PEWS group.

This was a research project in which it was not mandatory to participate, which meant that e.g. some urology patients were excluded as the surgeons did not think that their patients should be PEWS monitored and they thus deviated from the PEWS protocol. This could influence the external validity of the study.

The selection of unplanned transfers as a result of clinical deterioration was done by the PI. Addressing this limitation all transfers were identified in the electronic patient system by a data manager, and a secretary not involved in the project made hard copy prints of the patient charts. The PI, blinded by the randomization outcome, reviewed the patient charts. Ten percent of the charts were reviewed by the co-researcher and no disagreement was identified.

We had to obtain written informed consent from both parents if there was joint custody. The ethics committee did; however, approve the study as an “emergency study” so that we were allowed to do the randomization and start the PEWS observations before consent was achieved. If we failed to obtain consent from both parents, we were not allowed to access the data gathered. This procedure implied that we missed some patients. Both parents were not always present especially those of children hospitalized for a few hours or 1 day, and even though consent forms in pre-paid envelopes were handed out, some patients were missed. This factor might have influenced the data, as obtaining informed consent in admissions that were short was expected to be more difficult. However, there is no reason to believe that randomization to either PEWS influenced the consent. It would have strengthened this trial if we had investigated whether transfers were significantly higher in children where the parents did not give consent

to participate. However, we were only allowed to gather information from patients who gave consent.

The results of the present study should be interpreted with caution because of the limited number of patients experiencing unplanned transfer. Future studies focusing on meta-analyses could enrich evidence of PEWS.

Conclusion

No significant difference in unplanned transfer was identified using The Bedside PEWS compared with CDR PEWS. Shorter median time to PEWS reassessment when CDR PEWS was used and fewer reassessments being done too late could reflect that the CDR PEWS was more acceptable to staff. The significant reduction of transfers to a higher level of care in hospitals that have implemented PEWS should be investigated in future research.

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CRediT authorship contribution statement

Claus Sixtus Jensen: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing - original draft, Writing - review & editing, Visualization, Project administration, Funding acquisition. **Hanne Vebert Olesen:** Conceptualization, Methodology, Formal analysis, Validation, Data curation, Writing - review & editing, Supervision. **Hanne Aagaard:** Conceptualization, Methodology, Formal analysis, Validation, Data curation, Writing - review & editing, Supervision. **Marie Louise Overgaard Svendsen:** Conceptualization, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing - review & editing, Supervision. **Hans Kirkegaard:** Conceptualization, Methodology, Formal analysis, Validation, Data curation, Writing - review & editing, Supervision.

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Conflict of Interest

The authors have no potential conflicts of interest to disclose.

Clinical Trial Registration

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Contributors' Statement

Claus Sixtus Jensen, Hanne Aagaard, Hanne Vebert Olesen, Marie Louise Overgaard Svendsen and Hans Kirkegaard conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pedn.2018.11.001.

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