Identifying the critically ill paediatric oncology patient: a study protocol for a prospective observational cohort study for validation of a modified Bedside Paediatric Early Warning System score in hospitalised paediatric oncology patients

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Identifying the critically ill paediatric oncology patient: a study protocol for a prospective observational cohort study for validation of a modified Bedside Paediatric Early Warning System score in hospitalised paediatric oncology patients

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ABSTRACT

Introduction Hospitalised paediatric oncology patients are at risk to develop acute complications. Early identification of clinical deterioration enabling adequate escalation of care remains challenging. Various Paediatric Early Warning Systems (PEWSs) have been evaluated, also in paediatric oncology patients but mostly in retrospective or case–control study designs. This study protocol encompasses the first prospective cohort with the aim of evaluating the predictive performance of a modified Bedside PEWS score for non-elective paediatric intensive care unit (PICU) admission or cardiopulmonary resuscitation in hospitalised paediatric oncology patients.

Methods and analysis A prospective cohort study will be conducted at the 80-bed Dutch paediatric oncology hospital, where all national paediatric oncology care has been centralised, directly connected to a shared 22-bed PICU. All patients between 1 February 2019 and 1 February 2021 admitted to the inpatient nursing wards, aged 0–18 years, with an International Classification of Diseases for Oncology (ICD-O) diagnosis of paediatric malignancy will be eligible. A Cox proportional hazard regression model will be used to estimate the association between the modified Bedside PEWS and time to non-elective PICU transfer or cardiopulmonary arrest. Predictive performance (discrimination and calibration) will be assessed internally using resampling validation. To account for multiple occurrences of the event of interest within each patient, the unit of study is a single uninterrupted ward admission (a clinical episode).

Ethics and dissemination The study protocol has been approved by the institutional ethical review board of our hospital (MEC protocol number 16-572/C). We adapted our enrolment procedure to General Data Protection Regulation compliance. Results will be disseminated at scientific conferences, regional educational sessions and publication in peer-reviewed journals.

Strengths and limitations of this study

► This prospective cohort study will provide a valid and accurate estimation of the predictive performance of a modified Bedside Paediatric Early Warning System (PEWS) for non-elective paediatric intensive care unit transfer or cardiopulmonary resuscitation in hospitalised paediatric oncology patients.

► This is the first study that includes all PEWS scores—that is, no subset of scores as within a case–control study—of all hospitalised paediatric oncology patients, accounting for the longitudinal, time-dependent nature of the PEWS.

► This study involves a single paediatric oncology hospital which potentially may limit generalisability.

INTRODUCTION

Hospitalised paediatric oncology patients are prone to develop acute complications. Although the intensification of treatment over the past decades has improved outcome with a 5-year survival rate of up to 80%, treatment-related complications have increased.[1 2] These complications can be life-threatening and may require intensive care treatment.[1 2] Previous studies have shown that up to 38% of all paediatric oncology patients require admission to the paediatric intensive care unit (PICU) during their disease course, with sepsis and respiratory failure as the main admission reasons.[3 4] The PICU mortality of

these patients is high (25%–35%) compared with the mortality of the general PICU population (5%), despite advances in supportive and critical care.[5]

Timely identification of clinical deterioration is crucial for prompt escalation of care, thereby preventing further decline and reducing the risk of cardiopulmonary resuscitation.[6 7] Paediatric Early Warning System (PEWS) scores are often used as a prediction tool for detecting clinical deterioration.[8] PEWS scores typically consist of sequential monitoring of physiological parameters, generating a numerical score associated with clinical deterioration and trigger thresholds that are used for escalation of care. A broad range of PEWS scores are currently in use with variable predictive performance for identifying early clinical deterioration.[8] Among all PEWS scores studied, the most studied one is the Bedside PEWS by Parshuram *et al*[9–11] which was validated in the general paediatric patient population. A multicentre cluster randomised trial, comparing implementation of Bedside PEWS interventions versus usual care, showed no statistically significant reduction in mortality after PEWS implementation but did show a significant reduction in late PICU admission (significant clinical deterioration events).[9] In paediatric oncology patients, few studies have assessed the performance of a PEWS.[12–15] The majority of these studies were retrospective or case–control studies, and were conducted only in oncological subgroups, for example, stem cell transplant patients or haemato-oncology patients. Moreover, in most studies, the maximum PEWS score in the 24 hours prior to unplanned PICU admission was used to predict adverse outcomes without considering the time from that score to the event, which may have resulted in overestimating the predictive values of these scores.

In this project, we aim to validate a modified Bedside PEWS score for its predictive performance for unplanned PICU transfer or cardiopulmonary resuscitation (CPR) in hospitalised paediatric oncology patients. This article outlines the design and rationale for this study. The study design may be of interest to other research in the field of clinical prediction models for serious adverse events. The results of this study may add to the scientific basis for the use of the modified Bedside PEWS in this specific population. This may facilitate early recognition of a deteriorating patient and can be useful in clinical decision-making, ultimately aimed at improving the outcome of this vulnerable patient population.

METHODS AND ANALYSIS
Study design and setting
The prospective cohort study is conducted between 1 February 2019 and 1 February 2021 at the Princess Máxima Centre, an 80-bed hospital for paediatric oncology in the Netherlands that diagnoses approximately 550 new cases per year. This centre provides a unique setting as in this centre paediatric oncology care has been centralised for all patients in the Netherlands. All inpatient wards offer the possibility for continuous monitoring of vital

parameters. The PICU of the adjacent Wilhelmina Children's hospital is directly connected to, and shared with, the Princess Máxima Centre. This PICU consists of a 22-bed tertiary mixed medical-surgical unit. In case of any emergency, a rapid response team is available consisting of a paediatric intensivist, a paediatric anaesthetist and two critical care nurses.

Eligibility criteria
All patients with ICD-O diagnosis of paediatric malignancy (ICD-O morphology code 1, 2 or 3) aged 0–18 years admitted to the inpatient wards, including a haematological stem cell transplantation (HSCT) ward, of the Princess Máxima Centre will be eligible. In our centre, from age 0 to 18 years, the Bedside PEWS is used, and from 18 years onwards the adult early warning system is used at the wards. Patients admitted as outpatients for routine diagnostic and therapeutic procedures will be excluded. Patients with restrictions in care (palliative care only, do not resuscitate orders, no PICU admission) will be excluded from the moment restriction in care is registered as they can no longer experience the primary outcome event.

Outcome measures
The primary outcome will be the combined end point of a non-elective PICU admission or CPR. A non-elective PICU admission is defined as an unplanned admission to the PICU originating from the ward or operating room that the PICU was not expecting and/or is considered an emergency admission and could not have been postponed for >6 hours without adverse effect. Study definitions are elaborated in table 1.

Secondary outcomes and their definitions are shown in table 2. As non-elective PICU admission or CPR may be regarded as a late intervention in the course of clinical deterioration, we will also assess clinical deterioration requiring escalation of care but not resulting in a PICU admission (non-significant clinical deterioration), including the need for high-flow nasal cannula oxygen therapy or non-rebreathing mask, fluid resuscitation, or urgent PICU consultation.

Cohort dynamics and unit of study
This study consists of a dynamic cohort, since patients can enter or leave the study at variable times. A single patient may experience multiple admissions to the PICU during the study period, either within one single hospital admission or over multiple hospital admissions. Thus, a patient can be at risk of—or even experience—multiple primary outcome events. Therefore, the unit of study is not a single patient, but a single uninterrupted admission to the inpatient ward, referred to as a clinical episode. See table 1 for an elaboration of the definition of a clinical episode.

Data collection and management
Modified Bedside PEWS score assessment and registration
The modified Bedside PEWS has been used since the early start of the Princess Máxima Centre, in 2014.[16]

Table 1 Study definitions

Non-elective PICU admission	An unplanned admission to the PICU originating from the ward or operating room (OR) that the PICU was not expecting and/or is considered an emergency admission and could not have been postponed for >6 hours without adverse effect. PICU admissions initiated in the OR or PICU admissions following a non-elective procedure in the OR are also regarded as non-elective PICU admissions. Elective PICU admissions following elective surgery do not constitute a non-elective PICU admission and are thus censored.
Eligible inpatient ward	Areas where care is provided to paediatric oncology patients who are admitted to the hospital, other than the PICU, NICU, emergency department, outpatient department, OR and other designated areas where anaesthetist-supervised procedures are performed.
Clinical episode	An uninterrupted clinical admission at one of the eligible inpatient wards. This episode can be closed (1) by the primary outcome (non-elective PICU admission or cardiopulmonary resuscitation), (2) by discharge from the hospital (either to home or an other facility), (3) through restriction in care (eg, palliative care, do not resuscitate order or no PICU admission) from the moment the restriction in care is registered in the electronic healthcare system and (4) when the patient turns 18 years of age. A new clinical episode starts at (re-)admission to the inpatient ward.

NICU, neonatal intensive care unit; PICU, paediatric intensive care unit.

There are two minor modifications compared with the original Bedside PEWS score. First, temperature is added (addition of maximum two points to the total score of a patient) as data from adult early warning systems show the importance of temperature as a key physiological parameter in predicting clinical deterioration in adult oncology patients.[17] Second, the oxygen therapy is divided into room air (0 points), <2 L/min (2 points) or the use of high-flow nasal cannula oxygen therapy or non-rebreathing mask (4 points) (table 3). This results in an eight-parameter-based modified bedside PEWS with a possible scoring range of 0–28 points.

Modified Bedside PEWS score results are assessed and documented in patients' electronic health record (EHR) by nursing staff as part of routine care on all inpatient wards. All patients admitted to the paediatric oncology wards are routinely scored once every 8-hour shift unless their clinical condition deteriorates. In this case, the frequency of scoring is routinely intensified: at a score of 4–6 points, the scoring frequency is increased to every 4 hours, and at a score of 6–7 points, the scoring frequency is increased to every hour (figure 1). If the score exceeds

8, the nursing staff has to contact the attending physician within 10 min, enabling prompt evaluation of the patient. In addition, an urgent PICU evaluation is recommended if Bedside PEWS exceeds 10. Bedside computers are available on all inpatient wards, and nurses manually enter the vital signs. When the nurses want to calculate a modified Bedside PEWS, the score is automatically generated from the entered vital signs and shown with the corresponding clinical action. The adherence to the scoring algorithm will be calculated by the percentage of scoring of all items, and the time intervals between subsequent scores.

Clinical data—validation of modified Bedside PEWS

The modified Bedside PEWS score and its items will be collected from the EHR. Patient data that will be collected include demographics (age, weight and sex), reason for hospital admission, underlying cancer diagnosis and therapy, disease status (eg, initial diagnosis, during oncological treatment, end of treatment, relapse, refractory disease, progression and palliative phase), haematopoietic or autologous stem cell transplantation, and chimeric antigen receptor thymocyte cell therapy or other immunotherapy modalities. Outcome data including non-elective PICU admission, CPR and clinical deterioration events will be collected from the EHR. One of the challenges in data collection is that not all data are stored in a structured data field. For example, the escalation of care for a clinically deteriorating patient can be documented in the daily reports of nurses and physicians. Therefore, these data are retrieved in a systematic way from the non-structured text fields of the daily nurses' and physicians' reports, using standardised search terms. These search terms are listed in online supplemental table 1. First, we manually retrieve these data, and subsequently, we will automate (a large part) of this data collection, using the manually collected data to validate this automation. Admission reason for non-elective PICU admission will be manually classified into respiratory, cardiovascular, sepsis, neurologic deterioration, gastrointestinal, renal failure or non-elective postoperative care. For all patients admitted to the PICU, severity of illness scores will be calculated, such as the Paediatric Index of Mortality 3 score[18] and the Paediatric Logistic Organ Dysfunction (PELOD)-2 score.[19] This PELOD-2 score is a valid outcome measure to assess the severity of multiple organ dysfunction syndrome throughout the PICU stay. In addition, the following data will be collected for further research on the evolution of paediatric oncology patients at the PICU: PICU length of stay, use of PICU resources, for example, mechanical ventilation, need for vasopressors and/or inotropes, continuous renal replacement therapy, nitric oxide and extra corporeal life support.

Statistical analysis

Continuous variables will be reported as mean values along with their SD if they follow a normal distribution, or as medians with IQRs in case of a skewed distribution. Visual inspection of the data using Q–Q probability plots

Table 2 Secondary outcome parameters

Clinical ward	Definition
Non-significant clinical deterioration event*	The use of high-flow nasal cannula oxygen therapy or non-rebreathing mask but no positive pressure ventilation (bag mask or endotracheal); fluid resuscitation but no intravenous or intraosseous inotrope or vasoactive medications and/or urgent PICU consultation. If these interventions are given at <24-hour-interval, the interventions are clustered into one episode of non-significant clinical deterioration, with the start of the episode being the start of the first clinical deterioration event and the end of the episode being 24 hours after the start of the last clinical deterioration event.
Significant clinical deterioration event*	
Invasive respiratory support	Intubated and/or receiving endotracheal ventilation at the time of transfer or intubated within 1 hour of PICU admission.
Circulatory	>60 mL/kg intravenous or intraosseous fluid resuscitation given in the 12 hours before transfer, and/or administration of any intravenous or intraosseous inotrope or vasopressor at the time of transfer or at any stage in the 12 hours preceding transfer.
Late transfer	(1) Respiratory and (2) circulatory support before transfer
Hospital mortality	Mortality of an eligible patient at the eligible patient ward
Hospital length of stay	Will be assessed as the duration (days) of the stay of the patient at an eligible inpatient ward
Process of care	
Resuscitation team calls	Immediate medical assistance of the resuscitation team and equipment
Urgent PICU consultations	A total number of new PICU consultations will be counted. Patients who have been previously consulted will be regarded as having a new consult if an urgent call is made that results in a non-elective or earlier than planned review. Planned review involves visits by the ICU during their daily round.
Documentation and compliance to the Bedside PEWS scoring algorithm	The frequency of documenting the 'vital signs' (HR, RR, SBP, capillary refill, work of breathing, oxygen-saturation, additional oxygen therapy and temperature) and PEWS scores in 24 hours will be recorded during the study period. Moreover, the number of 'stat' calls to a physician, for example, request for immediate specific physician attendance to provide patient care to a patient admitted to an inpatient ward with Bedside PEWS score ≥8, will be documented.

*Adapted from the Children's Resuscitation Intensity Scale.
HR, heart rate; ICU, intensive care unit; PELOD, Paediatric Logistic Organ Dysfunction; PEWS, Paediatric Early Warning System; PICU, paediatric intensive care unit; PIM, paediatric index of mortality; RR, respiratory rate; SBP, systolic blood pressure.

together with D'Agostino test[20] for normality will be performed to assess departures from normality for each variable. Discrete variables will be expressed as numbers with percentages. A two-sided alpha of 0.05 will be considered to be statistically significant. The modified Bedside PEWS score is repeatedly measured in individual patients and may vary over time during hospital admissions. To study the association between modified Bedside PEWS and time to non-elective PICU transfer or cardiopulmonary resuscitation—from the first documented PEWS score—a Cox proportional hazard regression model will be estimated. To deal with the multiple hospital admissions, clusters of episodes will be incorporated into the Cox regression as they may contribute in the variation that needs to be accounted for when investigating the effect of the modified Bedside PEWS on the outcome event. As this study will validate an existing score in an applied setting, the modified Bedside PEWS and its items as measured and documented in daily practice will be used, including incomplete scores. The range of the modified Bedside PEWS is 0–28. A low score represents a good clinical condition. We will check the 5% highest range of modified Bedside PEWS to ensure these scores actually represent the patients' clinical condition. Other missing data will be multiple imputed using a regression approach.

The predictive performance of the model will be assessed internally using resampling validation.[21] Calibration and discrimination of the model will be investigated.[22] Calibration refers to how similar predicted probabilities and observed probabilities are. Well-known practices are to group patients from 'good' to 'poor' prognosis—a model is well calibrated if true and predicted group probabilities are very similar—or to calculate a calibration slope and intercept using bootstrapping to investigate possible overfitting. Discrimination refers to the ability of the model to provide higher predicted risk to patients who experience the event earlier compared with those experiencing the event later or not at all. To evaluate the discriminative ability of the model the C-index will be computed.[23] A C-index equal to 1 means that the model has perfect discrimination while a C-index equal to 0.5 means that the model predicts just as well as flipping a coin.

Table 3 The modified Bedside Paediatric Early Warning Score items

Item	Age group	Item sub score 0	1	2	4
Respiratory rate (breaths/min)	0–<3 months	30–60	≥61 or ≤29	≥81 or ≤19	≥91 or ≤15
	3–<12 months	25–50	≥51 or ≤24	≥71 o r≤19	≥81 or ≤15
	1–4 years	20–40	≥41 or ≤19	≥61 or ≤15	≥71 or ≤12
	>4–12 years	20–30	≥31 or ≤19	≥41 or ≤14	≥51 or ≤10
	>12 years	10–16	≥17 or ≤11	≥23 or ≤10	≥30 or ≤9
Respiratory effort		Normal	Mild increase	Moderate increase	Severe increase/any apnoea
Oxygen saturation (%)		>94	91–94	≤90	
Oxygen therapy		Room air		Oxygen 2 L/min	High-flow nasal cannula or non-rebreathing mask
Heart rate (beats/min)	0–<3 months	110–150	≥150 or ≤110	≥180 or ≤90	≥190 or ≤80
	3–<12 months	100–150	≥150 or ≤100	≥170 or ≤80	≥180 or ≤70
	1–4 years	90–120	≥120 or ≤90	≥150 or ≤70	≥170 or ≤60
	>4–12 years	70–110	≥110 or ≤70	≥130 or ≤60	≥150 or ≤50
	>12 years	60–100	≥100 or ≤60	≥120 or ≤50	≥140 or ≤40
Systolic blood pressure (mm Hg)	0–<3 months	60–80	≥80 or ≤60	≥100 or ≤50	≥130 or ≤45
	3–<12 months	80–100	≥100 or ≤80	≥120 or ≤70	≥150 or ≤60
	1–4 years	90–110	≥110 o r≤90	≥125 or ≤75	≥160 or ≤65
	>4–12 years	90–120	≥120 or ≤90	≥140 or ≤80	≥170 or ≤70
	>12 years	100–130	≥130 or ≤100	≥150 or ≤85	≥190 or ≤75
Capillary refill time		<3 s			≥3 s
Temperature (°C)		36.5–37.5	≤36.4 or ≥37.6	<36.0 or >38.5	

The expected number of events for a study period of 2 years were calculated. A retrospective analysis was performed between November 2014 and May 2016 in hospitalised paediatric oncology patients admitted to the two inpatient wards of the Princess Máxima Centre. In this study period, 39 primary outcome events were observed, which would be 50 events in 2 years. Before start of the study, the expected number of primary outcome events were estimated based on the information of the retrospective study. In 2017 and 2018, the Princess Máxima Centre has gradually grown an approximate 350% as a result of national centralisation of paediatric oncology
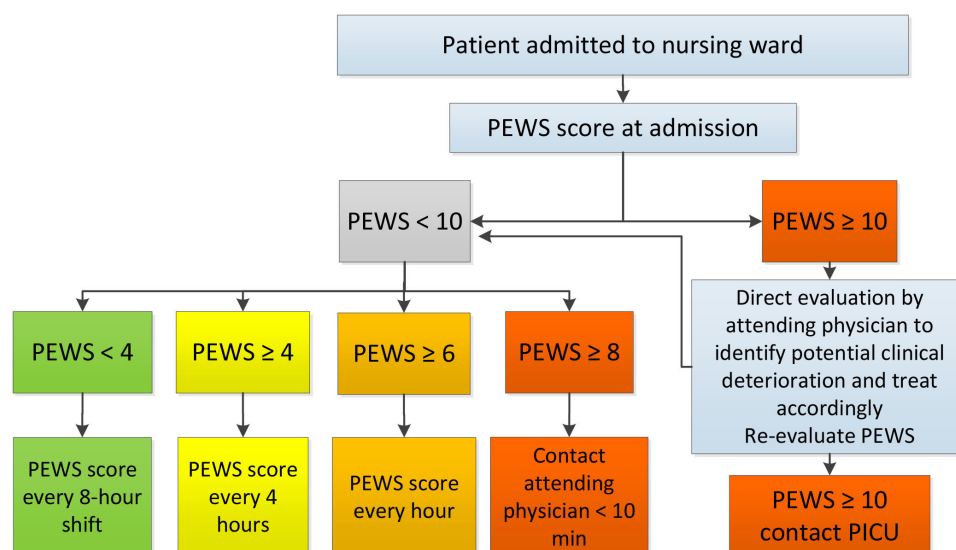

Figure 1 Flowchart of the scoring of the Bedside PEWS score as implemented in daily clinical practice in our study setting. PEWS, Paediatric Early Warning System; PICU, paediatric intensive care unit.

care and the accompanying opening of a new hospital in June 2018. As patients in the retrospective analysis may have already been more complicated cases, on average 300% more patients instead of 350% were expected to experience the primary outcome event. This would result in an anticipated number of 150 primary outcome events for the study period of 2 years.

The results of this study will be reported according to the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) statement.[24] Also, for this study protocol, relevant items are filled out in the TRIPOD statement checklist, see online supplemental eTable 2.

Patient and public involvement

The Dutch Association for Parents, Patients & Cancer fully supports the design, conduct and analysis of this project.

ETHICS AND DISSEMINATION

The study protocol has been approved by the institutional ethical review board of our hospital (MEC protocol number 16-572/C). Need for informed consent for this observational study was waived based on the non-interventional, non-burdening nature of the study. In addition, we adapted our enrolment procedure to General Data Protection Regulation compliance. Data collection started on 1 February 2019 and will last until 1 February 2021. The results from this study will be submitted for publication in a peer-reviewed journal, regardless of the results. Moreover, results will be presented at scientific conferences and disseminated to the healthcare staff and public via summaries and newsletters.

DISCUSSION

This article describes the background, rationale and design of the first prospective cohort study that aims to externally validate a modified Bedside PEWS score in an applied setting of hospitalised paediatric oncology patients. These patients are at risk to develop acute complications. A clinical prediction tool for the reliable detection of early deterioration in this high-risk population is needed. Recently, priorities for PEWS development and research in general paediatric patients have been suggested.[22] Among these priorities were the determination of the predictive characteristics of PEWS in different patient populations and the exploration of the role of technology in identification of deterioration and escalation of care.[25] With this prognostic study, we will provide an accurate and valid estimation of the modified Bedside PEWS' ability to predict non-elective PICU transfer or cardiopulmonary resuscitation at any time point during an uninterrupted inpatient ward admission in hospitalised paediatric oncology patients. In addition, we will also assess the predictive performance of the modified Bedside PEWS for non-significant clinical deterioration

events requiring escalation of care (such as the need for high flow oxygen therapy or fluid resuscitation). An overall key aspect in this external validation is the discrimination of the modified Bedside PEWS—that is, can this PEWS adequately discriminate between patients that will develop/experience the event and those experiencing the event not at all?[26]

Our study design has several strengths that may be interesting to other researchers in the field of clinical prediction models for critical decline. First, our prospective cohort study design enables to collect relevant routine clinical data in all patients that may potentially experience the primary outcome event. To date, validation studies of the PEWS in paediatric oncology patients most often employed a case–control design or retrospective cohort design, which may be susceptible to bias. In a case–control design, sampling based on the occurrence of the outcome event results in a study sample with a (much) higher prevalence of the outcome event that is no longer representative of the population. Therefore, risk prediction may not be straightforward, traditional risk modelling approaches (ie, traditional logistic regression) may not be effective, and may yield incorrect estimates of risk prediction.[27 28] Prospective data collection may minimise missing data or difficulties in abstracting certain PEWS components, that is a common source of bias in retrospective studies validating a PEWS.[8] Second, we include all subgroups of paediatric oncology patients (eg, patients with haemato-oncological malignancies including HSCT patients, solid tumours including immunotherapy patients, brain or central nervous system tumours), possibly improving generalisability as several studies validating a PEWS only included a subgroup of paediatric oncology patients. A third strength is the use of a single clinical episode as a study unit as opposed to a single patient. This enables us to account for re-occurrence of the outcome event and possible predictors. The longitudinal time-dependent nature of the predictors has not yet been used in validation studies of PEWSs for identifying clinical deterioration.[8]

Along with its strengths, our study design has limitations. First, our primary outcome event, non-elective PICU admission may be a rather subjective outcome measure. The decision to admit a patient to the PICU is complex, reflecting patient factors, resource availability and the decision-making of individual physicians.[29] In our setting, such decisions are made in a multidisciplinary approach by treating oncologists and intensivists. The modified Bedside PEWS could stimulate an increased situation awareness about children requiring intensive care therapy and may support, not replace, clinical judgement. The use of a hard outcome measure, such as mortality, may be limited in studies conducted in critically ill paediatric patients due to its relatively low occurrence.[30 31] This is illustrated by the first multicentre, randomised controlled trial of Bedside PEWS, which showed that implementation of this score compared with usual care did not significantly decrease all-cause mortality among

hospitalised children.[9] Despite the evaluation of 144 539 patient discharges, that study may have been underpowered as the overall mortality rate was significantly lower than anticipated.[32] Second, our study design involves a observational prospective cohort study, to validate a clinical prediction model in an applied setting. Consequently, we are not able to identify the underlying cause of clinical deterioration, since this would require a comparative study design. Third, in this study we will validate a modified Bedside PEWS. There are many different PEWS implemented, also in paediatric oncology patients.[12–16 33] Therefore, the results of our study may not be generalisable to other PEWS scores. Finally, the setting of a single paediatric oncology hospital with direct access to a PICU and availability of a rapid response team may also limit the generalisability of our findings to other settings.

The results of this study will contribute to the evidence of the performance of the modified Bedside PEWS in predicting non-elective PICU admission or CPR as well as escalation of care during hospitalisation in paediatric oncology patients. A good predictive performance is required for the modified Bedside PEWS to meet its clinical goal: timely detection of clinical deterioration that will prompt appropriate escalation of care. For that purpose, we would expect that the modified Bedside PEWS errs on the side of caution, implying that a highly modified Bedside PEWS (score ≥8) should have a low threshold of signalling a possible clinical deterioration. Still, it should not result in an unreasonable number of false positives. However, a low-modified Bedside PEWS (score <8) should indicate that no deterioration will occur, that is, a very low number of false negatives. We, therefore, consider the predictive performance of the modified Bedside PEWS optimal when at most 80 of 100 patients with a score ≥8 are false positive (a positive predictive value ≥20%). In contrast, there should be at most 2 of 100 patients with a score <8 that are false negative (a negative predictive value ≥98%). The modified Bedside PEWS is considered suboptimal when either of the predictive values does not meet its prespecified target. We will prospectively collect all relevant clinically available data to enable optimisation in future studies.

CONCLUSION

This study is the first prospective observational cohort study to evaluate the predictive performance of the Bedside PEWS score as a clinical prediction model to identify hospitalised paediatric oncology patients with evolving critical illness. The outcome of this study may strengthen the evidence for the use of the modified Bedside PEWS for detection of clinical deterioration in hospitalised paediatric oncology patients, or may indicate that the modified Bedside PEWS may need optimisation in this population.

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