Paediatric Track and Trigger Systems:

Validity, Reliability and Utility

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Doctor of Philosophy

Declaration

I, Susan Margaret Chapman confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed: 

Date: 20th February 2017

Abstract

Paediatric Track and Trigger Systems (PTTS) should alert staff to deteriorating children and accelerate access to resuscitation. The thesis presents a series of linked studies exploring selected aspects of PTTS use.

Study 1: Systematic review

Fifty-five papers describing 33 PTTS were identified. Implemented without a rapid response team (RRT), PTTS did not demonstrate statistically significant relative reduction in cardiac or respiratory arrest, or mortality. Implemented as part of a RRT PTTS demonstrated a statistically significant reduction in the relative and absolute risk of death in hospital, death on the ward and death following PICU transfer.

Study 2: Validity

This case-controlled study compared the predictive validity of 18 PTTS using case-controlled methodology. The area under the receiver operator characteristic curve (AUROC) varied (0.62 to 0.89). Three systems demonstrated statistically better performance. Incorporation of evidence-based thresholds for heart and respiratory rate did not improve the AUROC of high-performing systems.

Study 3: Reliability

This study examined the accuracy and completeness of PTTS documentation and compliance to a monitoring and escalation protocol. Of the 13,816 observation sets, 10,518 (76.1%) had an accurately calculated PTTS. Just 4957 (35.9%) contained all the required parameters. Only 3.3% of patients (20/608) met the required standard for monitoring and escalation.

Study 4: Utility

This mixed-methods study examined the understanding and experiences of children, young people, parents and nurses surrounding the use of a PTTS. Three main themes emerged: benefits and burdens, watchfulness and wisdom, and collaboration and conflict. Findings indicate that use of a PTTS is complex and greater collaboration between children/young people, families and healthcare professionals is likely to improve their use in clinical practice.

Conclusion:

There may be a relationship between validity, reliability and utility which, at present, is poorly understood. Better understanding of this relationship may improve outcomes for children and young people.

Acknowledgement

Firstly, I would like to thank my husband Steve for tolerating (with a smile) all the lost weekends, disrupted holidays and sustained periods of absence when I have been locked in my ‘office’ working on my PhD. His constant understanding and support has been invaluable and I know I would not have completed my research without him. I am only sorry that my Mum is not here to share in his delight at its completion.

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I would like to acknowledge the assistance of Dr Samiran Ray, who calculated the z-scores and p values reported in chapter three and produced Figure 3.1, Mr. Andrew Gilroy who collected data on 20 of the patients reported in chapters three and four and Mrs Sue Pike who conducted two of the six focus groups reported in chapter five.

My family and work colleagues have vicariously ‘experienced‘ my PhD. I thank them for the encouragement and support they have provided along the way.

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Abbreviations

Abbreviation	In full
AUROC	Area under the Receiver Operator Characteristic Curve
AVPU	Alert-Voice-Pain-Unresponsive
BP	Blood pressure
CEWS	Children's Early Warning Score
CI	Confidence interval
CPAP	Continuous positive airways pressure
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HDU	High Dependency Unit
ICU	Intensive Care Unit
IQR	Interquartile range
LTV	Long-term ventilation
MET	Medical Emergency Team
NEWS	National Early Warning System
NICE	National Institute for Health and Care Excellence
NPV	Negative Predictive Value
PEW	Paediatric Early Warning
PEWS	Paediatric Early Warning System
PICU	Paediatric Intensive Care Unit
PPV	Positive Predictive Value
PTTS	Paediatric Track and Trigger System
ROC	Receiver Operator Characteristic Curve
RR	Relative Risk
RRT	Rapid Response Team

Abbreviation	In full
SBP	Systolic blood pressure
SPSS	Statistical Package for the Social Sciences
WHO	World Health Organisation

Chapter 1 Introduction

1.1 Overview

More than 3000 children and young people between the ages of one month and 18 years die each year in the United Kingdom (UK).[1] Although the death of a child remains a relatively rare event in the UK, each represents an individual tragedy for those involved. That tragedy is exacerbated if the death was preventable. Most childhood deaths occur in hospital.[2] A confidential enquiry into childhood deaths found that 21% of hospital deaths had avoidable factors with 49% assessed as having potentially avoidable factors.[3] The most significant recurrent avoidable factor was the failure to recognise serious illness.[1]

Recognising and responding to serious illness in childhood is one of the most important clinical skills for nurses and other health professionals, however identification of critical illness in children is complex. It requires the clinician to take a clear and full history, appropriately assess and examine the child and effectively communicate with children/young people, their families and other members of the multidisciplinary team. This requires training, experience and good judgment.[3]

To assist clinicians in the early identification of childhood critical illness, standardised monitoring systems have been developed. These paediatric track and trigger systems (PTTS) aim to alert staff to patients at risk of critical illness through uniform monitoring of vital signs and other clinical indicators linked to a risk assessment.[4] Their use has been recommended by a number of national bodies[3,5,6] despite only weak evidence that they improve outcomes.

Although PTTS would intuitively seem to be a good thing, relatively little is known about their 'real world' performance, reliability and utility. Purported as a 'panacea' they have not, as yet, delivered the expected benefits. The reasons for this are complex. We do not know which PTTS might be best for which children in which setting. We are unsure whether PTTS are used effectively and the effect this may have on their accuracy. We are also uncertain whether they are valued and trusted by the staff they were designed to assist. Despite a drive towards involving children/young people and their families in their care there is little evidence of their views on PTTS having been sought. This thesis aims to explore some of these factors.

This thesis makes a number of original contributions to the evidence base:

1. A systematic review of published PTTS which highlighted 33 differing PTTS with variable validity and reliability
2. A pooled analysis of published PTTS which identified very low level evidence for PTTS implementation and moderate to low evidence for PTTS implementation as part of a package of interventions such as a rapid response system
3. A comparative analysis of validity (as assessed by the area under the receiver operator characteristic curve) which identified significant differences in the performance of published PTTS
4. A comparative analysis of validity which identified that modifying published PTTS with percentile-derived vital sign thresholds does not significantly improve the performance of the best performing systems
5. An evaluation of nursing practice which identified that only 35.9% of observation sets had simultaneous recording of the six components required to calculate the local PTTS score
6. An evaluation of nursing practice which identified that 7.3% of observation sets had no recorded local PTTS value and 19.6% had a local PTTS value which was incorrect
7. An assessment of adherence to the local PTTS monitoring and escalation protocol using an ‘all or nothing’ approach which identified that no case patients and only 6.4% of controls fully adhered to the protocol
8. A qualitative study with junior and senior nurses, parents and children and young people to elicit their perceptions and experiences of in-patient vital sign monitoring and the use of PTTS

1.2 Background

1.2.1 Childhood mortality in the UK

In 2014 3868 children between the ages of one month and 15 years died in the UK.[7] The majority (2,842) died within the first year of life (Table 1.1).

Table 1.1 UK childhood deaths in 2014

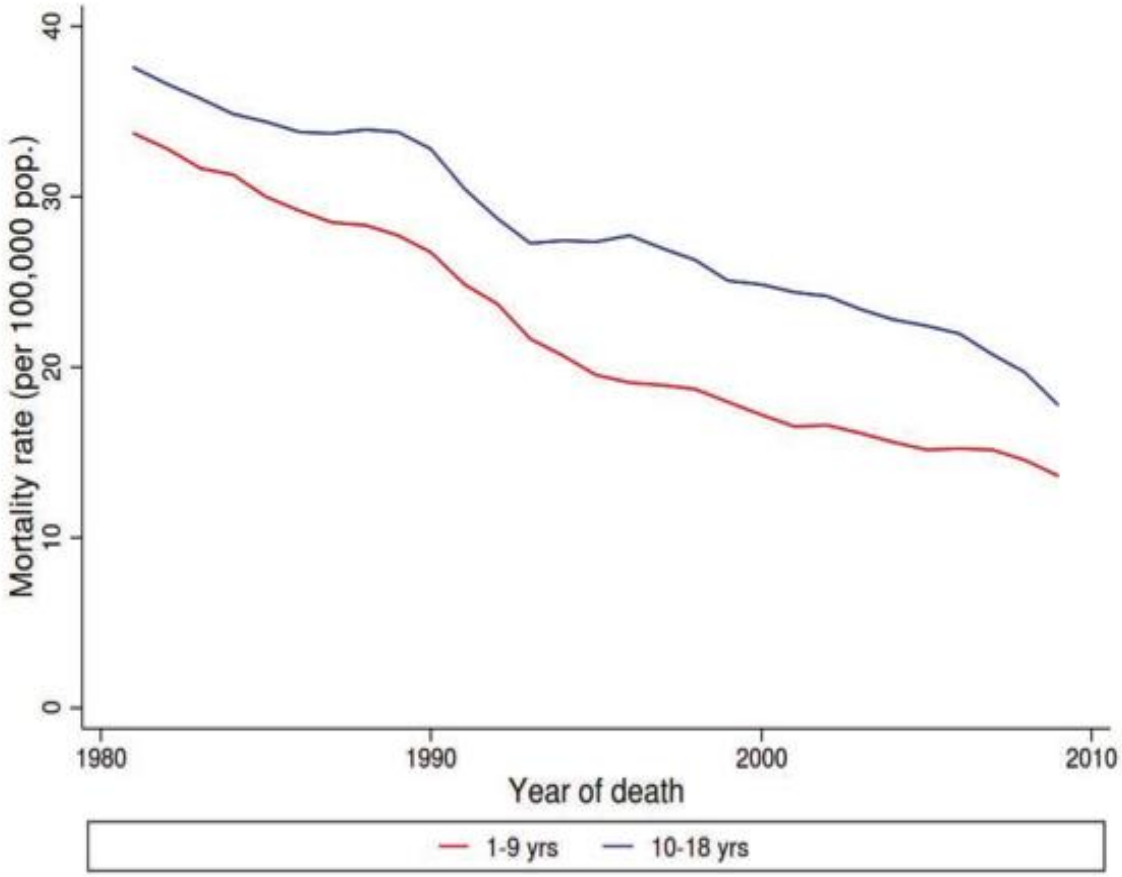
	Age in years			
	Infant	1-4 years	5-9 years	10-14
Deaths	2,842	442	294	290
Deaths per 100,000 population of the same age	3.7 *	14	8	8

*Data for infants (28 days -1 year of age) are presented as deaths per 1000 live births
Reproduced from Office for National Statistics[7]

Overall childhood mortality is declining (Figure 1.1). From 1980-2010 all cause mortality fell by 50-70% across the UK.[8] A similar reduction in the rate of death was seen in both younger (1-9 year olds) and older (10-18 year olds) children and young people.

The cause of death varies by age (Figure 1.2). Preterm birth has been demonstrated to contribute to mortality outside of the neonatal period.[8] For 1-4 year olds injuries and poisoning ('external causes' – 15%), cancer (15%) and congenital conditions (14%) were the most common cause of death. From five to nine years, injuries and poisoning (15%), cancer (15%) and congenital causes were most prevalent. Disorders of the nervous system (11%), respiratory conditions (11%) and infections (9%) were also common. Injuries and poisonings (24%), and cancer (24%) were the most frequent cause of death in older children/young people aged 10-14 years, and accounted for almost half of deaths overall. Deaths due to disorders of the nervous system and developmental conditions were also common (14%). Although childhood mortality has fallen and continues to fall, the UK lags behind other developed countries both in Europe and wider afield. The reasons for this are uncertain.

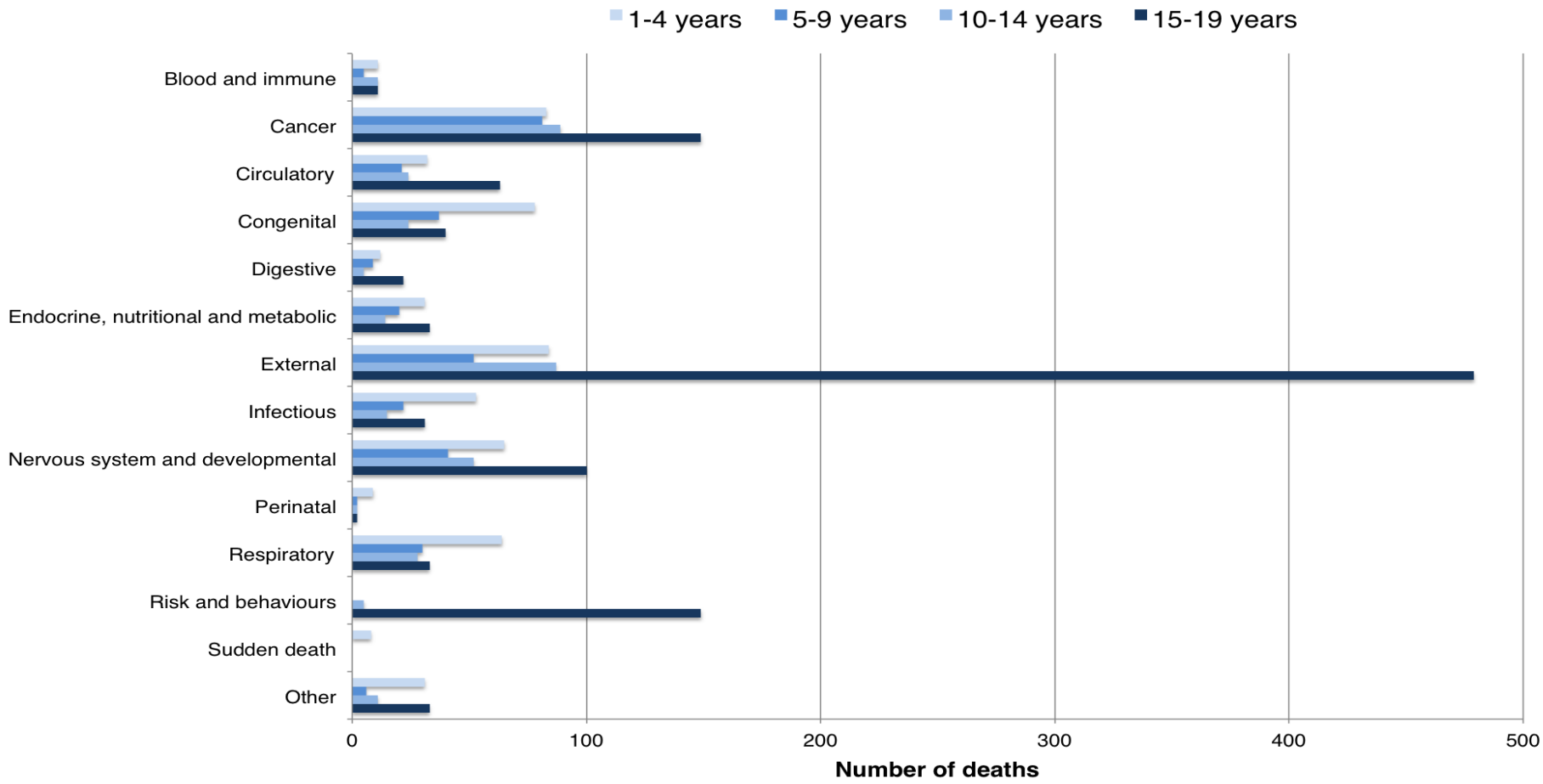
Figure 1.1 Smoothed child mortality rates by year and age group, UK 1980-2010



Mortality is presented as deaths per 100,000 population of the same age.

Reproduced from Office for National Statistics[7]

Figure 1.2 Causes of death by age of children and young people in the UK in 2012



Adapted from Royal College of Paediatrics and Child Health[9]

1.2.2 In-hospital childhood mortality

A significant proportion of children who die do so in the hospital environment. Some deaths are expected with children/young people and families working in partnership with palliative care professionals. However many children/young people are still receiving active treatment or being cared for within the intensive care environment at the time of their death.

In the UK the majority of paediatric in-hospital deaths appear to occur within intensive care. A study of the characteristics of death in a tertiary paediatric hospital identified that 85.7% occurred in the intensive care setting, with only 14.3% on wards outside of PICU.[2] Infants account for 57.7%, reflective of the national picture of childhood death.

The picture differed for deaths inside and outside of intensive care (Table 1.2). Most children who died in intensive care were less than one year of age, whilst the majority on the ward were aged 1-14 years. Congenital malformations (21.9%), perinatal disease (20.8%) and cardiovascular causes (16.4%) were the most prevalent cause of death within intensive care, whilst neoplasms (37.3%) and congenital malformations (23.6%) accounted for over half of the deaths of children in the ward. Whilst most deaths on the ward are anticipated, some follow acute events leading to cardiac arrest.

Table 1.2 Comparison of characteristics of ward and intensive care non-survivors in a single centre tertiary children's hospital

Characteristic	Intensive Care n (%)	Ward n (%)
Age group		
Newborn (<28 days)	282 (29.2)	0 (0)
Infant (1 – 12 months)	304 (31.45)	64 (39.7)
Child (1-14 years)	322 (33.3)	85 (52.8)
Young adults (>14 years)	58 (6.0)	12 (7.5)

Characteristic	Intensive Care n (%)	Ward n (%)
Diagnostic category		
Congenital malformation	212 (21.9)	38 (23.6)
Cardiovascular	158 (16.4)	11 (6.8)
Gastroenterology	18 (1.9)	10 (6.2)
Infections	43 (4.5)	3 (1.9)
Injury/poisonings	82 (8.5)	4 (2.5)
Metabolic disorders	25 (2.6)	12 (7.5)
Neoplasms	81 (8.4)	60 (37.3)
Neurological	68 (7.0)	15 (9.3)
Perinatal diseases	201 (20.8)	0 (0)
Respiratory	72 (7.5)	6 (3.7)
Other	6 (0.6)	2 (1.2)
Total	966 (100)	161 (100)

Deaths in each age-group and diagnostic category are presented as a proportion of the total number of deaths in intensive care and the ward.

Reproduced from Ramnarayan et al 2007[2]

1.2.3 Aetiology of cardiac arrest in hospitalised children

Cardiac arrest in children in hospital wards is relatively rare at 0.1-20/1000 children.[10] Survival to hospital discharge varies from 27-50% and is often associated with significant morbidity.[10] Emphasis has traditionally been on education and training in cardiopulmonary resuscitation, but evidence indicates that even with optimal resuscitation and post-resuscitation care, there remains significant mortality and morbidity associated with cardiopulmonary arrest.[11,12] Prevention is now seen as the best strategy.[10,13]

The causes of cardiorespiratory arrest in children differ from those in adults. In adults events are more likely to arise from cardiac arrhythmias, where the cardiorespiratory arrest is the primary event. By contrast most paediatric events are secondary events arising from decompensated respiratory or circulatory failure (Figure 1.3). They are often preceded by significant periods of physiological instability which is either not recognised or inadequately treated. As such, occurrence of cardiorespiratory arrest in a non-monitored unit has been proposed as a potentially avoidable event.[14]

Figure 1.3 Pathways to cardiac arrest in children

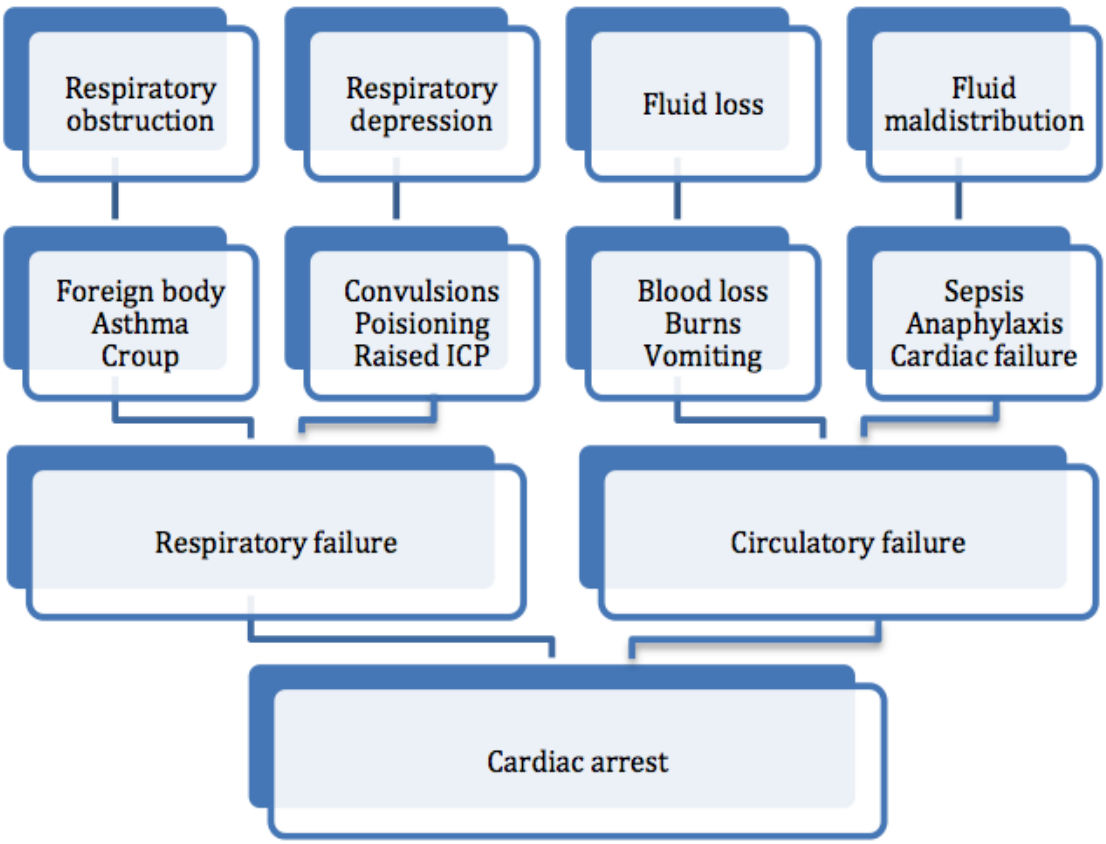


Figure represents the differing aetiologies leading to respiratory and circulatory failure in children.

Reproduced from Advanced Paediatric Life Support Manual[15]

1.2.4 The role of intensive care

The Paediatric Intensive Care Unit (PICU) facilitates a higher level of monitoring and intervention than is available on a normal ward. Many children and young people require life-sustaining support by way of mechanical ventilation, drugs to support the cardiovascular system and other complex therapies. The overall aim is to prevent death and adverse events such as cardiopulmonary arrest. However for PICU to

provide the most benefit, children at risk of cardiopulmonary arrest need to be identified and transferred sufficiently early to facilitate treatment.

Between 2012 and 2014 59,637 children were admitted to PICU in the UK and Ireland (Table 1.3 and Figure 1.4). Almost half (27,949, 47%) were under one year of age and a third of those children were less than one month old at admission (9382, 34%). Around a third of children were admitted electively following surgery (20662, 34.6%) with a smaller proportion admitted as a planned event (3912, 6.6%). However the majority of children were admitted as an emergency, either following deterioration in their condition (32054, 53.7%) or following a surgical procedure (2895, 4.9%).

Table 1.3 Source of admissions to PICU 2012-2014

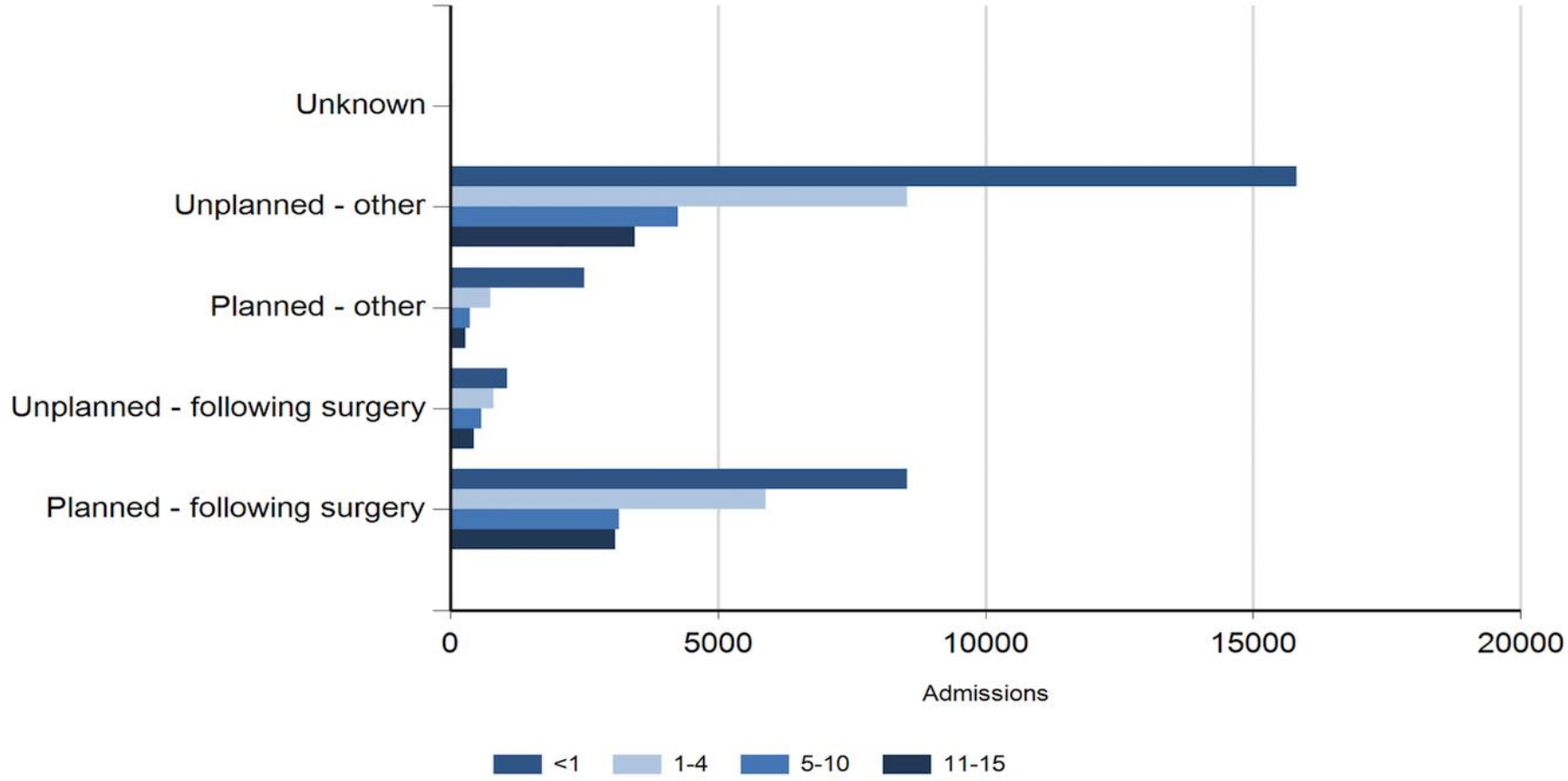
Admission type	Age in years									
	<1		1-4		5-10		11-15		Total	
	n	%	n	%	n	%	n	%	n	%
Unplanned (other)	15817	(49.3)	8530	(26.6)	4260	(13.3)	3447	(10.8)	32054	(53.7)
Planned (following surgery)	8529	(41.3)	5899	(28.5)	3155	(15.3)	3079	(14.9)	20662	(34.6)
Planned (other)	2503	(63.9)	745	(19.0)	375	(9.6)	289	(7.4)	3912	(6.6)
Unplanned (following surgery)	1065	(36.8)	808	(27.9)	580	(20.0)	442	(15.3)	2895	(4.9)
Unknown	35	(30.7)	40	(35.1)	18	(15.8)	21	(18.4)	114	(0.2)
Total	**27949**	**(46.9)**	**16022**	**(26.9)**	**8388**	**(14.1)**	**7278**	**(12.2)**	**59637**	**(100.0)**

Table is reproduced from data submitted to the UK Paediatric Intensive Care Audit Network (PICANet)[16]

The unshaded area presents the number of children in each age group for each admission type and percentages are presented for each age band separately.

Percentages in the total column represent the proportion of total admissions of each admission type

Figure 1.4 Source of admissions to PICU 2012-2014



The bar chart represents the number of children in each age group for each admission type. The exact number of admissions is presented in Table 1.3.

Reproduced from the PICANET 2015 Annual Report[16]

Reason for admission to PICU varies across age group (Table 1.4). For infants cardiovascular problems, primarily from congenital heart disease are the most common reason followed by gastro-intestinal diseases. Respiratory disease is the most prevalent diagnostic group for children aged 1-10 years. Musculo-skeletal disorders associated with trauma are most common in older children.

Table 1.4 Diagnostic group at admission to PICU 2012-2014

Diagnostic group	Age group (years)									
	<1		1-4		5-10		11-15		Total	
	n	%	n	%	n	%	n	%	n	%
Blood / lymphatic	102	(18.8)	169	(31.1)	154	(28.4)	118	(21.7)	543	(0.9)
Body wall and cavities	880	(85.0)	106	(10.2)	29	(2.8)	20	(1.9)	1035	(1.7)
Cardio-vascular	10817	(61.6)	3839	(21.8)	1810	(10.3)	1105	(6.3)	17571	(29.5)
Endocrine / metabolic	501	(34.5)	394	(27.1)	248	(17.1)	309	(21.3)	1452	(2.4)
Gastro-intestinal	2109	(59.6)	672	(19.0)	385	(10.9)	371	(10.5)	3537	(5.9)
Infection	1450	(49.2)	851	(28.9)	358	(12.2)	287	(9.7)	2946	(4.9)
Multisystem	119	(57.2)	50	(24.0)	22	(10.6)	17	(8.2)	208	(0.3)
Musculo-skeletal	178	(6.9)	455	(17.5)	487	(18.8)	1475	(56.8)	2595	(4.4)
Neurological	1640	(26.4)	2294	(36.9)	1390	(22.3)	898	(14.4)	6222	(10.4)
Oncology	308	(15.2)	721	(35.7)	597	(29.5)	394	(19.5)	2020	(3.4)
Respiratory	8582	(51.2)	4959	(29.6)	1979	(11.8)	1228	(7.3)	16748	(28.1)
Trauma	120	(8.9)	452	(33.4)	375	(27.7)	408	(30.1)	1355	(2.3)
Other	1101	(33.8)	1005	(30.8)	522	(16.0)	630	(19.3)	3258	(5.5)
Unknown	42	(28.2)	55	(36.9)	32	(21.5)	18	(12.1)	147	(0.2)
Total	27949	(46.9)	16022	(26.9)	8388	(14.1)	7278	(12.2)	59637	(100)

Table is reproduced from data submitted to the UK Paediatric Intensive Care Audit Network (PICANet).[16]

The unshaded area presents the number of children in each age group for each diagnostic group and percentages are presented for each age band separately.

Percentages in the total column represent the proportion of total admissions of each diagnostic group.

Recent research has highlighted that children and young people admitted to PICU from the ward have a worse outcome than patients admitted from the accident and emergency unit.[17] They also stay longer in PICU. It has therefore been suggested that strategies to reduce PICU mortality need to be targeted at admissions from hospital wards. Compelling evidence from retrospective reviews of adults indicates that sub-optimal care before transfer to intensive care is frequent.[18-28]

1.2.4.1 Sub-optimal care of hospitalised adults

The use of track and trigger systems for adults was driven by several retrospective reviews of the quality of care before cardiac arrest and unplanned transfer to intensive care. All identified significant and often prolonged periods of physiological instability which were either not recognised or poorly managed.[18-25] A confidential enquiry into the quality of care before unplanned admission to intensive care considered that just 20% of adults were well managed. Significant deficiencies were identified in 54% of cases with the failure to appreciate the severity of the patient's condition and failure to escalate to a senior clinician identified as major contributing factors. Suboptimal care was considered to have contributed to morbidity or mortality in most cases.[26]

A UK study of 317 adults dying unexpectedly on hospital wards or after unplanned admission to intensive care also identified failures in care. Of the patients dying following failed resuscitation, 65% were considered avoidable. Eighty-six patients were admitted as an emergency to intensive care. In 31 cases (36%) the management before intensive care was considered sub-optimal due to non-recognition of deterioration (12 cases) or inappropriate treatment (19 cases). Mortality in intensive care (52% vs 35%) and hospital (65 vs 42%) was significantly higher in the poorly managed group ($p<.0001$).[27]

A subsequent national confidential enquiry into the management of adult acute medical patients yielded similar findings.[28] Of patients transferred to intensive care 65% exhibited physiological instability for more than 12 hours. The report recommended the use of track and trigger systems for all in-patients.

1.2.5 Sub-optimal care of hospitalised children

The research on sub-optimal care in paediatrics is much less developed. A six-year review of 1612 records of children who died, had an unplanned admission to PICU and were referred for specific review identified 325 adverse events (20.2%).

Although the nature of the adverse events was not reported in detail, training in acute paediatric life support and the recognition of septic shock, together with the introduction of a medical emergency team, were key interventions resulting from the review.[29]

Research in paediatrics has largely focused on the management of sepsis. A case note review of 47 children who died following PICU admission assessed the occurrence of critical incidents (undesirable events which could/did to lead to patient harm but did not contribute to death) and adverse events (undesirable events which contributed to death).[30] There were 37 critical incidents in 28 cases and 22 adverse events in 17 children. Adverse events included the failure to recognise and manage acute illness. Most deficiencies in care occurred in hospital wards, prior to PICU transfer.

A study in 2005 of children with meningococcal disease compared the management of 143 children who died with that of 355 who survived.[31] Failure to recognise complications, failure to appreciate disease severity, failure in supervision, lack of involvement of a paediatric team in care and inadequacies of fluid and inotrope administration were all significantly associated with death. Vital signs were often inadequately documented and signs of shock were not recognised. In particular, the review highlighted that age-appropriate values for vital signs were not appreciated, with extreme values for pulse and respiratory rate recorded but not acted upon. A later study in 2010 of children who died from severe bacterial infection also identified sub-optimal care in 76% of cases.[32] The failure to appreciate the severity of the disease and failure to recognise the signs of shock were again cited.

A landmark confidential enquiry in 2008 identified significant avoidable factors associated with the death of children.[3] A detailed review was undertaken in 89 cases where the death occurred in hospital. Whilst most deaths occurred in the PICU (25%) or other critical care setting (10%) a significant proportion were found in the general ward or adolescent unit (25%). Avoidable factors, such as the failure to recognise clear indicators of meningitis, were found in 19 (21%) cases. Potentially avoidable factors were found in 44 (49%). Avoidable factors were found more frequently in children who did not have a life-limiting illness. In only 26 (29%) of the cases was the death considered to be unavoidable. The recognition of the severity of illness, including the failure to examine or interpret clinical signs (including vital signs) correctly was highlighted as an area of particular concern. This led the

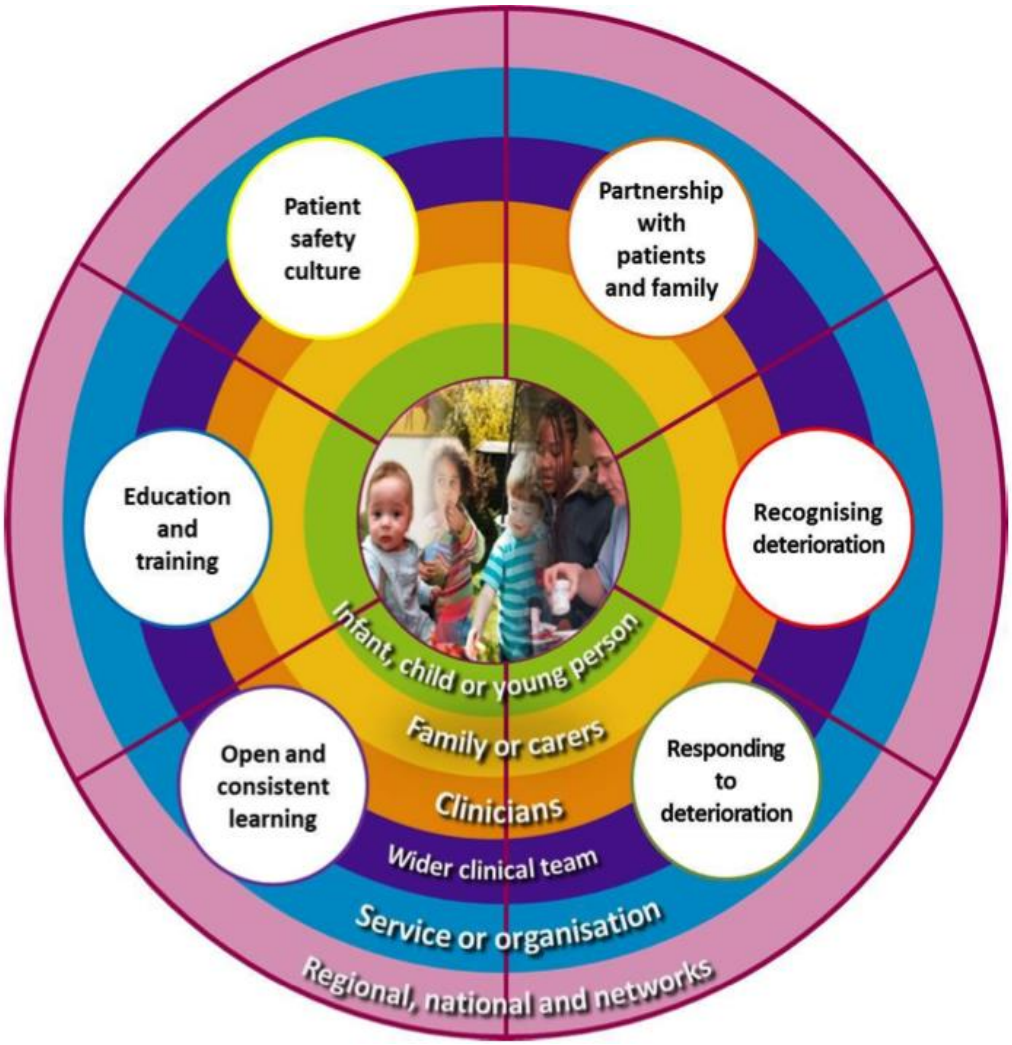
authors to recommend a standardised and rational monitoring system with an embedded early identification system to assist with the detection of developing critical illness for paediatric care in hospital. The authors identified this identification system as an early warning score.

A subsequent confidential enquiry into the care of children who died following surgery in 2011[6] also made recommendations regarding PTTS. Although they identified that 56.4% of hospitals (155/275) were using a PTTS, they highlighted concern about the number of hospitals that did not have a policy for identifying sick children or a resuscitation policy for children. Again the use of a PTTS was recommended as standard practice, however the report also recommended that the National Institute for Health and Clinical Excellence (NICE) should develop guidance on the recognition and response to the seriously ill child in hospital. To date this has not been addressed.

1.2.6 A safe system to improve in-hospital mortality

There is increasing recognition that identifying and managing clinical deterioration is complex. It relies on multiple component factors which are inter-linked and inter-dependent. Recently a framework has been proposed by the Royal College of Paediatrics and Child Health (RCPCH) and NHS Improvement.[33] This 'safe system' is has six core elements but also acknowledges the groups of individuals who influence or contribute to safe management of the deteriorating child. Whilst the infant, child or young person is at the centre they are surrounded by their family and carers, clinicians, the wider clinical team, the service or organisation where they are currently based and regional and national networks of individuals and organisations that influence care delivery. The safe system framework can be seen at Figure 1.5.

Figure 1.5 Safe system framework for hospitalised children



Reproduced from NHS Improvement and RCPCH[33]

The safe system framework has six core elements, each focusing on a particular aspect of the system. These core elements describe the essential components of a safe system and are described in Table 1.5.

Table 1.5 Core elements of the safe system framework

Core Element	Safe System Framework Description
Patient safety culture	A large and challenging element covering many of the aspects including a commitment to overall improvement in patient safety, prioritising safety, leadership and executive accountability, and monitoring and measuring patient safety
Partnership with patients and their family	While all the core elements focus on the patient and family, this partnership is an area of increased growth and central to supporting all the others
Recognising deterioration	The ability to spot physiological deviations before significant changes in care are required or harm occurs is a fundamental working element that is central to the system
Responding to deterioration	Ensuring a timely and accurate response encompassing all necessary support and treatment from all those involved in the care of the patient is the vital element that is often the key change required
Open and consistent learning	Consideration of the system errors and individual responsibility, recording, investigating and evaluating incidents as well as best practice in order to learn and effect change will drive forward continual improvements in all elements
Education and training	Consistently building clinical knowledge and capability as well as patient safety and improvement methods will provide the foundation for all elements to be enhanced

Adapted from the RCPCH and NHS Improvement Safe System Framework[33]

Of particular relevance to this thesis are recognising deterioration, responding to deterioration and partnership with patients and families, however education and training, open and consistent learning and patient safety culture are also key factors in successful management of the deteriorating child.

1.2.7 Evolution of track and trigger systems

In the late 1990's a small but significant body of research challenged the widely held belief that critical deterioration events in adults were unpredictable and therefore unpreventable. Periods of physiological instability were demonstrated to occur for many hours before critical deterioration events, such as unplanned admission to

intensive care, cardiac arrest and unexpected death.[21,22,25-27] This physiological instability was often identified through the routine monitoring of vital signs but was either overlooked or inadequately treated by healthcare staff.

Track and trigger systems evolved to assist staff in detecting developing critical illness. The first system was developed in Australia as part of a wider system to facilitate rapid access to critical care within the ward environment.[34] Selected vital signs and other clinical indicators were periodically monitored and when thresholds for abnormal values were breeched, this 'triggered' the member of staff to activate a specialist team of critical care clinicians known as the 'rapid response team'.

More sophisticated systems were subsequently developed incorporating a scoring matrix. Scores were assigned based on the degree of abnormality of the clinical sign, with higher scores indicating greater physiological abnormality. These scores were then aggregated to produce a single numerical value, generally referred to as the early warning score. Positive scores indicate patients at risk of deterioration, with higher scores associated with increasing risk.[35]

A variety of systems then developed, with differing names such as early warning scores, early warning systems, alert criteria, activation criteria and trigger criteria. However they shared two common characteristics: the ability to 'track' the patient's progress through monitoring of selected vital signs and the ability to 'trigger' a response when predetermined criteria were met. The term track and trigger system was subsequently adopted to include these related but differing systems.[36,37] Track and trigger systems were often associated with specialist teams who were also known by a variety of names: critical care outreach, patient at risk, rapid response team, rapid response system and medical emergency team.

Track and trigger systems are now routinely used to monitor all hospitalised adults in the UK following recommendations by NICE.[37] Despite their widespread use, studies of track and trigger systems have failed to demonstrate a significant impact on patient outcomes in the adult population.[36,38]

1.2.8 Paediatric track and trigger systems

1.2.8.1 The first paediatric track and trigger system

The first reported PTTS for hospitalised children, the Paediatric Early Warning Score,[39] was published in 2005. The system was developed at the Royal Alexandra Hospital for Sick Children in Brighton, UK.

In February 2001 a working group was established at the Royal Alexandra Hospital to investigate the feasibility of extending the existing adult critical care outreach to children. By October 2001, a pilot was underway. Initially ward staff referred children about whom they had concerns, and the team, including staff from PICU, attended. However ward staff reported feeling deskilled, undermined and undervalued.

Focus shifted to implementing mechanisms to assist staff in the early identification of the deteriorating child. No paediatric-specific system could be identified from the literature so the working group adapted the existing adult system. Because a system based solely on vital signs would require different versions to address age-appropriate values, three main indicators were adopted: behavior, cardiovascular and respiratory status. Specific thresholds for vital signs were not provided. The system is shown in Figure 1.6.

Figure 1.6: The Royal Alexandra Children's Hospital Paediatric Early Warning Score

	0	1	2	3
Behaviour	Playing/ appropriate	Sleeping	Irritable	Lethargic/ confused Reduce response to pain
Cardiovascular	Pink or capillary refill 1-2 seconds	Pale or capillary refill 3 seconds	Grey or capillary refill 4 seconds. Tachycardia of 20 above normal rate	Grey or mottled or capillary refill 5 seconds or above. Tachycardia of 30 above normal rate or bradycardia
Respiratory	Within normal parameters, no recession or tracheal tug	>10 above normal parameters, using accessory muscles, 30+% FiO2 or 4+litres/min	>20 above normal parameters recessing, tracheal tug. 40+% FiO2 or 6+ litres/min	5 below normal parameters with sternal recession, tracheal tug or grunting. 50% FiO2 or 8+ litres/min

Total score is derived from assessment of behaviour, cardiovascular and respiratory status.
Reproduced from Monaghan 2005[39]

Staff assessed the child against the guidance, assigning a score of zero to three for each of the three indicators. The total score was then assessed against guidance which prompted one of five actions:

- Continue current care
- Inform the nurse in charge
- Increase the frequency of the observations
- Call for a medical review and inform the outreach team for a score of four
- Call the full medical team and outreach team for any score greater than four

Any child who scored in the ‘red’ zone (a score of three in any one indicator) would also be escalated to the medical and outreach team.

Initial feedback on the score was variable, with reports that:

> *"Some staff could not see why we needed a score as they felt they were quite capable of recognising patients at risk"*
>
> (Monaghan, p35[39])

Concerns were also raised about the assessment being time-consuming, although when investigated, completing the early warning score only took 30 seconds over and above the time taken to record the vital signs.

During the three-month pilot 30 patients scored four, prompting the nurse to request a review by the medical team. The majority (96%) were seen within 15 minutes. All required medical intervention, after which 83% improved whilst the remaining 17% were transferred to the PICU. Children who staff felt should have scored higher prompted revision of the score to include additional weighting for prolonged post-operative vomiting.

Subsequent feedback from thirty-three staff on the acute medical and surgical wards revealed that 80% felt that the score had improved their confidence in recognising a child at risk of deterioration. Although the author reported that assessment of the sensitivity of the score was underway, with assessment of inter-rater reliability planned in the future, no subsequent publications could be identified.

Despite its limited evaluation, the study remains an important milestone, marking the first publication of PTTS.

1.2.8.2 An alternative approach

On the other side of the world another paediatric hospital was also working to improve the management of the deteriorating child. The Royal Children's Hospital in Melbourne, Australia developed a specialist team to respond to the deteriorating child known as the Medical Emergency Team or MET.[40] The MET could be activated by clinical staff if any one of nine criteria was present (Figure 1.7). Eight of the criteria represented clinical indicators and vital signs values associated with serious illness, but the MET could also be activated if the nurse or doctor was 'worried' about the child's condition. Explicit age-related criteria for vital signs were specified but unlike the Paediatric Early Warning System no scoring matrix was used. This 'trigger' based approach was simpler and required no mathematical calculation, but unlike the Paediatric Early Warning Score, the outcome was dichotomous, with an 'all or nothing' response.

Figure 1.7 Criteria for activation of the medical emergency team

Any one or more of:

1. Nurse or doctor *worried* about clinical state
2. Airway threat
3. Hypoxaemia:

   SpO2 <90% in any amount of oxygen

   SpO2 <60% in any amount of oxygen (cyanotic heart disease)
4. Severe respiratory distress, apnoea, or cyanosis
5. Tachypnoea:

Age	Respiratory rate/min
Term-3 months	>60
4-12 months	>50
1-4 years	>40
5-12 years	>30
12 years+	>30

6. Tachycardia or bradycardia

Age	Bradycardia (beats/min)	Tachycardia (beats/min)
Term-3 months	<100	>180
4-12 months	<100	>180
1-4 years	<90	>160
5-12 years	<80	>140
12 years+	<60	>130

7. Hypotension

Age	BP (systolic mm Hg)
Term-3 months	<50
4-12 months	<60
1-4 years	<70
5-12 years	<80
12 years+	<90

8. Acute change in neurological status or convulsion
9. Cardiac or respiratory arrest

- Some of the values for respiratory rate, heart rate, and blood pressure are outside the normal ranges for age: they represent concerning levels that may indicate serious illness, and that require expert review.
- It is also important to look for worsening trends in vital signs and report these
- If a child fulfils any of these criteria, notify the treating medical team and the MET service (via switchboard)

Fulfillment of any single category would trigger a referral to the medical emergency team. Reproduced from Tibballs et al 2005[40]

1.2.8.3 Subsequent development of paediatric track and trigger systems

Although the first publications on PTTS were in 2005, many hospitals had been developing and implementing their own local systems. A 2005 survey of 186 UK hospital trusts identified 144 who were delivering paediatric services.[41] Thirty-one of these (21.5%) reported using a PTTS. Many appeared to be the same or local adaptions of the Monaghan[39] Paediatric Early Warning Score or the subsequently published Bristol Paediatric Early Warning Score.[42]

The 31 centres were asked to report the component parameters of their PTTS. Of the 36 identified parameters (Table 1.6), respiratory and heart rate, nurse and doctor concern and respiratory effort were most prevalent.[41]

Table 1.6 Frequency of the component parameters reported by the 31 hospitals using an early identification system in 2005

Parameter	Frequency	Parameter	Frequency
Respiratory rate	18	Diabetic ketoacidosis	5
Heart rate	17	Meningocaccaemia	5
Nurse concern	16	Acidosis	5
Doctor concern	14	Abnormal serum potassium	5
Respiratory effort	13	Fluid bolus >10ml/kg	5
Shock	12	Artificial airway	4
Systolic blood pressure	11	Abnormal serum sodium	4
Oxygen saturation	11	Abnormal coagulation	4
Abnormal consciousness	11	Inotrope infusion	4
Oxygen therapy	10	Apnoea	3
Stridor / wheeze	8	Arrhythmia	3
Past ICU discharge	8	Mean blood pressure	3
Nebulised medication	8	Neutropaenia	2
Urine output	7	Central line (temporary)	1
Temperature	7	Cardiac pacing (temporary	1
Exhaustion	6	Major trauma	1
Prolonged seizures	6	Burns > 10%	1
Respiratory arrest	5	Need for ventilation	1

Frequency of the component parameters in the 31 early identification systems reported by the 2005 survey respondents.
Reproduced from Duncan[41]

The survey was repeated in 2013[43] with a response rate of 94.9% (149/157). The majority were district general hospitals (119/126) with 30 (out of 31) respondents from tertiary hospitals. Of the 149 centres who responded 99 of the 119 (83%)

district general hospitals and 27 of the 30 (90%) tertiary care hospitals reported they had a PTTS in place. Eleven district general hospitals and 15 tertiary hospitals had also introduced a rapid response team.

Respondents were asked to identify the origin of their PTTS (Table 1.7). Only a third reported that their system was based on a previously published tool, with the remainder using a mix of systems adapted from other hospitals and those purposely designed for the individual unit. The number of differing parameters had increased to 47, however respiratory and heart rate remained the most commonly cited parameters.

Table 1.7 Origin of systems

PTTS based on:	Number of responses (%)
Previously published system	26 (33.8%)
Unpublished system in use at another hospital	19 (24.7%)
Purposely designed for own unit	15 (19.5%)
Unsure	8 (10.4%)
No response	9 (11.7%)
Total	77 (100%)

Respondents to a survey were asked to identify the origin of their current PTTS system. Reproduced from Roland[43]

The authors of the 2013 survey recommended a collaborative approach to PTTS similar to that led by the Royal College of Physicians for adult patients.[43,44] They advocated that all PTTS must be simple to use and be acceptable to the end user if they are to be widely accepted and adopted into clinical practice. They proposed that respiratory rate, heart rate and oxygen saturation levels should be considered core parameters as they were the top three items in the survey results. The authors also suggested that conscious level, respiratory effort, nursing concern, blood pressure and oxygen therapy should be considered for inclusion on the basis that at least 50% of units currently included these items in their PTTS and they had also been highlighted in a systematic review of clinical features of serious illness in children.[45] Finally they identified that the ideal PTTS would utilise routinely collected data. To allow expert help to be mobilised and interventions to be implemented, it

would also accurately identify patients who are deteriorating at a sufficiently early stage.

This rapid uptake in PTTS usage has been characterised as an 'explosion'.[46] Although many systems are in existence, all have adopted either the score-based approach pioneered by the Royal Alexandra Hospital or the trigger-based approach promoted by the Royal Children's Hospital. Whilst both approaches aim to identify children at risk of clinical deterioration, there are important differences between score-based and trigger-based systems.

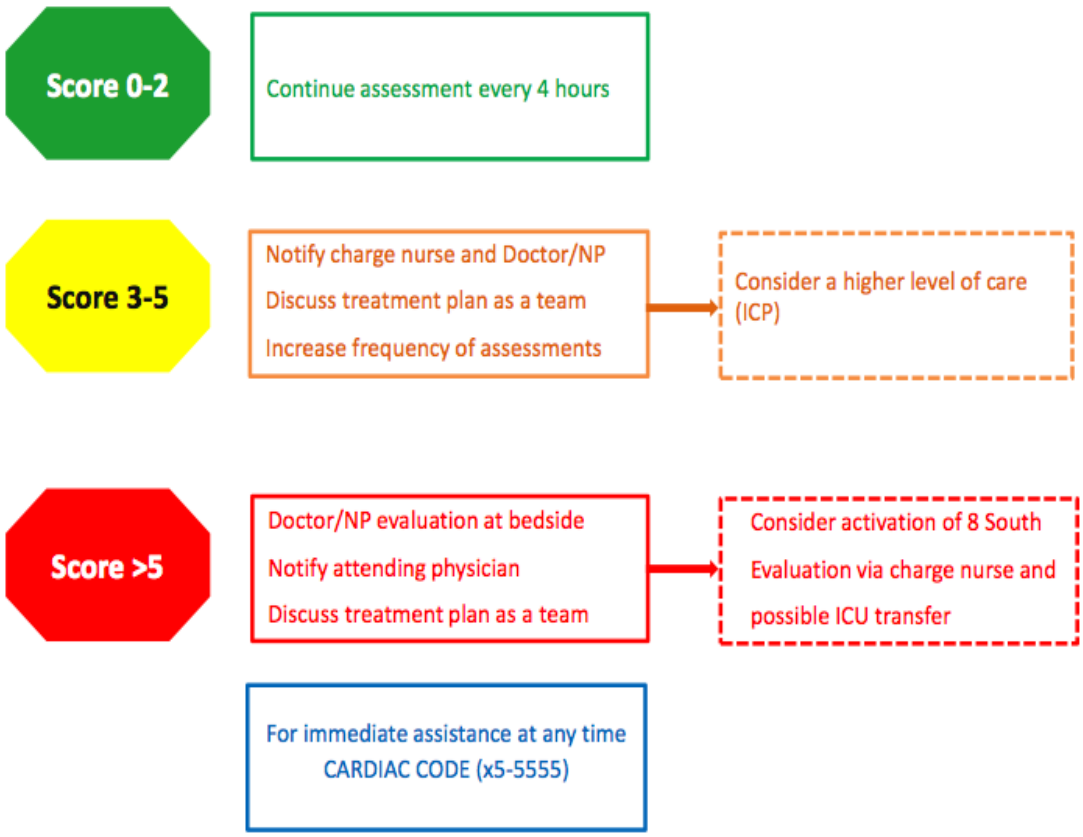
1.2.9 Types of paediatric track and trigger systems

1.2.9.1 Scoring systems

Score-based systems such as the Paediatric Early Warning Score[39] shown at Figure 1.6 assign values to vital signs, and other clinical indicators, representing the extent of deviation from 'normal'. Children are assessed at periodic intervals against the scoring matrix and assigned a score for each parameter. Component values are combined to generate an overall score. Scores of zero generally indicate 'normal' or 'stable' status with increasing scores indicating greater physiological abnormality. Higher scores should represent an increased risk of deterioration, prompting more rapid review by senior clinicians.[35]

Scoring systems are designed to link with an escalation algorithm to indicate the response to each score. Algorithms can vary in their complexity. At their simplest, this may be a set of instructions which indicate the response required for the assigned score, as shown in Figure 1.8.

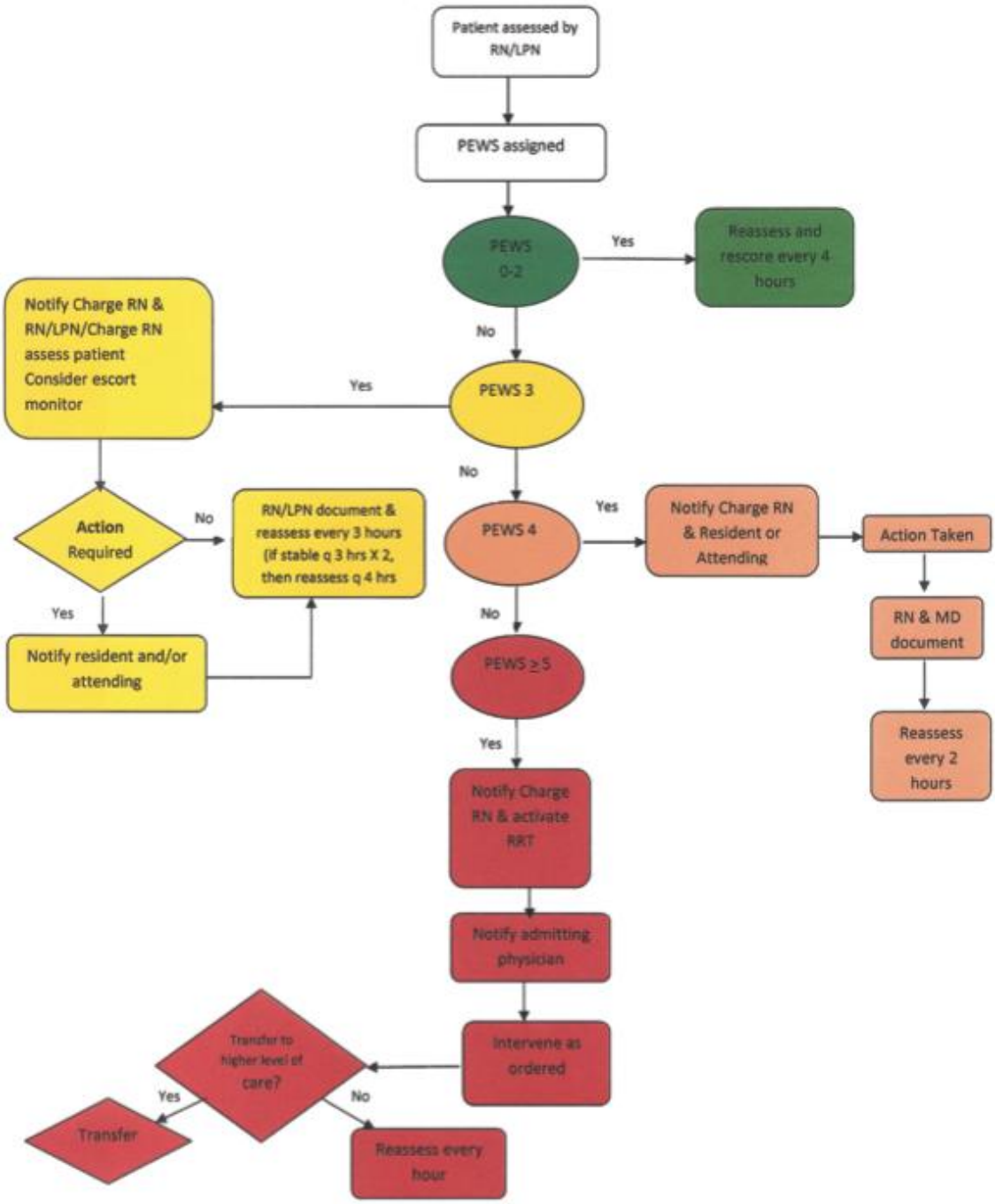
Figure 1.8 Example of a simple escalation algorithm to accompany a scoring system



The score identified on the left was generated from the Cardiac Children's Hospital Early Warning Score. Boxes with a solid line indicate actions to be taken for the relevant score. Boxes in hatched lines indicate additional actions to be considered by the nurse.
Adapted from McLellan[47]

The majority of escalation algorithms represent a set of instructions to prompt review by a doctor or specialist personnel, such as a rapid response team. However some PTTS have been associated with more detailed and complex algorithms such as that shown in Figure 1.9.

Figure 1.9 Example of a complex algorithm for a scoring system



The flow chart starts from the top white box. The relevant PTTS score would be identified in the colour coded circles and the appropriate part of the flow chart followed.
Reproduced from Skaletzky et al 2009[48]

1.2.9.2 Trigger systems

Trigger-based systems, such as the MET activation criteria[40] (Figure 1.7), contain a number of pre-defined thresholds. When one or more thresholds are breeched, this 'triggers' a pre-determined response. Unlike score-based systems, there is no associated algorithm. Trigger-based systems result in a dichotomous 'all or nothing' response. This typically means activation of a rapid response system (RRS) (also known as 'critical care outreach', 'rapid response' or 'medical emergency' teams).

1.2.9.3 Scoring versus trigger-systems

Although no national guidance exists to recommend the type of PTTS for hospitalised children, NICE has previously assessed the advantages and disadvantages of different types of track and trigger systems for identifying the acutely ill hospitalised adult.[37] The main findings are summarised in Table 1.8.

Table 1.8 Comparison of trigger and scoring systems reported by NICE

Type of system	Advantages	Disadvantages
Scoring system	Allow monitoring of clinical progress Allow for a graded response strategy Widely used in UK hospitals	May lack reproducibility and reliability because systems are prone to human calculation errors A range of sensitivities and specificities depending on the cut-off score used, but it is possible to achieve high sensitivity and specificity at defined cut-off point
Trigger system	Simple to use Simple system with better reproducibility	Does not allow a patient's progress to be tracked Does not allow a graded response strategy Evidence[36] suggested that trigger systems have low sensitivity, low positive predictive value but high specificity. This could potentially cause increased triggers that are not related to an adverse event Not widely adopted in the UK adult setting.

Advantages and disadvantages were identified relevant to the track and trigger systems used for acutely ill hospitalised adults.

Reproduced from NICE 2007[37]

Use of a scoring system facilitates a graded response. This may be more advantageous as escalation algorithms can be developed that are tailored to local needs and available resources. However scoring systems are recognised as being more complex, requiring correct allocation of individual parameter scores and correct summation of the overall score.[49,50] This may be particularly important for paediatric scoring systems, which may be more complex due to the need to acknowledge age-appropriate vital sign thresholds.

Not all settings that care for children have access to a rapid response team, and this may limit the utility of a trigger-based system. However trigger systems are generally easier to use and eliminate the additional mathematical calculation required by score-based systems.

1.2.10 Mechanisms by which track and trigger systems may work

Track and trigger systems have been used to identify patients on wards outside of critical care who are at risk of clinically deteriorating, in order that timely attendance by appropriately skilled staff can be ensured.[36,51] Despite their widespread use, there is still limited understanding of the mechanisms by which they improve clinical management and patient outcomes.

Critical illness is often preceded by physiological deterioration.[18,20-22,24,52,53] Heart and respiratory rate, temperature, blood pressure, oxygenation and consciousness are commonly monitored in hospitalised patients with the aim of detecting the early signs of deterioration.[54] However studies have demonstrated that nursing and healthcare support workers often fail to interpret these signs correctly, and opportunities to intervene and possibly avert adverse events such as cardiac arrest are consequently lost.[26,30,52,55-60]

Track and trigger systems are intended to facilitate objective decision-making and, thus, aid the timely recognition of developing critical illness in patients outside of the critical care setting.[53] As described in section 1.2.8, they ‘track’ the patient’s progress and when thresholds for abnormal values are breeched ‘trigger’ or prompt the staff member to intervene. Although this has been perceived as the primary mechanism by which these systems improve the management of patients, other benefits are emerging.

Vital signs are a core component of track and trigger systems[36,41,43,61] Introduction of a track and trigger system often prompts the development of associated policies and guidelines which specify the expected standard for vital sign monitoring.[37,62] This has been associated with improved frequency and completeness of vital sign monitoring[63-69] Introduction of a track and trigger systems may also prompt a review of the observation chart design, which has been linked with improvements to the recognition of abnormal vital signs and the speed of response.[70-75]

Improve communication between healthcare professionals may be another benefit of track and trigger systems. Score-based systems have been described as valuable by staff as they provide quantifiable evidence of the patients deterioration.[76-81] This can be particularly useful for junior staff who find it difficult or stressful to escalate a deteriorating patients condition to senior colleagues. Rather than reporting changes in individual vital signs, the track and trigger score effectively 'packages' them together.[77] This results in a 'shared language' between different professional groups.[82] and has been reported to offer a more precise, concise and unambiguous means of communicating deterioration, with a subsequent increase in nursing confidence.[77-79,81]

More recently, researchers have reported that track and trigger systems may have a positive impact on situational awareness. Situational awareness is (i) the perception of data elements, (ii) the comprehension of their meaning in context and (iii) the projection of their status in the near future.[83,84] More simply, it is described as "knowing what's going on".[85] A study of situational awareness in the paediatric setting reported that PTTS can improve situational awareness by providing an objective assessment framework and shared training and language regarding patient risk.[83] Other researchers have also reported benefits in terms of stronger team-working and empowerment of junior staff.[63,79,81]

1.2.11 Sub-optimal use of track and trigger systems

1.2.11.1 Deficiencies in the use of adult track and trigger systems

The use of track and trigger systems is now considered standard practice for adults in the UK. Despite widespread use they have failed to demonstrate significant improvements in mortality and morbidity. The reasons are unclear but deficiencies in their use by clinical staff have been identified as a contributing factor.

Errors in the recording of track and trigger systems of between 64% to 86% have been reported.[49,86-91] These errors have been particularly prevalent in score-based systems, where accurate scoring requires correct allocation of parameter scores, correct summation of sub-score values and documentation of total scores.[90] Absent track and trigger scores have also been noted, with only 50% to 69.5% of observation sets having a corresponding track and trigger score.[49,54,86,92] Errors have resulted in both under and over scoring,[49,88,90] but the clinical impact on patients remains uncertain. However, under-scoring errors have been noted to result in a lack of clinical escalation.[89] Patients with more deranged vital signs appear to be at greater risk of mis-scoring.[49]

Infrequent and incomplete recording of component observations have also been identified as problematic. The pattern of vital sign recording has been identified as variable, with infrequent recordings at night.[93] More recent evidence has suggested that alerts for patients who were becoming physiologically unstable were commonly missed when observation sets were incomplete.[94] A review of deaths reported to the UK national safety database identified that 14 of the 64 patients had no observations for a prolonged period prior to death. In 30 patients vital signs were recorded but not acted upon.[60] Deficiencies in observation recording following surgery have also been noted, with only 17% of patients having the minimum level of vitals signs documented in the first three post-operative days.[95] Just 33.1% had a full set of vital signs recorded each nursing shift for the first six post-operative days.[96] Recording of respiratory rate in particular was highlighted as poor.[69,97-100]

Even when track and trigger systems are recorded as intended, the system is not always acted upon. A cluster randomised controlled trial of MET versus traditional cardiac arrest teams in Australia demonstrated no significant difference in rates of cardiac arrests, unplanned admissions to intensive care and deaths.[101] There was no difference in the rate of calls to the MET versus the cardiac arrest team for patients breeching the MET criteria for cardiac arrest (30% vs 44%, $p = .031$), unplanned intensive care admissions (51% vs 55%, $p = .596$) and unexpected deaths (50% vs 55%, $p = .660$). The overall call rate was sub-optimal in both groups. Communication between nurses and doctors has been highlighted as inadequate[102] and this may contribute to insufficient activation of the MET. Delayed or missed MET activation has been identified by other non-randomised studies, and this has been noted even with systems considered to be well-developed and established.[92,103-110]

Several studies have examined the reasons for these deficiencies. Interprofessional relationships,[81,111] teamworking,[81,111] and institutional hierarchy[81,112,113] have been identified as contributory factors by nursing and medical staff. Deficiencies have also been attributed to the inexperience of nurses[111,114] and doctors,[102,111] nursing workload,[111] and shortages of both medical and nursing staff.[113]

1.2.11.2 Deficiencies in the use of paediatric track and trigger systems

There are indications that, similar to the care delivered to adults, PTTS may not always be used effectively. Studies evaluating the predictive validity of PTTS have reported wide variation in the completeness of observation recording, with 5- 89% of observation sets having all the necessary components simultaneously recorded.[115,116] The recording of blood pressure has been reported as particularly poor.[59,117]

Missing PTTS values in 15% of observation sets have been reported.[115] In a study of PTTS implementation only 71% of patients had their PTTS value recorded every four hours, notwithstanding this being the required standard. Inaccuracies in the PTTS value were noted in 9% of cases. This was despite a hospital wide education and assessment process.[118] For age-dependent PTTS, documentation on an incorrect age-appropriate chart has been noted in 3% of vital sign recordings.[119]

1.3 Motivation for the thesis

1.3.1 Gaps in the research on paediatric track and trigger systems

The use of PTTS has been advocated for all children in hospital. There is evidence that they are gaining momentum and that the majority of centres caring for children currently use them.[43] However evidence to support their use is largely based on outcomes of confidential reviews and evidence extrapolated from adult studies. Track and trigger systems are an accepted part of care for hospitalised adults following numerous studies highlighting sub-optimal care prior to intensive care admission, cardiac arrest and death on the wards.[20,21,26,27,58,120] They are recommended by NICE despite the associated systematic review identifying little evidence of their reliability, validity and utility.[36] The significant body of evidence of sub-optimal care of hospitalised adults made a compelling case for the use of track and trigger systems. However they have not, as yet, delivered the large improvements in morbidity and mortality that were hoped for.

Research on PTTS is far more limited and has not, as yet, been subject to systematic review. The number and nature of published PTTS is unclear. The evidence to support their use in terms of validity, reliability and utility has not been summarised and no meta-analysis has been performed.

We know that many differing PTTS exist.[43] We do not, as yet, know if there are significant differences in their performance. The characteristics of the best performing PTTS have not been identified and it is currently unclear whether scoring or triggering systems may be best and under what circumstances. Only one study has compared the performance of three PTTS in predicting actual or impending cardiac arrest.[121] No studies have compared the ability of different PTTS to predict unplanned admission to PICU or unexpected death on the ward.

Studies of adult track and trigger systems have indicated that they may not be reliably used in clinical practice. Documentation may be less frequent at night and at the weekend.[93] There is a lack of paediatric studies on the frequency and completeness of vital sign and PTTS recording. Of the limited paediatric studies available most have evaluated practices at or close to the time of implementation of a PTTS. Although inaccuracies in PTTS calculation have been observed, no studies have described the prevalence of, or reasons for, these errors. In particular, the clinical significance and nature of scoring errors have not been quantified. Errors of over-scoring will waste resources and may increase anxiety in children/young people, their families and healthcare staff. Underscoring may lead to missed detection of developing critical illness and impact on morbidity and mortality. Understanding the nature of these errors may identify aspects which are amenable to change.

Understanding the experiences of patients is an essential component of high quality care. In hospital, the relationship between child patient's, parents and nurse is characterised as a partnership and differs from the relationship experienced by adult patients. A small number of adult and paediatric studies have explored family activation of a rapid response team (RRT).[122-127] However, the majority of current PTTS are activated exclusively by healthcare professionals, despite the acknowledgment that parents contribute a unique understanding of their own child.[128] It is unclear, in these circumstances, whether PTTS provide children, young people and families with reassurance or raise their level of anxiety. Paediatric nursing is built on a partnership between children, young people and families but it

is unclear how much partnership is involved in monitoring and acting on PTTS. The first step is to explore their views on the use of PTTS. Finally nurses are the professional group who record and act on PTTS. It is unclear whether they find PTTS helpful.

1.3.2 Questions and problems

Four main research questions have been identified:

1. What are the number, nature and characteristics of published PTTS and what is the evidence of their validity, reliability and utility?
2. Does predictive validity, as assessed by the area under the receiver operator characteristic curve (AUROC), vary between differing PTTS and can the substitution of percentile-derived thresholds for heart and respiratory rate improve performance?
3. When PTTS are used in clinical practice are they reliably recorded, accurately calculated and appropriately escalated?
4. What are the views of children/young people, their families and ward nursing staff on PTTS?

1.3.3 The value of this research

Over 3000 children die each year in the UK. Although many die from life-limiting conditions which are not ameliorable to treatment, there is evidence that some deaths are unnecessary.[3] The death of a child is a life-changing event for families and carers and can have a profound effect on healthcare providers.[129] Prevention of unnecessary childhood death is therefore a priority to healthcare providers, families and carers alike.

The use of PTTS to facilitate early identification of children who are deteriorating has been advocated. Use is now widespread despite limited evidence of their validity, reliability and utility.[43] Greater understanding of these factors will allow clinicians and managers to make informed choices about whether to implement a PTTS or not. If a decision is made to implement a PTTS, this research may identify which one might be best and under what circumstances. For scoring systems, performance at differing scoring thresholds will allow escalation algorithms to be developed which match the needs and resources of the hospital.

Understanding the prevalence and nature of scoring errors will assist with identifying the limitations of PTTS and provide a framework for the training and education of staff.

Finally understanding the views of children, young people and their families about PTTS will allow nurses to structure their communication about PTTS in a more meaningful way. Engaging with children, young people and families in this way strengthens the philosophy of partnership working. Children, young people and families may also identify improvements that can be made to PTTS. Understanding the views of the staff who monitor and act on PTTS may provide greater insights into why implementation and utilisation are not always successful.

Detecting and acting on the signs of deterioration is complex and influenced by many factors.[111] This series of linked studies will support the development, implementation and use of PTTS in clinical practice.

1.3.4 Motivation for this research

The motivation for this research grew from a need to address real-world problems identified in the course of my work as a paediatric nurse.

In 2003 a decision was made in my hospital to implement a PTTS in light of national recommendations and NHS governance requirements. I was asked to lead the process. The lack of high quality evidence meant decisions were made on a pragmatic basis. We chose to implement a locally developed PTTS, the Children's Early Warning Score or CEWS. Whilst there was some improvement and standardisation in practice, the impact on outcomes such as unplanned PICU transfer, cardiac and respiratory arrest and mortality was uncertain. This research sets out to address some of the gaps in the literature that I identified during that process.

1.4 My research

1.4.1 Overall aim of the thesis

In this thesis I will present a series of linked studies on PTTS which summarise the current evidence on PTTS and explore aspects of their validity, reliability and utility. The thesis will be structured around the safe system framework described in section 1.2.6, Figure 1.5 and Table 1.5. This will provide an underpinning framework to link

the studies, placing them within the national context for managing deterioration in hospitalised children.

1.4.2 Component studies

The aim of this thesis is to explore some aspects of PTTS usage. It is a multi-method series of linked studies on important aspects of PTTS. Exploration of these factors may identify aspects which are ameliorable to change to optimise the impact of PTTS.

The first study is a systematic review of the number, nature and characteristics of published PTTS and an appraisal of the evidence on their validity, utility and reliability.

The second study compares the predictive validity of 17 published PTTS identified through the systematic review, together with the local PTTS in use at the time of the study. A retrospective case-controlled methodology was selected as this allowed comparison of the differing PTTS without exposing the patients to unnecessary risk. Patients who suffered a critical deterioration event were matched 1:1 with 'stable' children. Sensitivity, specificity, positive/negative predictive values, likelihood ratios and the area under the receiver operator characteristic curve were calculated. Systems were then modified by the addition of percentile-derived heart and respiratory rate thresholds and re-evaluated to see if performance improved.

Reliability of PTTS monitoring and escalation was then examined through a case-controlled study. Vital sign observation sets were examined for frequency, completeness and errors in PTTS scoring. Nursing care was assessed through adherence to the local PTTS protocol and compliance to the escalation of elevated PTTS scores.

Finally, utility of PTTS was explored through semi-structured interviews with 15 parents and 10 children, and six focus groups with junior and senior nurses to elicit their experiences of vital sign and PTTS monitoring. Results were analysed using the framework approach.

1.4.3 Boundaries of the thesis

In this thesis I have not sought to evaluate all aspects of PTTS validity, reliability or utility. I have chosen to look at selected 'real world' problems encountered when implementing and using a PTTS. The findings may be of most relevance to other

specialist children's hospitals, particularly those without an emergency department. However given the increasing acuity of hospitalised children, findings may have relevance for patients in the secondary care setting.

Validity will look at predictive validity assessed by the AUROC, sensitivity and specificity for the composite outcome of critical deterioration. It will not look at validity across the individual outcomes of death, cardiac or respiratory arrest and unexpected death on the ward, nor will it explore validity of alternative outcomes such as length of PICU stay.

Reliability will examine the completeness of the recording of component parameters of the PTTS and accuracy of the calculation of the PTTS score. It will not look at inter-rater reliability or intra-rater reliability.

Utility will be examined through qualitative evaluation of the experiences of front line nurses, patients and their families. It will not seek to examine the views of other important PTTS users, such as doctors or nurse managers, not will it look at economic aspects through a cost-benefit analysis.

1.4.4 Structure of the thesis

Chapter two is a systematic review and pooled analysis of PTTS. This provides a foundation to the thesis by identifying the strengths and limitations of the research promoting 'open and consistent learning' and increasing knowledge on the 'recognition of deterioration' identified by the safe system framework[33] for children at risk of deterioration.

Chapter three compares the validity of 18 PTTS and the national early warning score (NEWS) in their ability to detect critical deterioration. This supports the recognition of deterioration within the safe system framework.[33]

Chapter four explores the reliability of PTTS used in practice in terms of their accuracy and completeness. It also explores compliance to the monitoring and escalation protocol in the clinical setting. This chapter supports the recognition and response to deterioration and open and consistent learning within the safe system framework.[33]

Chapter five examines the utility of PTTS by exploring the views of children/young people, families and nurse of PTTS. Partnership with patients and families is cited

as an area of priority and growth with the safe system framework[33] and is considered central to the support of other core elements.

Finally in chapter six the findings are synthesised. The studies are related to the safe system framework[33] and recommendations are made for clinical practice and future research.

Chapter 2 A systematic review of paediatric track and trigger systems

2.1 Introduction

The purpose of this chapter is to systematically review the literature on paediatric track and trigger systems (PTTS). Systematic reviews provide a summary of evidence relating to a specific question. They differ from narrative reviews by applying rigorous methodology to the search, appraisal and synthesis process[130] to make the available research more accessible to clinicians.[131]

> *A systematic review attempts to identify, appraise and synthesise all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question. Researchers conducting systematic reviews use explicit methods aimed at minimising bias, in order to produce more reliable findings that can be used to inform decision-making.*
>
> (University of York p v[132])

The systematic review contributes to the safe system framework by promoting open and consistent learning. Identifying, summarising and synthesising evidence in this way facilitates research to be adopted into practice and informs clinical decision-making.

The methodology adopted for the review is firstly described and justified. The number and nature of PTTS are summarised and the evidence for their validity, calibration, reliability and clinical utility are rigorously evaluated. Where possible, results are pooled to improve the power of small or inconclusive studies. The evidence is synthesised and recommendations for clinical practice advanced. This will underpin the subsequent thesis by identifying strengths and weaknesses in the evidence.

2.1.1 Validity

Validity is the degree to which an instrument measures what it is supposed to be measuring. In the context of PTTS, this is the ability to discriminate between 'well' children and those 'at risk' of developing critical deterioration at a sufficiently early stage in their illness for intervention to be effective. A variety of statistical tests have been employed to assess diagnostic accuracy, most commonly in terms of

sensitivity, specificity, positive and negative predictive value and receiver operating characteristic (ROC) curve analysis.

2.1.1.1 Sensitivity and specificity

Sensitivity (the true positive rate) is the proportion of patients with critical deterioration who triggered the PTTS at a given scoring threshold.[133] Assessment of sensitivity is 'retrospective', in that it shows the probability that a child suffering critical deterioration will have a 'significant' PTTS score. Specificity (the true negative rate) is the proportion of 'well' patients without critical deterioration who did not trigger the system at a given scoring threshold.[133] Specificity demonstrates that a 'well' child will have a non-significant, low score.

High sensitivity will ensure that children who are at risk of critical deterioration are accurately identified, whilst high specificity will prevent unnecessary reviews and interventions in children who are not at risk of deterioration, protecting scarce resources. The ideal PTTS will have high levels of both sensitivity and specificity and appraisal of these values at differing scores can identify the most appropriate thresholds for clinical intervention.

2.1.1.2 Receiver operator characteristic curve

In scoring-based PTTS, values for sensitivity and specificity depend on the scoring-threshold selected. Higher levels of sensitivity can be achieved but at the expense of lower specificity. The ROC curve plots sensitivity against 1-specificity for each of the score thresholds. Overall predictive validity is assessed by calculating the area under the curve. Larger values represent better predictive ability.[134]

2.1.2 Calibration

Calibration is the degree to which differing PTTS scores agree with the observed outcome. It is appraised by plotting the observed against the predicted outcome.[134] A perfectly calibrated PTTS would display a 45^{O} straight line. Poor calibration has been noted as easier to resolve than poor discrimination.[134]

2.1.3 Reliability

Reliability is the extent to which a test will yield the same results over time or with different observers. Incomplete recording of component vital sign parameters and incorrect calculation of PTTS values will impact the reliability of the score. Effective use of score-based PTTS also require adherence to the escalation protocol.

2.1.4 Utility

Clinical utility has traditionally been associated with evidence on the effectiveness of an intervention. However it has been suggested that this narrow view of clinical utility excludes practitioners' views on the usefulness, benefits and potential drawbacks of an intervention.[135] A model to describe clinical utility has been proposed which encompasses four dimensions (Table 2.1).[135]

Table 2.1 Multi-dimensional model of clinical utility

Component	Aspect	Issues that might be considered
Appropriate	Effective	Formal evidence of effectiveness
	Relevant	Impact on existing treatment process and importance for clinical decision-making
Accessible	Resources	Cost and cost-effectiveness
	Procurement	Availability, supply and quality
Practicable	Functional	Is the tool fit for purpose and ready to use
	Suitable	Is the tool suitable for use in the clinical setting?
	Training and knowledge	Levels and costs of training required
Acceptable	To clinician	Ethical, legal, societal, or psychological concerns and preferences to clinicians, children and families and society at large
	To patients/ families	
	To society	

Adapted from a multi-dimensional model of clinical utility derived from a review of the literature described by Smart[135]

2.1.5 Initial systematic review

An initial systematic review was undertaken in 2009 at the start of the PhD process. The aim was to identify the key characteristics and evidence for the clinical utility,

reliability and validity of PTTS together with the strengths and weaknesses of the evidence base.

The review followed the 2009 NHS Centre for Reviews and Dissemination (CRD) guidance on conducting systematic reviews of interventions and clinical tests in healthcare,[131] the methodology recommended at the time by leading healthcare journals and bodies such as the National Institute for Health and Care Excellence (NICE) and the Cochrane collaborative. Methodological quality was assessed using the Scottish Intercollegiate Guidelines Network (SIGN) grading system.[136]

In February 2009, eleven papers[39,40,42,137-144] describing 10 PTTS were identified from the literature. Six studies described the introduction and use of the PTTS,[39,40,139-141,143] Four examined the development and testing of the system,[42,137,138,144] and one described both.[142] There was marked variability across all aspects of the PTTS, including the method of development, and the number and type of component parameters. As a result, the evidence supporting the validity, reliability and utility of PTTS was characterised as weak and further research was recommended before their widespread adoption into clinical practice could be advocated. The findings were published in a leading critical care journal in 2010[4] and are summarised in Table 2.2.

Table 2.2 Major findings of the initial systematic review

	Main findings
Methodology	NHS Centre for Reviews and Dissemination guidance on systematic reviews of interventions and clinical tests in healthcare.[131]
Search strategy	Database search: CINAHL, Cochrane Library, Database of Reviews of Effectiveness, EMBASE and Medline from January 1990 to February 2009. Hand searching of reference lists and citation search of papers identified by database searching. Correspondence with experts and lead authors.
Search results	Eleven papers[39,40,42,137-144] describing 10 systems.
General characteristics	Marked variability across all aspects including the method of development, type of system, and the number and type of parameters.

	Main findings
Validity	Five studies[42,137,138,142,144] explored the predictive validity, but only three[137,138,144] used appropriate methodology and analysis.
Clinical effectiveness	Only one study evaluated the effectiveness of implementing a PTTS[144]. However five papers reported the effect of a rapid response team activated by a PTTS[40,139,141-143] of which two[141,143] reported statistically significant improvements in hospital wide mortality, code rates and 'preventable' cardiopulmonary arrest.
Reliability	One study evaluated reliability,[144] which was found to be high.
Utility	No studies evaluated utility, other than effectiveness.
Implications for practice	The lack of evidence on PTTS raises concerns about widespread adoption without more research. Hospitals with a track and trigger system should monitor and modify their system. Hospitals considering introducing a PTTS should consider systems that meet their local needs and patient population.
Implications for research	Further studies on validity, reliability and clinical utility and the impact of PTTS on patient outcomes are needed. Age-related thresholds for vital signs and their role in identifying physiological instability warrants further investigation.
Conclusion	The role of PTTS in aiding early detection of critical deterioration in hospitalised children has not, as yet, been demonstrated.

The table summarises the findings of the initial systematic review. The full publication can be seen at Appendix 12.1.

2.1.6 Developments since the initial systematic review.

In chapter one a considerable increase in the use of PTTS over recent years was reported. A cross sectional survey of UK hospitals with paediatric services in 2013 identified that 83% of district general hospitals and 90% of tertiary care hospitals had a PTTS in place. This was in contrast to the findings of an earlier survey in 2005, which identified only 21.5% of centres with a PTTS in place.[41]

Respondents to the 2013 survey were asked to identify the origin of their PTTS (Table 1.7). Only a third of respondents reported that their system was based on a previously published tool, with the remainder using a mix of systems adapted from those in other hospitals and those purposely designed for the individual unit. A total of 47 different parameters were identified within the reported PTTS, an increase from 36 in 2005. Respiratory and heart rate remained the most commonly cited parameters in both surveys.

The authors of the 2013 survey recommended a collaborative approach to PTTS similar to that led by the Royal College of Physicians in respect of identifying the deteriorating adult patient.[43,44] The authors proposed that respiratory rate, heart rate and oxygen saturation levels be considered core parameters as they were the top three items in the survey results. They also suggested that conscious level, respiratory effort, nursing concern, blood pressure and oxygen therapy should be considered for inclusion on the basis that at least 50% of units currently included these items in their PTTS and they had also been highlighted in a systematic review of clinical features of serious illness in children.[45] They suggested that the ideal PTTS would accurately identify patients who are deteriorating sufficiently early in the course of their illness to mobilise expert help. They advocated that, if PTTS are to be widely accepted and adopted into clinical practice, they must be simple to use and acceptable to the end user.

In light of the findings of the 2013 survey an updated review was conducted in 2015 towards the end of the PhD process to see if the initial findings are still valid. The findings of this updated review will be reported in detail.

2.2 Systematic review methodology

2.2.1 Aim of the systematic review

The systematic review is intended to assess the evidence on the use of PTTS to detect critical deterioration in hospitalised children. For the purposes of this review, PTTS were defined to be any system which attempts to identify – through ongoing monitoring of clinical signs (either alone or as part of a package of interventions) – hospitalised children who are at risk of, or suffering from, critical deterioration. Children in critical care units, theatres and the emergency room were excluded

because differing strategies to detect deterioration are employed and these environments have differing levels of monitoring and staffing.

2.2.2 Research questions

1. What are the characteristics, key features and parameters of PTTS?
2. What is the evidence for the predictive validity of PTTS?
3. What is the evidence for the calibration of PTTS?
4. What is the evidence for the reliability of PTTS?
5. What is the evidence for the clinical utility of PTTS?

2.2.3 Review method

The review followed the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.[145] GRADE is recommended as it offers a transparent and structured approach for developing and summarising evidence for systematic reviews. GRADE is now widely endorsed by peer review journals and organisations such as the Cochrane collaborative and NICE.

Within GRADE, the scope of the review is firstly framed using the PICOS (Participants, Intervention, Comparison, Outcome, Study design) approach. Outcomes are then identified and rated in terms of their importance to patients.[146] Evidence is systematically searched and assessed against the PICOS criteria. The quality of evidence for each patient-important outcome is then assessed across all studies, rather than for each individual study. A body of evidence is rated as high, moderate, low or very low quality (Table 2.3).

Table 2.3 GRADE quality definitions

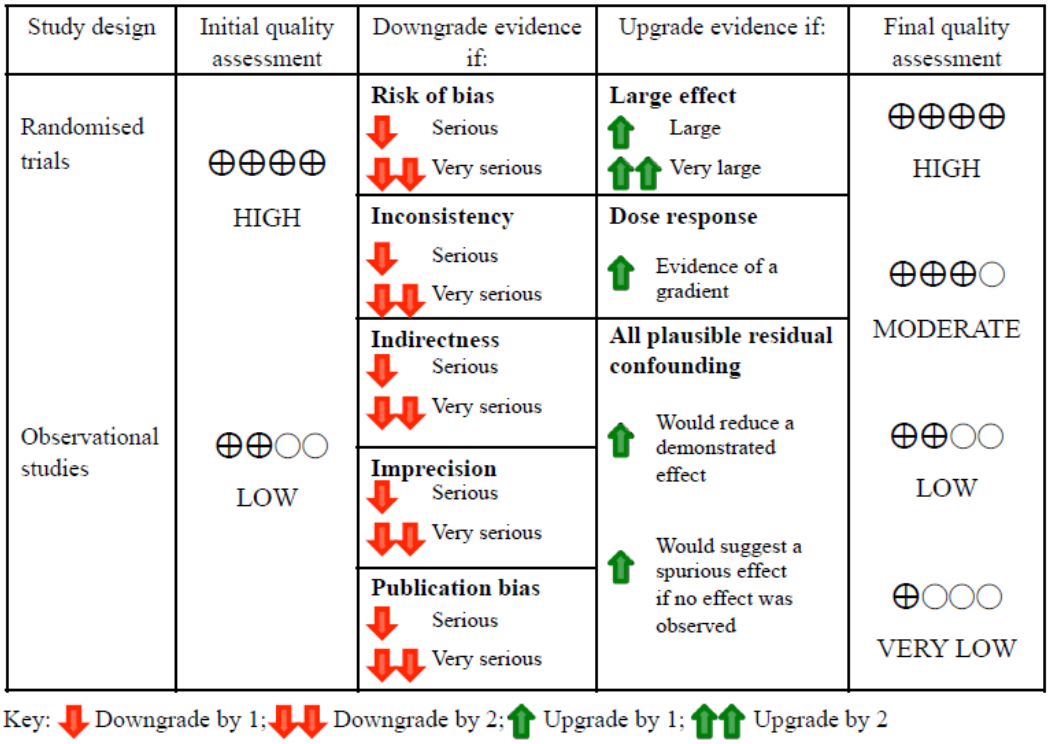
Quality level	Icon	Definition
High	⨁⨁⨁⨁ HIGH	We are very confident that the true effect lies close to that of the estimate of effect
Moderate	⨁⨁⨁◯ MODERATE	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different
Low	⨁⨁◯◯ LOW	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect
Very low	⨁◯◯◯ VERY LOW	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Reproduced from GRADE[147]

Quality of evidence undergoes systematic ranking within GRADE. Figure 2.1 summarises the factors which can increase or decrease the quality assessment. Randomised controlled trials start as high quality evidence, and observational studies as low level. This is seen in the first and second columns on the left of Figure 2.1. Five factors can lead to the evidence being downgraded. This is shown in column three. Risk of bias across the studies, inconsistency between and across the studies findings, indirectness (indicated by differences in outcome measures, study populations, interventions or indirect comparisons) and imprecision of the findings (indicated by wide confidence intervals or small sample size) and publication bias can result in the initial quality assessment being decreased by one or two levels dependent on the severity. Three factors may result in evidence being upgraded. Where the studies demonstrate a large or very large magnitude effect, the initial quality assessment can be upgraded by one or two levels. The presence of a dose-response gradient may also result in evidence being upgraded, but by a maximum of one level. On occasions, all plausible residual confounding from

observational studies may be working to reduce the demonstrated effect or increase the effect, if no effect was observed. This can lead to evidence being upgraded by one level. Once all the adjustments to downgrade or upgrade the evidence have been made, the final quality assessment, seen in the far right column, is determined.

Figure 2.1 Summary of the GRADE approach to quality assessment



The table represents a summary of the factors affecting the quality rating.
The initial quality assessment is determined by the study design, however the quality rating can be downgraded and/or upgraded according to the above factors. The final quality assessment is shown in the far right column.
Adapted from GRADE[147]

When presenting results, GRADE recommends evidence profiles. The profile presents a detailed assessment of the quality of the evidence together with a summary of the findings for each important patient outcome. Evidence for diagnostic tests are often indirect, with research focusing on the accuracy of the diagnostic test itself rather than the effect of the test on patient important outcomes. Inferences must be made about the likely impact of the test in terms of the available outcomes (true positives, true negatives, false positives, false negatives). However, diagnostic accuracy can still provide important information to clinicians.[145] In this situation,

cross-sectional and cohort studies start as high quality evidence but can move to low or very low quality dependent on other factors.[147]

2.2.3.1 The scope of the review

The scope of the review was outlined by the PICOS criteria as seen in Table 2.4.

Table 2.4 PICOS criteria for the systematic review

Participants	Hospitalised children (0-18 years) on paediatric wards excluding critical care, theatre, accident and emergency
Intervention	Development, use or evaluation of a PTTS to detect clinical deterioration
Comparison	PTTS use (either alone or as part of a package of care) versus normal care
Outcome	Any patient related outcome including (but not restricted to) death, admission to intensive care, cardiac and/or respiratory arrest, patient/family satisfaction Any user related outcomes including (but not restricted to) staff satisfaction, inter-user reliability, utility
Study design	All designs excluding reviews

2.2.3.2 Outcomes of interest

Primary outcomes were identified from the previous systematic review, the candidate's knowledge of the literature and clinical expertise. The identified outcomes were then ranked in terms of their importance to patients using the framework from adult studies and the researcher's clinical expertise (Table 2.5). No outcomes were ranked as being of low importance (rank 1-3).

Table 2.5 Patient important outcomes

Importance and rank		Direct outcomes	Surrogate outcomes
Critical for decision making	9	Death	
	8	Cardiac arrest Respiratory arrest	CPR (chest compressions and/or bag-valve-mask) Call for immediate assistance Code Blue
	7	PICU admission	Severity of illness scores (PiM2) Severity of illness markers (pH, lactate) Treatment markers (days of ventilation, length of PICU stay)
Important, but not critical for decision making	6	HDU admission	Severity of illness scores (PiM2) Severity of illness markers (pH, lactate) Treatment markers (days of non-invasive ventilation, length of HDU stay)
	5	Length of hospital stay	Rapid response team activation Urgent call to a healthcare professional
	4		
Low importance for decision making	3		
	2		
	1		

Direct and surrogate outcomes were identified from the literature and candidates expertise. No outcomes were identified that were considered to be of low importance (rank 1-3).

Abbreviations: CPR: Cardiopulmonary resuscitation; **HDU:** High Dependency Unit; **PiM2:** Pediatric Index of Mortality 2; **PICU:** Paediatric Intensive Care Unit

2.2.3.3 Inclusion and exclusion criteria

Papers were included if they described the development, testing or use of a PTTS to detect critical deterioration in children on hospital wards. Reports and reviews were excluded. Studies set in the emergency department, operating theatre or critical care unit were excluded as were those concerning both adult and paediatric patients unless the data relating to children could be adequately separated.

2.2.3.4 Search strategy

The following databases were searched: AMED, CINAHL, Cochrane Library, EMBASE, and OVID PubMed. A broad search strategy was adopted, informed by a previous systematic review of paediatric alert criteria,[4] with Medical Subject Headings (MeSH) and free text searching using keywords in the title or abstract. Results were limited to papers from 1990 relating to children. Google scholar was searched using the terms paediatric early warning system/score, paediatric track and trigger system/score and paediatric rapid response/medical emergency team. Abstracts from the annual conferences of the Royal College of Paediatrics and Child Health (RCPCH), European Society of Paediatric and Neonatal Intensive Care (ESPNIC) and European Society of Intensive Care Medicine (ESCIM), together with the bi-annual World Congress in Paediatric Intensive Care were hand-searched from 2000 onwards.

After removal of duplicates, the title and abstract of records were screened by the candidate and the primary supervisor. Full-text papers were reviewed and the references and citations of eligible studies were manually searched on the Web of Science database. Uncertainty regarding inclusion of a paper was resolved through discussion within the supervisory team.

2.2.3.5 Data extraction:

Based on findings from the initial systematic review, three data extraction forms were developed for randomised control trials, observational studies and studies of diagnostic accuracy.[4] The main categories of data are summarised in Figure 2.2. Extracted data were entered into Microsoft Excel for Mac 2011 (version 14.4.7).

Figure 2.2 Data extracted

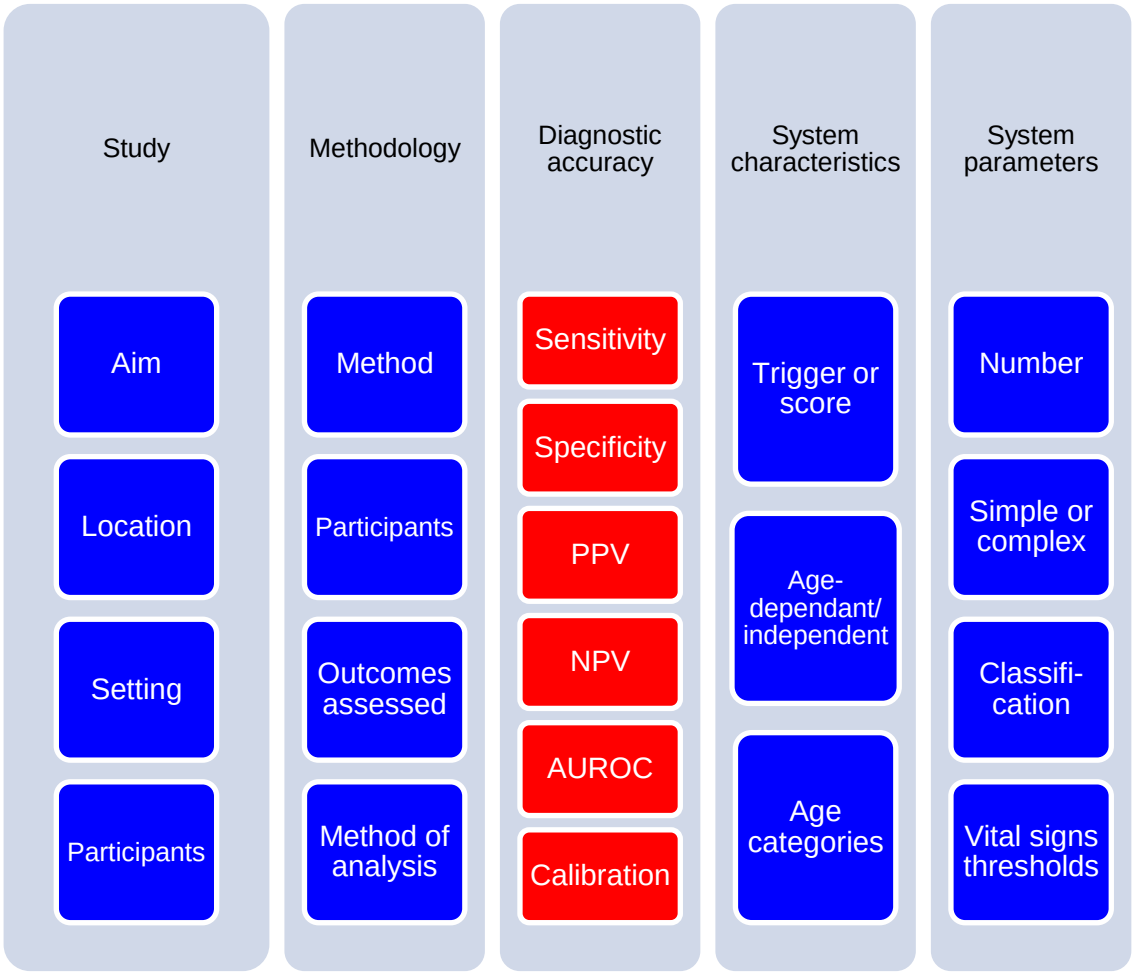


Figure summarises the main categories of data extracted from papers identified for inclusion in the systematic review.

Abbreviations: AUROC: Area under the reciver operator characteristic curve; **NPV:** Negative predictive value; **PPV**: Positive predictive value

2.2.3.6 Evidence appraisal and analysis.

PTTS were firstly categorised as '*scoring'* or '*trigger'* systems. Systems were then classified as being either '*age-dependent'* (multiple systems with differing age-related thresholds) or '*age-independent'* (a single system applied regardless of age).

Risk of bias for diagnostic accuracy studies were assessed using QUADAS 2[148] (Appendix 5.1). Remaining quantitative studies were assessed against criteria in the GRADE handbook[147] (Appendix 5.1). The risk of bias in qualitative studies was assessed using the Critical Appraisal Skills Programme (CASP) checklist (Appendix 5.3).[149] Pooled risk ratio and 95% confidence intervals for each outcome were

calculated using GRADE Pro GDT[150] and Vasser Stats.[151] The overall quality of evidence for each patient-important outcome was ranked following the GRADE approach. Evidence profiles were formulated in GRADE Pro GDT.[150]

Where sufficient detail was provided, the risk ratio and 95% confidence intervals for each outcome were calculated. Results were separated into studies examining the introduction of a PTTS alone and those introducing a PTTS as part of a package of interventions, such as a rapid response team. Predictive validity was also summarised.

2.3 Results

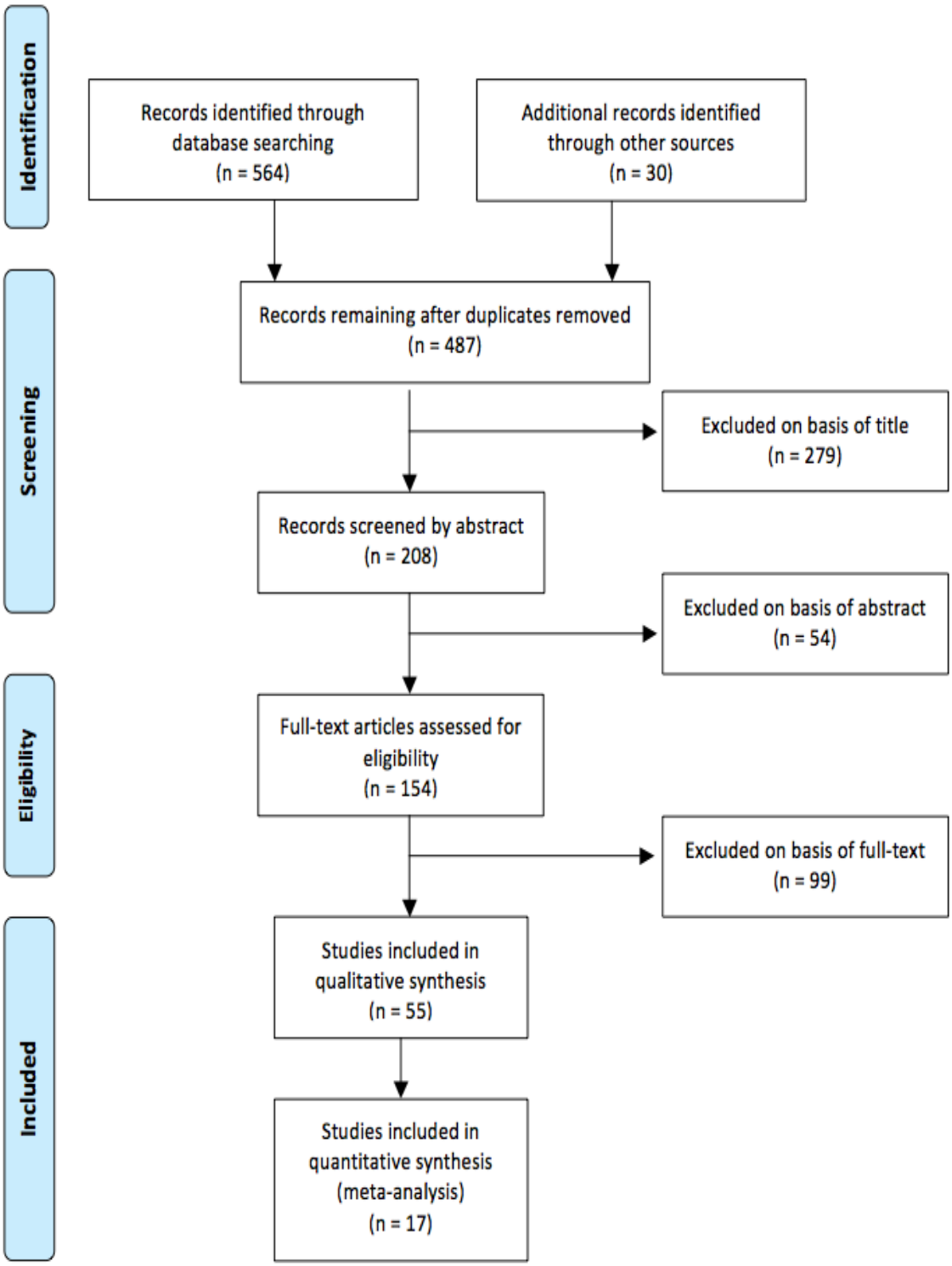
2.3.1 Search results

The search was conducted on 20th May 2016. An overview of the search results are shown in Figure 2.3. Database searching yielded 564 papers with another 30 identified from other sources (28 from grey literature, two from citation searching). After removal of duplicates 487 papers remained.

The abstracts of 208 papers were reviewed. Forty were excluded because the subject was inappropriate, 10 because the study was not set in the hospital ward and four because the participants were not children. This left 154 abstracts which required further review.

The full text of these 154 papers was obtained. Review papers (22) and papers with insufficient detail (42), such as conference abstracts and short reports were excluded. A further 19 papers were excluded as the subject (12) or setting (7) were inappropriate. Ten papers did not contain the outcomes of interest and six were excluded for other reasons, including research protocols (2), tools which only assessed clinical status on admission (2), cost benefit analysis (1) and electronic screening tools (1). This resulted in 55 papers for inclusion.

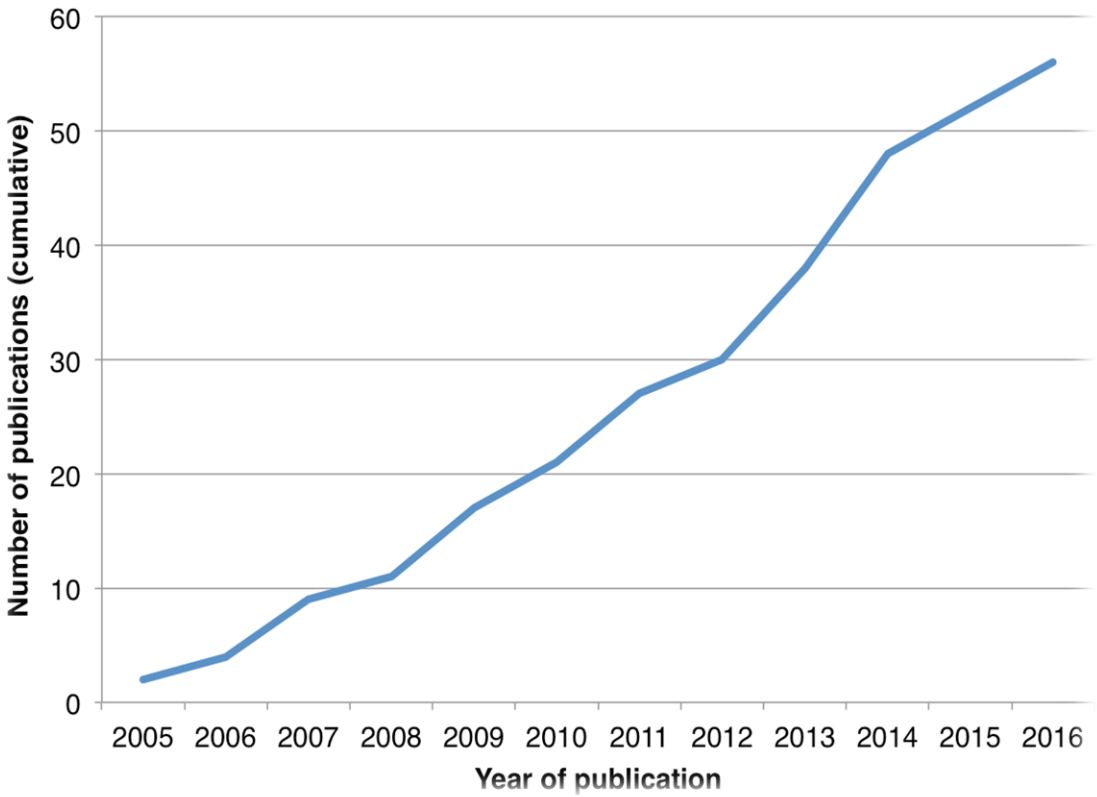
Figure 2.3 Search results



2.3.2 Included studies

All 55 studies were included in the qualitative synthesis with 17 suitable for quantitative pooled analysis. The first study was published in 2005 and there has been a steady increase in the number of yearly publications (Figure 2.4).

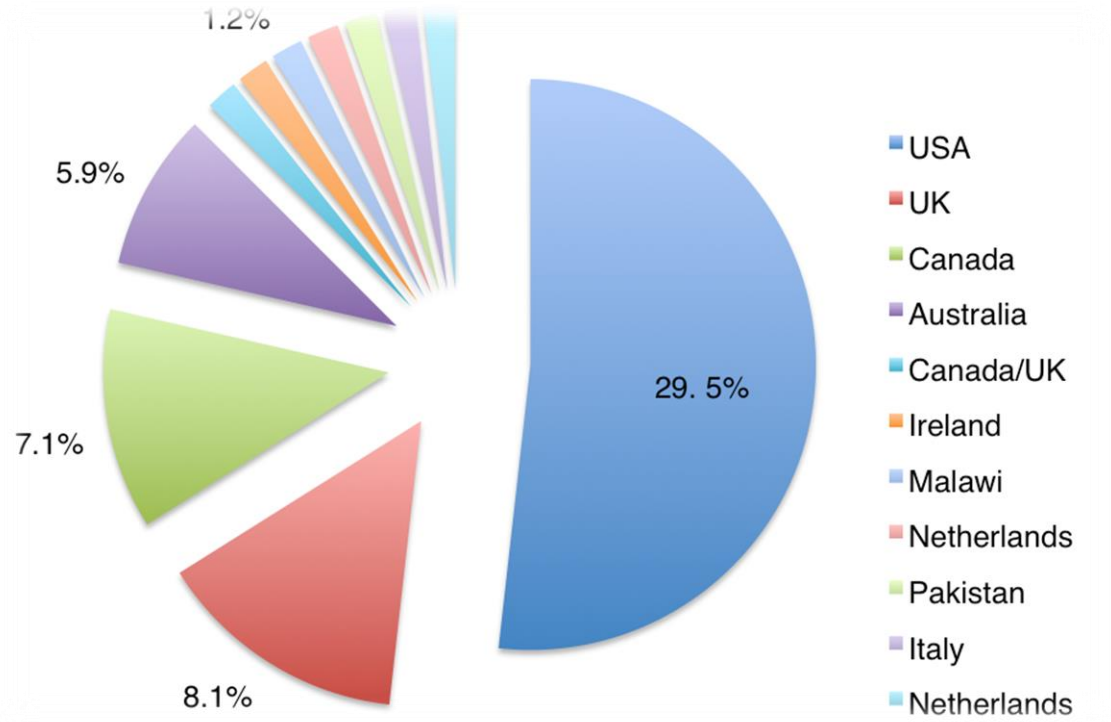
Figure 2.4 Number of publications per year (cumulative)



Note: Figure is cumulative, representing the total number of publications available in the literature for each year

The majority of studies were conducted in North America, with a number of studies in the UK and Australia. Single studies were carried out in Ireland, Malawi, Netherlands, Italy and Pakistan (Figure 2.5).

Figure 2.5 Country in which the study was conducted



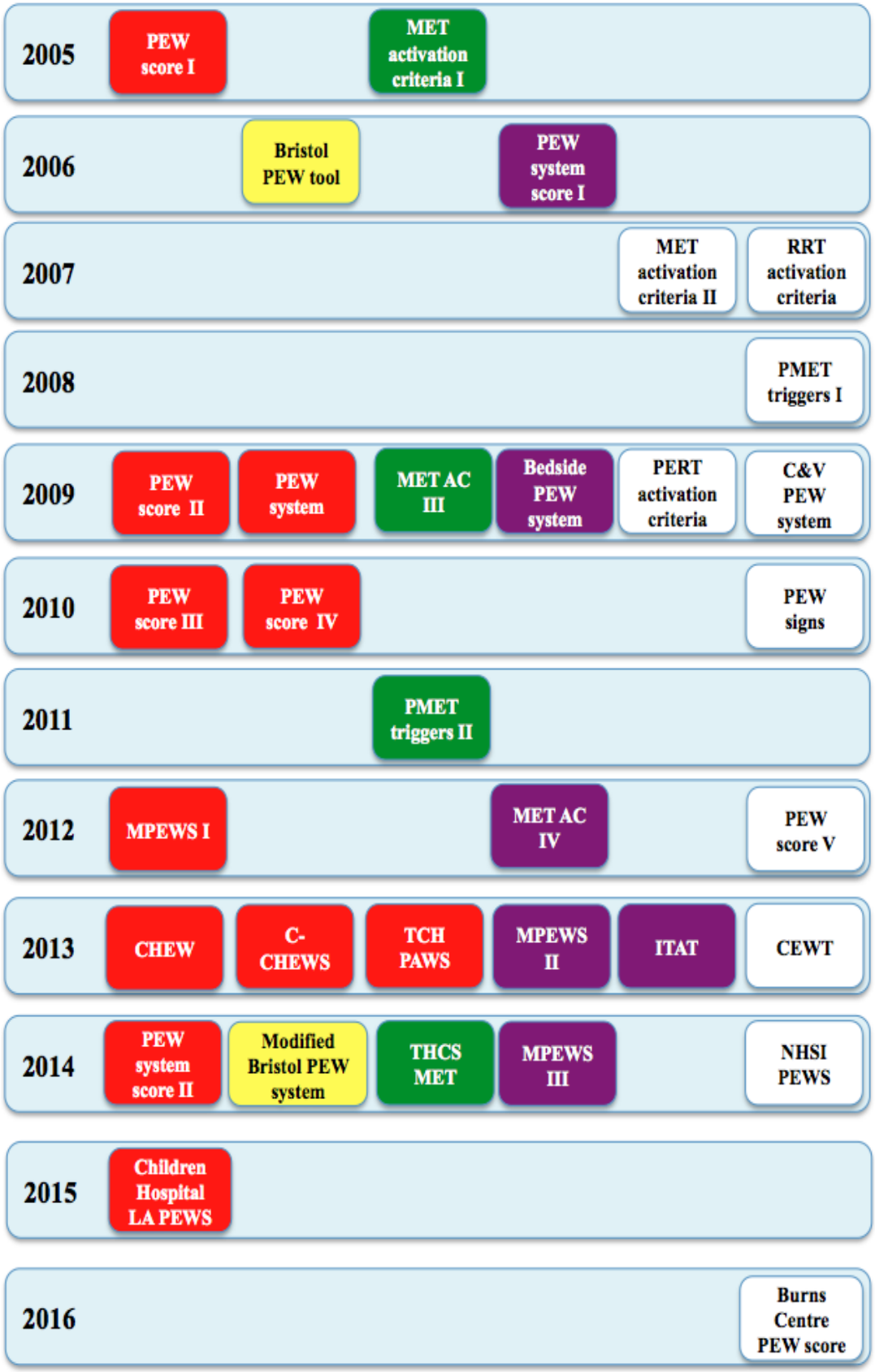
Pie chart shows the country where the study was conducted for the 55 papers included in the review

2.3.3 Published paediatric track and trigger systems

Thirty-three PTTS were identified. Different PTTS with the same name were numbered in order of publication to distinguish between them. Figure 2.6 represents an overview of the year each PTTS was first published. Many were minor modifications of previously published PTTS. Those PTTS reported to be based on a previously published tool are presented in the same colour. Single PTTS which were not identified as an adaption of a previously reported system are present in white.

The first published PTTS, the *Paediatric Early Warning Score I*[39] has been adapted 10 times. The *Paediatric Early Warning System Score I* underpinned five further systems, with the *Medical Emergency Team Activation Criteria I* spawning three variants. The *Bristol Paediatric Early Warning Score* was modified once. The remaining 11 PTTS were considered unique, although there were many shared characteristics with previous PTTS.

Figure 2.6 Year of first publication of identified PTTS



Footnotes can be seen on the next page

Footnotes to Figure 2.5.

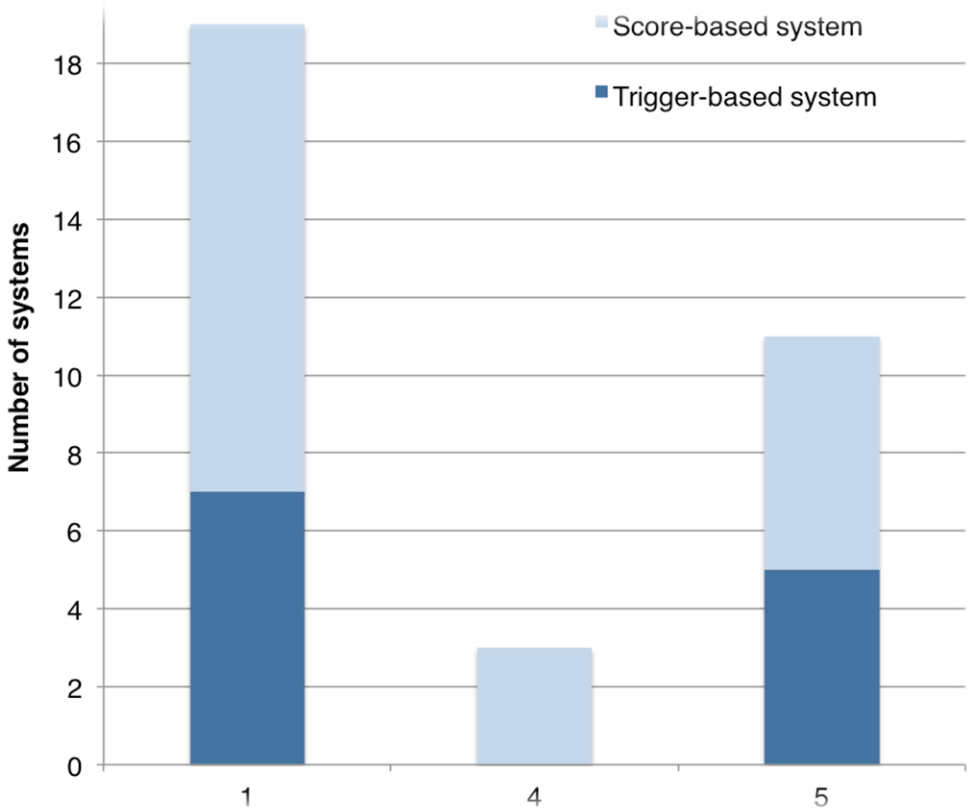
The 33 identified PTTS are presented by the year of first publication. Those PTTS which are adaptions of previously published tools are identified by the same colour. PTTS in white are consider unique.

Abbreviations: AC: Activation criteria**; C-CHEWS:** Cardiac Children's Hospital Early Warning Score; **CHEWS:** Cardiac Children's Hospital Early Warning Score; **CEWT:** Children's early warning tool; **ITAT:** Inpatient triage, assessment and treatment score; **LA:** Los Angeles; **MET:** Medical Emergency Team; **MPEWS:** Modified Pediatric Early Warning Score; **NHSI:** NHS Institute; **PAWS:** Pediatric Advanced Warning Score; **PERT:** Pediatric Early Response Team; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET:** Pediatric Medical Emergency Team; **TCH:** Texas Children's Hospital; **THSC:** Toronto Hospital for Sick Children

2.3.3.1 Types of system

Twenty-one systems were classified as ‘scoring systems’, and 12 as ‘trigger systems’. Fourteen were ‘age-dependent’ and 19 ‘age-independent’ (Figure 2.7).

Figure 2.7 Frequency of score and trigger based systems with one, four and five differing age-categories



Age-independent systems have a single category. Age-dependent systems had either four or five differing age categories

2.3.4 Key characteristics

Table 2.6 summarises the included studies, PTTS key characteristics and parameters, together with the quality rating for each study.

Two papers[152,153] reported a system for activation of a rapid response team but did not describe its characteristics. There was a wide variety in the number and type of parameters within the PTTS. The median number of parameters per system was six, with a range of three to 19. Some broader parameters shared the same name (such as ‘respiratory’ or ‘cardiovascular’) but were constituted from differing component parts or had differing thresholds for scoring/triggering.

Table 2.6 Overview of included studies, key characteristics and parameters

System	Paper (First author, year)	Country	Setting*	Score or trigger	Age categories (n)	Parameters (n)	Vital signs						Concern		Clinical indicators								Therapies		Other parameters	Risk of bias
							Oxygen saturation	Heart rate	Respiratory rate	Systolic BP	CRT	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Vomiting post-surgery	Airway threat	15-mimute nebulisers	Oxygen therapy		
Bedside PEWS	Parshuram 2009[154]	Canada	CH	S	5	7	✓	✓	✓	✓	✓									✓				✓		H
	Parsharam 2011a[119]	Canada	CCH																							H
	Parsharam 2011b[116]	Canada (3) & UK	CH																							L
	Robson 2013[121]	USA	CH																							H
	Bonafide 2014[155]	USA	CH																							L
	Kaul 2014[156]	USA	CH																							S
	Gawronski 2016[157]	Italy	CH																							H
Bristol PEW tool	Haines 2006[42]	UK	CH	T	5	14	✓[1]	✓[3]	✓				✓						✓						Apnoea ±bradycardia; DKA; clinically tiring or complete airway obstruction; GCS ≥ 11 or unresponsive or responding only to pain; hyperkalaemia; nebulised adrenaline; signs of shock (e.g. prolonged CRT (3s), poor perfusion, ± low BP); suspected meningococcus	H
	Tume 2007[59]	UK	CH																							H
	Robson 2013[121]	USA	CH																							H
	McLellan 2014[158]	USA	CH																							H

System	Paper (First author, year)	Country	Setting*	Score or trigger	Age categories (n)	Parameters (n)	Vital signs						Concern		Clinical indicators								Therapies		Other parameters	Risk of bias
							Oxygen saturation	Heart rate	Respiratory rate	Systolic BP	CRT	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Vomiting post-surgery	Airway threat	15-mimute nebulisers	Oxygen therapy		
Burns Centre PEWS	Rahman 2016[159]	USA	CH	S	1	7		✓	✓			✓				✓									Intake; Output; Skin	H
Cardiff and Vale PEWS	Edwards 2009[137]	UK	UH	S	5	8	✓	✓	✓	✓			✓		✓			✓				✓		✓		L
C-CHEWS	McLellan 2013[47] McLellan 2014[158] Agulnik 2016[160]	USA USA USA	CH CH CH	S	1	5							✓	✓	✓	✓	✓								Family absent	H H H
CHEW	McLellan 2013[47]	USA	CH	S	1	5							✓	✓	✓	✓	✓								Family absent	H
Children's Early Warning Tool	McKay 2013[67]	Australia	UH	S	4	9	✓	✓	✓	✓	✓	✓						✓		✓				✓		H
CH LA PEWS	Mandell 2015[161]	USA	CH	S	1	4									✓	✓	✓								Medical history	H
ITAT	Olson 2013[162]	Malawi	RH	S	5	4	✓	✓	✓			✓														H

System	Paper (First author, year)	Country	Setting*				Vital signs						Concern		Clinical indicators								Therapies		Other parameters	
				Score or trigger	Age categories (n)	Parameters (n)	Oxygen saturation	Heart rate	Respiratory rate	Systolic BP	CRT	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Vomiting post-surgery	Airway threat	15-mimute nebulisers	Oxygen therapy		Risk of bias
MET AC I	Tibballs 2005[40] Tume 2007[59] Kinney 2008[163] Edwards 2011[164] Krmpotic 2013[165]	Australia UK Australia UK Canada	CH CH CH UH CH	T	5	9	✓[1]	✓	✓	✓			✓					✓	✓	✓		✓		✓	Cardiac or respiratory arrest; apnoea or cyanosis	H H H L H
MET AC II	Brilli 2007[142]	USA	CH	T	1	4	✓						✓	✓				✓		✓				✓	*W*orsening retractions; Cyanosis	L
MET AC III	Tibballs 2009[141] Azzopardi 2011[166] Lobos 2014[167]	Australia Australia Canada	CH CH CH	T	5	9	✓[1]	✓	✓	✓			✓	✓				✓	✓	✓		✓		✓	Cardiac or respiratory arrest; apnoea or cyanosis	H S H
MET AC IV	Bonafide 2012[168]	USA	CH	T	1	6							✓	✓	✓	✓	✓								Early Warning Score in red zone	L

System	Paper (First author, year)	Country	Setting*				Vital signs						Concern		Clinical indicators								Therapies		Other parameters	
				Score or trigger	Age categories (n)	Parameters (n)	Oxygen saturation	Heart rate	Respiratory rate	Systolic BP	CRT	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Vomiting post-surgery	Airway threat	15-mimute nebulisers	Oxygen therapy		Risk of bias
Modified Bristol PEWS	Sefton 2014[169]	UK	CH	T	5	16	✓[1]	✓[3]	✓				✓						✓						Apnoea ±bradycardia; Clinically tiring or complete airway obstruction; GCS ≤ 11 or falling, children responding only to pain or unresponsive on AVPU; Hyperkalaemia; Marked increased work of breathing; Nebulised adrenaline (or no improvement); pH <7.2, Poor perfusion, prolonged CRT (≥3s), ± low BP, large central/peripheral temp gradient; Unresolved pain on current analgesia therapy	H
MPEWS I	Skaletzky 2012[170]	USA	CH	S	1	3									✓	✓	✓									H

System	Paper (First author, year)	Country	Setting*	Score or trigger	Age categories (n)	Parameters (n)	Vital signs						Concern		Clinical indicators								Therapies		Other parameters	Risk of bias
							Oxygen saturation	Heart rate	Respiratory rate	Systolic BP	CRT	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Vomiting post-surgery	Airway threat	15-mimute nebulisers	Oxygen therapy		
MPEWS II	Bonafide 2013[79] Roberts 2014[171]	USA USA	CH CH	S	5	18	✓	✓	✓	✓	✓	✓						✓		✓				✓	Abnormal airway or positive pressure ventilation; Active acquired or congenital heart disease or history of heart surgery; Baseline supplemental oxygen requirement; CVL; IV bolus fluid or blood product within past 4 hours; Pre/post any transplant; Presence of gastrostomy or jejunostomy tube; Previous ICU admission; Severe developmental, neurological or neuromuscular disease	L L
MPEWS III	Fuijkschot 2014[172]	NL	CH	S	5	8	✓	✓	✓	✓	✓	✓								✓				✓		H
NHSI PEWS	Ennis 2014[173] Mason 2016[174]	Ireland UK	UH UH	S	4	7	✓	✓	✓				✓	✓				✓		✓						H L
PERT AC	Van Voorhis 2009[126]	USA	CH	T	1	5	✓	✓	✓	✓			✓					✓	✓						Pain or agitation that is difficult to control	H

System	Paper (First author, year)	Country	Setting*	Score or trigger	Age categories (n)	Parameters (n)	Vital signs: Oxygen saturation	Vital signs: Heart rate	Vital signs: Respiratory rate	Vital signs: Systolic BP	Vital signs: CRT	Vital signs: Temperature	Concern: Staff concern	Concern: Parent concern	Clinical indicators: Respiratory	Clinical indicators: Behaviour	Clinical indicators: Cardiovascular	Clinical indicators: Consciousness	Clinical indicators: Seizure	Clinical indicators: Respiratory distress	Clinical indicators: Vomiting post-surgery	Clinical indicators: Airway threat	Therapies: 15-mimute nebulisers	Therapies: Oxygen therapy	Other parameters	Risk of bias
PEW score I	Monaghan 2005[39]	UK	CH	S	1	4									✓	✓	✓				✓		✓			H
	Randhawa 2011[118]	USA	CH																							H
	Watson 2014[152]	USA	CH																							H
PEW score II	Tucker 2009[144]	USA	CH	S	1	4									✓	✓	✓				✓		✓			H
	Brady 2013[84]	USA	CH																							L
	Brady 2014[83]	USA	CH																							L
	McLellan 2014[158]	USA	CH																							H
	Fenix 2015[175]	USA	CH																							H
PEW score III	Demmel 2010[176]	USA	CH	S	1	4								✓	✓	✓	✓									H
PEW score IV	Akre 2010[177]	USA	CH	S	1	4									✓	✓	✓				✓		✓			H
PEW score V	Henderson 2012[178]	UK	RR	S	4	6	✓	✓	✓	✓		✓						✓								H
PEW signs	Anwar-ul-Haque 2010[179]	Pakistan	UH	T	1	8	✓	✓	✓	✓			✓					✓	✓	✓						H
PEWS	Skaletzky 2009[48]	USA	CH	S	1	3									✓	✓	✓									H

System	Paper (First author, year)	Country	Setting*	Score or trigger	Age categories (n)	Parameters (n)	Vital signs						Concern		Clinical indicators								Therapies		Other parameters	Risk of bias
							Oxygen saturation	Heart rate	Respiratory rate	Systolic BP	CRT	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Vomiting post-surgery	Airway threat	15-mimute nebulisers	Oxygen therapy		
PEWS score I	Duncan 2006[138] Robson 2011[121]	Canada UK	CH CH	S	5	19	✓	✓	✓	✓	✓	✓												✓	>3 medical specialities involved in care; abnormal airway (not tracheostomy); bolus fluid; CVL in situ; gastrostomy; GCS; home oxygen; medication score; previous admission to ICU; pulses; severe cerebral palsy; transplant recipient	H H
PEWS score II	Panesar 2014[180]	USA	CH	S	1	3									✓	✓	✓									H
PMET triggers I	Shilksofski[140] Hunt 2008[180]	USA	CH	T	1	12	✓						✓	✓				✓	✓	✓					Abnormal/worsening respiratory symptoms; progressive lethargy; circulatory compromise/acute shock syndrome; SVT/ other dysrhythmia; respiratory arrest; cardiac arrest	H H
PMET triggers II	Kotsakis 2011[139]	Canada (4)	CH (4)	T	5	7	✓	✓	✓	✓			✓	✓					✓						GCS	L
RRT AC	Sharek 2007[181]	USA	CH	T	1	6	✓	✓	✓	✓			✓					✓								L
TCH PAWS	Bell 2013[143]	USA	CH	S	1	5									✓	✓	✓				✓				Every hour respiratory treatments	H

System	Paper (First author, year)	Country	Setting*	Score or trigger	Age categories (n)	Parameters (n)	Vital signs: Oxygen saturation	Vital signs: Heart rate	Vital signs: Respiratory rate	Vital signs: Systolic BP	Vital signs: CRT	Vital signs: Temperature	Concern: Staff concern	Concern: Parent concern	Clinical indicators: Respiratory	Clinical indicators: Behaviour	Clinical indicators: Cardiovascular	Clinical indicators: Consciousness	Clinical indicators: Seizure	Clinical indicators: Respiratory distress	Clinical indicators: Vomiting post-surgery	Clinical indicators: Airway threat	Therapies: 15-mimute nebulisers	Therapies: Oxygen therapy	Other parameters	Risk of bias
THCS MET criteria	Kukreti 2014[182]	Canada	CH	T	1	7	✓[1]	✓	✓	✓	✓		✓					✓	✓	✓		✓		✓	Poor peripheral pulses, mottled extremities, GCS	S
Not specified	Hanson 2010[183]	USA	CH	NS	NS	NS																				L
	Zenker 2007[115]	USA	CH																							H

Key: Coloured text links indicators that are combined within a single parameter; [1] separate parameters for children with and without cyanotic heart disease; [2] in preceding 72 hours; [3] following one bolus of 10mls/kg fluid; *All studies are single centre unless otherwise stated.

Overall risk of bias: **L**: Low; **H:** High; **S**: Survey (not assessed)

Abbreviations: **AC:** Activation criteria**; BP:** blood pressure; **C-CHEWS:** Cardiac Children's Hospital Early Warning Score; **CCH:** Children's community hospital; **CH:** Children's hospital; **CRT:** Capillary refill time; **CVL:** Central venous line; **DKA**: Diabetic ketoacidosis; **GCS:** Glasgow Coma Score; **ICU:** Intensive Care Unit; **ITAT:** Inpatient triage, assessment and treatment score; **IV:** Intravenous; **LA**: Los Angeles; **MET:** Medical Emergency Team; **MPEWS:** Modified Pediatric Early Warning Score; **NHSI:** NHS Institute; **NL**: Netherlands; **NS:** Not specified; **PAWS:** Pediatric Advanced Warning Score; **PERT:** Pediatric Early Response Team; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET:** Pediatric Medical Emergency Team; **RH:** Referral hospital; **RR:** Remote rural; **RRT:** Rapid Response Team; **SVT:** Super ventricular tachycardia; **TCH:** Texas Children's Hospital; **THSC:** Toronto Hospital for Sick Children; **UH:** University Hospital

2.3.5 Vital signs

All PTTS included one or more vital signs. Method of utilisation varied, but largely took one of three forms. At the simplest level, a single vital sign was assessed against a scoring matrix with clear thresholds for normal and abnormal values. Other PTTS assessed vital signs against subjective criteria where some interpretation or evaluation was required by the clinician. Examples include '*acute change'* in vital sign or a recording '*above the baseline'*. At its most complex level, the vital sign was one part of a parameter requiring assessment of two or more component parts simultaneously. These complex parameters most commonly include subjective measures of vital signs combined with other related clinical features. For example, the 'respiratory' parameter within the '*Paediatric Early Warning System Score I*'[39] combines assessment of respiratory rate, oxygen therapy and respiratory effort. Abnormal vital signs could also be combined with specific interventions, such as low oxygen saturation levels despite additional oxygen therapy or high heart rate despite the administration of a fluid bolus.

Additional guidance was present in some systems to assist with identification of 'normal' and 'abnormal' values. Thresholds prompting a positive score or trigger within the PTTS are seen in Table 2.7. Four PTTS[170,176,177,179] presented additional guidance on age-appropriate vital signs to assist clinicians in determining normal and abnormal values and these can be seen in Table 2.8.

Most PTTS appeared to be developed from expert opinion and did not reference the source of their vital sign thresholds. Differences in thresholds were often minor. Age categories varied as did the thresholds for systolic blood pressure, heart and respiratory rate, which resulted in marked differences in scoring for some PTTS. Some PTTS provided different values dependent on whether the child was awake or sleeping, male or female. Trigger values for oxygen saturation were largely consistent, but the method of measurement varied, with some requiring measurement in oxygen, others in air or detecting a decrease despite non-specified first line interventions. Thresholds for capillary refill time and temperature were broadly similar; however, they were less frequently incorporated into the PTTS compared to other vital signs.

Table 2.7 Vital sign thresholds within PTTS

System	Age range	Heart Rate		Respiratory Rate		Systolic BP		CRT	Oxygen saturation	Temperature	
Bedside PEW system[116,119,121,154,156]	0 - <3 m	≤110	≥150	≤29	≥61	≤60	≥80	≥3 s	≤94%		
	3 - <12m	≤100	≥150	≤24	≥51	≤80	≥100				
	1-4y	≤90	≥120	≤19	≥41	≤90	≥110				
	< 4-12y	≤70	≥110	≤19	≥31	≤90	≥120				
	>12y	≤60	≥100	≤11	≥17	≤100	≥130				
Bristol PEW tool[42,59,121,158]	>6 m	≤95[$]	≥150		≥70			3s	≥92% in oxygen ≥75% in oxygen (CHD)		
	6-12 m	≤95[$]	≥150		≥60						
	1-5 y	≤95[$]	≥150		≥40						
	5-12 y		≥120		≥25						
	>12 y		≥100		≥25						
Burns Centre PEWS[159]	All			10 above normal parameter				≥2 s	>95% with supplemental oxygen	<36.5	>38.4
Cardiff and Vale PEW system[137]	<1 y	<90	>160	<20	>50	<70	>90		Requiring oxygen to keep above 90%		
	1-2 y	<80	>150	<15	>45	<80	>95				
	2-5 y	<75	>140	<15	>40	<80	>100				
	5-12 y	<60	>120	<10	>35	<90	>110				
	>12 y	<55	>100	<10	>30	<100	>120				

System	Age range	Heart Rate		Respiratory Rate		Systolic BP		CRT	Oxygen saturation	Temperature	
C-CHEWS[47,158]	All	Mild tachycardia (≥10% for age)		Mild tachypnoea (≥10% for age)				≥3 s	Mild desaturation below baseline		
Children's Early Warning Tool[67]	<1y	≤100	>160	≤20	>45	≤75	>150	>2s	≤93%	<35.5	>38.0
	1-4y	≤90	>140	≤15	>35	≤80	>150				
	5-11y	≤80	>130	≤15	>30	≤85	>150				
	>12y	≤60	>120	≤15	>25	≤95	>150				
Children's Hospital LA PEWS[160]	All	20 above normal rate		> 10 above normal parameter				≥3 s	Requiring oxygen to maintain normal saturations		
ITAT[162]	<3 m	<110	>150	<30	>60				≤95%	<36	>37.4
	3-12m	<100	>150	<25	>50						
	1-4y	<90	>120	<20	>40						
	4-12y	<70	>110	<20	>30						
	>12y	<60	>100	<12	>15						
MET activation criteria I[42,59,121,158] MET activation criteria III[141,166]	Term-3 m	<100	>180		>60	<50			<90% in oxygen <60% in oxygen (CHD)		
	4-12 m	<100	>180		>50	<60					
	1-4 y	<90	>160		>40	<70					
	5-12 y	<80	>140		>30	<80					
	>12 y	<60	>130		>30	<90					

System	Age range	Heart Rate		Respiratory Rate		Systolic BP		CRT	Oxygen saturation	Temperature	
MET activation criteria II[142]	All								<90% in oxygen		
MPEWS I[170] PEW score I[39,118] PEW score II[83,84,144,158] PEW score III[176] PEW score IV[177] PEW system score II[180]	All	20 above normal rate		> 10 above normal parameter				≥3 s			
MPEWS II[79,171]	<3 m	<110	>160	<30	>60	<60	>90	≥ 2s	<95	<36	>38.4
	3-<12 m	<100	>150	<25	>50	<80	>110				
	1-<4 y	<90	>130	<20	>40	<90	>120				
	4-<12 y	<70	>120	<20	>30	<90	>120				
	>/=12 y	<60	>110	<12	>16	<100	>130				
MPEWS III[172]	0 - <3 m	≤110	≥150	≤29	≥61	≤60	≥80	≥3 s	≤94%	<36.5	>37.5
	3 - <12m	≤100	≥150	≤24	≥51	≤80	≥100				
	1-4y	≤90	≥120	≤19	≥41	≤90	≥110				
	< 4-12y	≤70	≥110	≤19	≥31	≤90	≥120				
	>12y	≤60	≥100	≤11	≥17	≤100	≥130				

System	Age range	Heart Rate		Respiratory Rate		Systolic BP	CRT	Oxygen saturation	Temperature
Modified Bristol PEW system[169]	<3 m	≤95[$]	≥150	<20	≥70		≥3s	≤92% in oxygen ≤75% in oxygen (CHD)	
	3-6 m	≤95[$]	≥150	Half lower value for resps for age	≥70				
	6-12 m	≤95[$]	≥150		≥60				
	1-5 y	≤95[$]	≥150		≥40				
	5-12 y		≥120		≥25				
	>12 y		≥100		≥25				
PERT activation criteria[126] RRT activation criteria[143]	All	Acute change		Acute change		Acute change		Acute change	
PEW signs[179]	All	Acute change		Acute change		Acute change		Acute change <90%	
PMET triggers I[139,140]	All							Decrease despite 1st-line interventions	
PMET triggers II[181] THCS MET calling criteria[183]	Term-3m	<100	>180		>60	<50		<90% in oxygen <60% in oxygen (CHD)	
	4-12m	<100	>180		>50	<60			
	1-4y	<90	>160		>40	<70			
	5-12y	<80	>140		>40	<80			
	>12y	<60	>130		>30	<90			

System	Age range	Heart Rate		Respiratory Rate		Systolic BP		CRT	Oxygen saturation	Temperature	
NHSI PEWS[173,174]	0-11m	<90	>160	<30	>60						
	1-4y	<90	>140	<20	>40						
	5-12y	<70	>120	<20	>30						
	13-18y	<60	>100	<10	>20						
PEW system score I[121,138]	<3 m	<110	>150	<30	>60	<60	>80	≥2s	≤95	<36.0	>38.5
	3-12 m	<100	>150	<25	>50	<80	>100				
	1-4 y	<90	>120	<20	>40	<90	>110				
	4-12 y	<70	>110	<20	>30	<90	>120				
	>12 y	<60	>100	<12	>16	<100	>130				
TCH PAWS[182]	All	≥20 above baseline		≥10 above baseline				≥3 s	5 points below baseline		

Thresholds for vital signs represent a score of one or more within a PTTS scoring system or a trigger threshold.

Key: [♯]Persistent tachycardia following one bolus of 10mls/kg fluid; [$:]Apnoea ± bradycardia

Abbreviation: BP: Blood pressure; **C-CHEWS:** Cardiac Children's Hospital Early Warning Score; **CHD:** cyanotic heart disease; **CRT:** Capillary Refill Time; **GCS:** Glasgow Coma Score; **ITAT:** Inpatient Triage, Assessment and Treatment score; **PAWS:** Pediatric Advanced Warning Score; **PERT:** Pediatric Early Response Team; **PEW:** Paediatric/Pediatric Early Warning; **MET:** Medical Emergency Team; **MPEWS:** Modified Pediatric Early Warning Score; **PMET:** Pediatric Medical Emergency Team; **RRT:** Rapid Response Team; **TCH:** Texas Children's Hospital; **THSC:** Toronto Hospital for Sick Children

Table 2.8 Additional guidance for vital sign thresholds

System	Age range	Heart Rate		Respiratory Rate
MPEWS I[170]		Awake	Sleeping	
	0-3 months	85 - 205	80 - 160	
	3 months-2 years	100 - 190	75 - 160	
	2-10 years	60 - 140	60 - 90	
	>10 years	60 - 100	50 - 90	
	<1 years			30 - 60
	1-3 years			24 - 40
	4-5 years			22 - 24
	6-12 years			18 - 30
	13-18 years			12 - 16
PEW score III[176]	Neonate	70 - 190		30 - 50
	1-11 months	80 - 160		30 - 45
	1-2 years	80 - 130		20 - 30
	3-4 years	80 - 120		20 - 30
	5-7 years	70 - 115		20 - 25
	8-11 years	80 - 110		12 - 20
	12-15 years (male)	80 - 100		12 - 20
	12-15 years (female)	80 - 110		12 - 20
	>15 years (male)	75 - 95		12 - 20
	>15 years (female)	70 - 100		12 - 20
PEW score IV[177]	0-1 month	100 - 180		40 - 60
	1-12 month	100 - 180		35 - 40
	13 months – 3 years	70 - 110		25 - 30
	4-6 years	70 - 110		21 - 23
	7-12 years	70 - 110		19 - 21
	13-19 years	55 - 90		16 - 18
PEW signs[179]	0-12 months	80 - 200		20 - 60
	1-14 years	80 - 180		10 - 40

Additional guidance on normal vital sign ranges to be used in conjunction with the relevant PTTS.

Key: PEW: Paediatric/Pediatric Early Warning; **MPEWS:** Modified Pediatric Early Warning System

2.3.6 Comparison of PTTS heart and respiratory rate thresholds to evidence based values

Heart rate thresholds within PTTS were compared to evidence-based references ranges for hospitalised children derived from percentile curves.[184] The recommended values for each percentile were plotted graphically against the relevant age threshold. As an example, the percentile values for heart rate can be seen at Figure 2.8. Thresholds for the 1st, 5th, 10th, 90th, 95th and 99th are presented in grey, with the relevant value noted on the right of the figure. The 50th percentile or median value is presented in black.

Thresholds for the scoring thresholds of each PTTS were then superimposed over the percentile based thresholds. Each different score was represented by a different colour. Where a PTTS provided an upper and lower threshold for a given score these were presented using the same line colour. An example of a PTTS with three upper and three lower scoring thresholds for scores of one, two and four can be seen at Figure 2.9.

Each PTTS was plotted in this way and the process was repeated for the appropriate respiratory rate thresholds.

Figure 2.8 Percentile values for heart rate

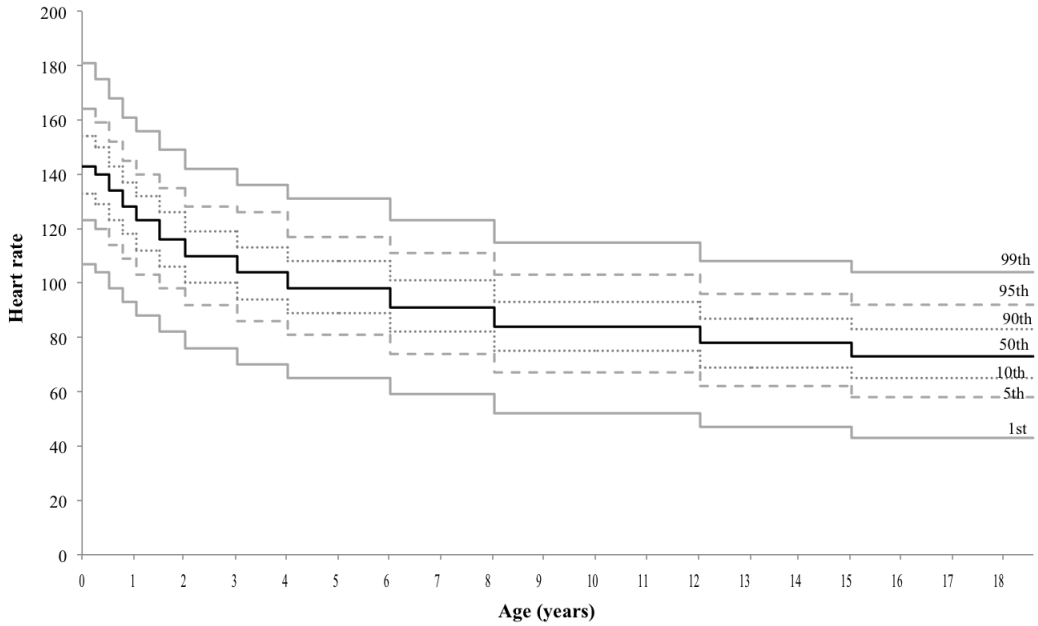
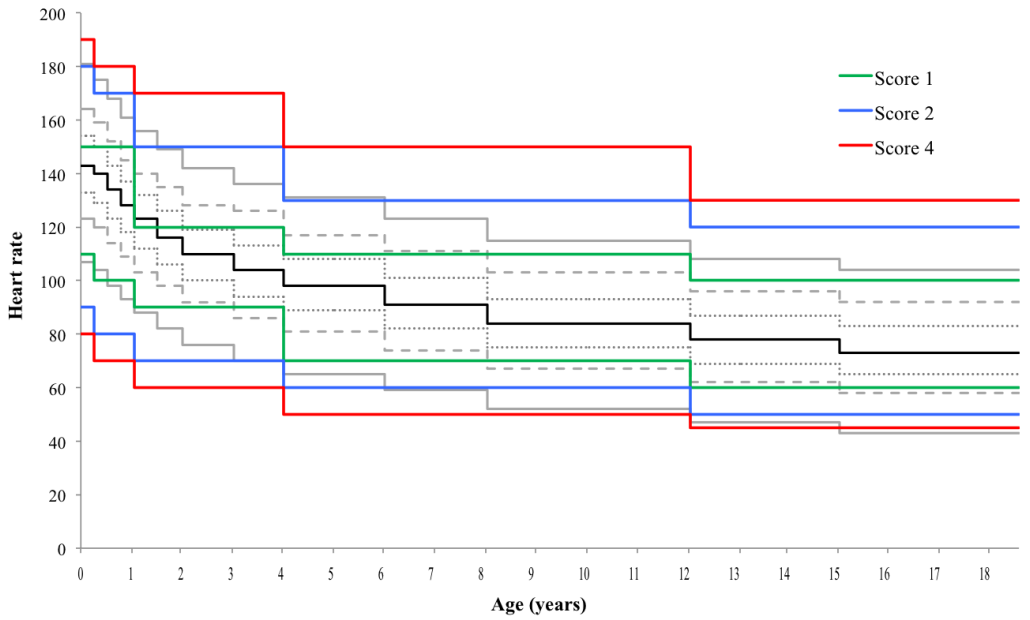


Figure 2.9 Example of heart rate thresholds for a score-based PTTS



2.3.6.1 Comparison of heart rate thresholds

Thresholds for the heart rate of PTTS scoring systems are seen at Figure 2.10, with those for trigger systems at Figure 2.11. Four systems provided guidance on expected 'normal values' for heart rate. These can be seen at Table 2.8.

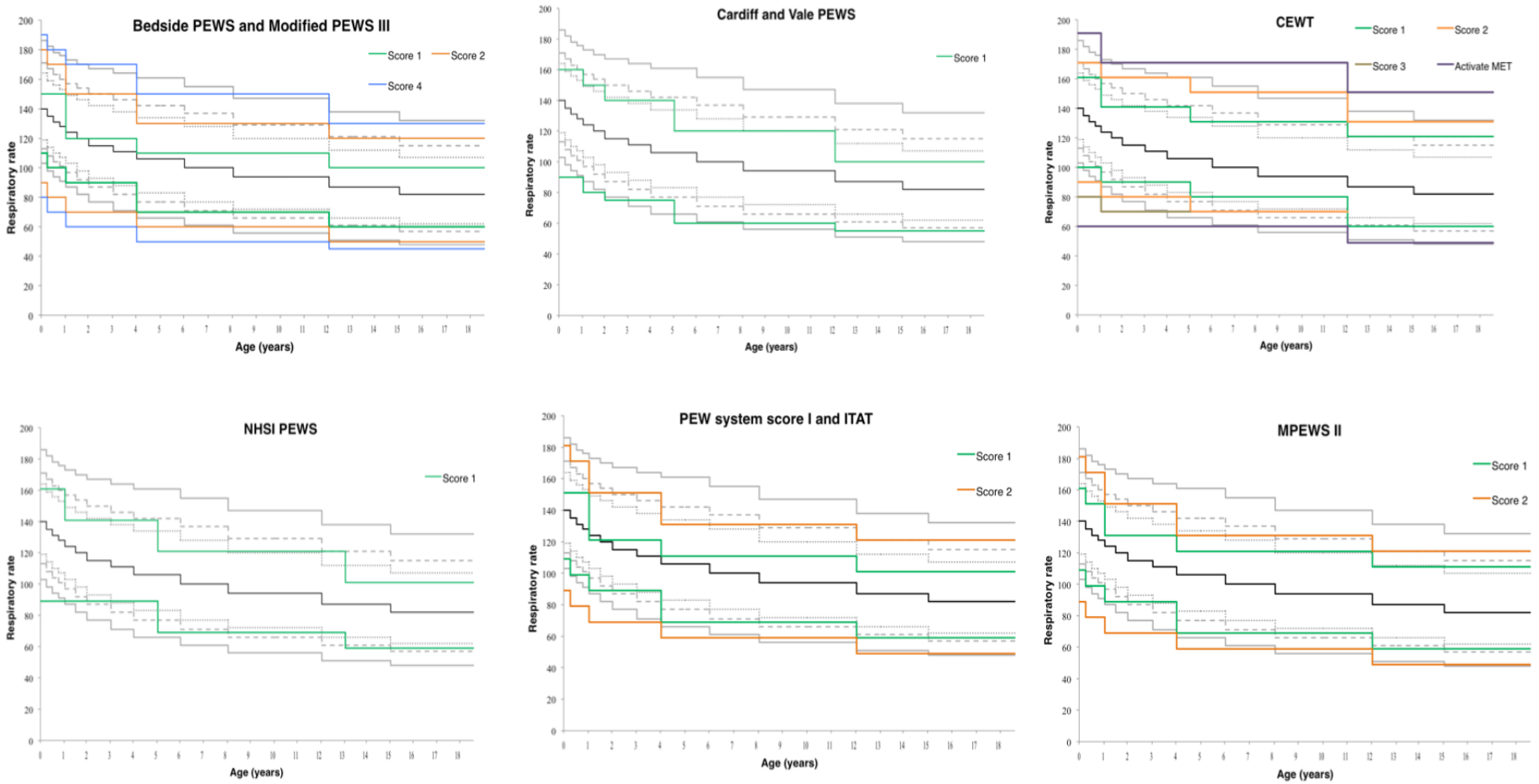
The eight PTTS scoring systems had six differing thresholds and scoring weightings (Figure 2.10). Differences were sometimes minor, such as that between the *Paediatric Early Warning (PEW) system score I*, *Inpatient triage, assessment and treatment score (ITAT)* and the *Modified Paediatric Early Warning Score (MPEWS)* II. There was inconsistency between the scoring thresholds and percentile values. For example, the *PEWS scoring system I* and *ITAT* 'upper score' of one sits around the 95th centile for younger children but dips below the 50th centile for children aged 12-18 months of age.

Four scoring systems (*Bedside PEWS, Modified PEWS III, PEW system score I* and *ITAT*) had a score threshold that breeched the 50th percentile for younger children and infants. This represents the median and as such is considered to be the 'normal' value. Thresholds for the maximum score for the *Bedside PEWS, Modified PEWS III* and the *Children's Early Warning Tool (CEWT)* also exceeded the 99th percentile for infants. These represent extreme values falling far outside of the expected range. There appeared to be particularly poor association between percentile-based reference ranges and the PTTS scoring thresholds in younger children.

There was greater consensus on heart rate limits for trigger systems, with four systems sharing the same thresholds (Figure 2.11). The thresholds for infants for the *Bristol/Modified Bristol* tool sat well below the 90th percentile. Given that PTTS trigger systems are often used to activate specialist teams of intensive care staff, this was surprising.

Four systems provided values for the expected or 'normal' heart rate to assist staff using the PTTS (Figure 2.12). There was wide variation in these thresholds and poor agreement with the percentile thresholds. The upper limit for the *PEW signs* PTTS sat far outside the 99th percentile for all age-ranges, whilst the *PEW score IV* had upper thresholds which were in excess of the 99th percentile for children of one year of age which fell to below the median for those aged one to three years.

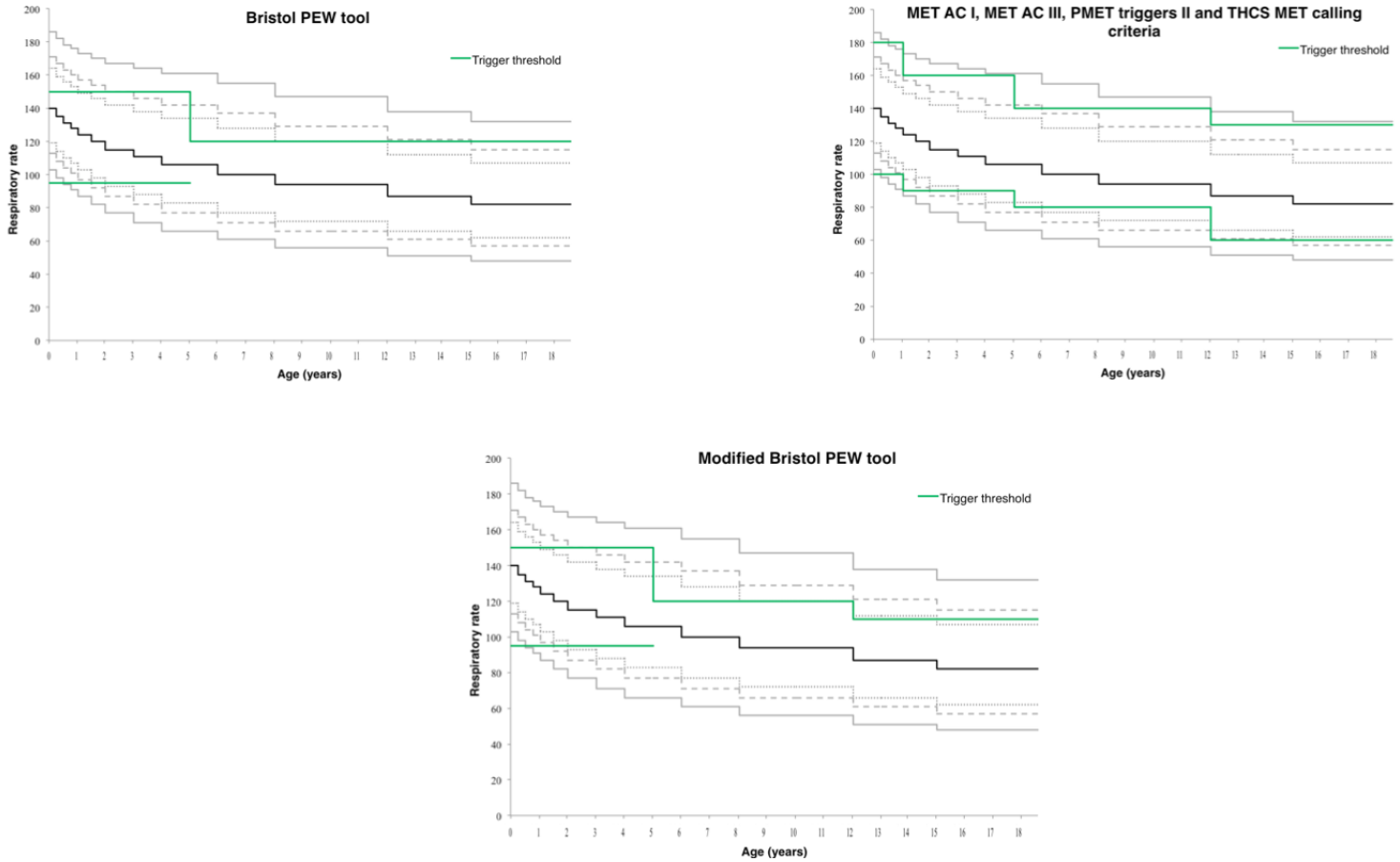
Figure 2.10 Comparison of heart rate thresholds within PTTS scoring systems to validated reference ranges



Heart rate thresholds from PTTS systems are plotted against validated reference ranges derived from percentile curves for hospitalised children[185]

Legend (percentile values): 99th and 1st ——; 95th and 5th: - - - -; 90th and 10th: ·····; 50th: ——

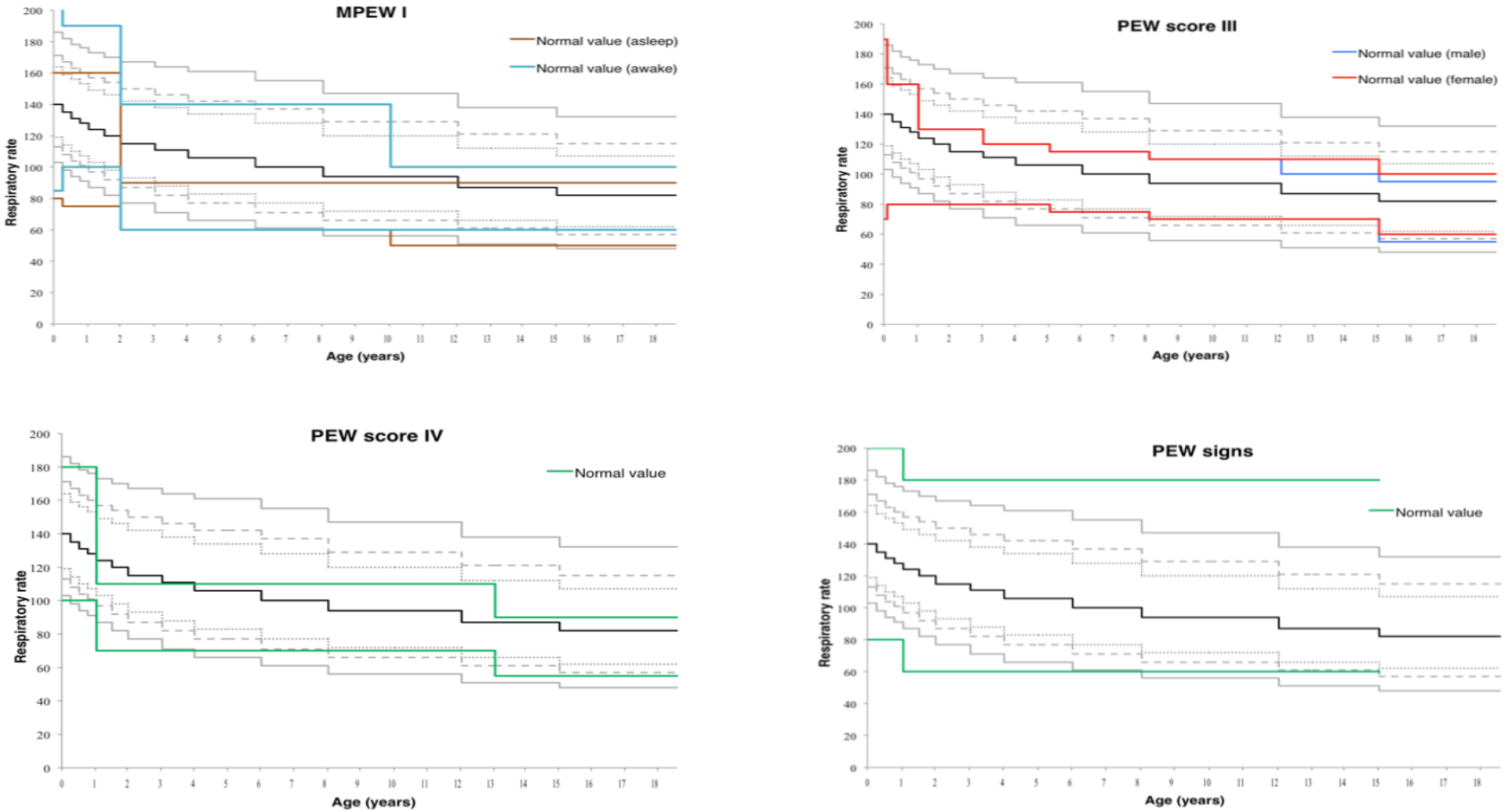
Figure 2.11 Comparison of heart rate thresholds within PTTS <u>trigger systems</u> to validated reference ranges



Heart rate thresholds from PTTS systems are plotted against validated reference ranges derived from percentile curves for hospitalised children[185]

Legend (percentile values): —— 99th; - - - - 95th; ····· 90th; ——50th; ·····10th; - - - - 5th; ——1st

Figure 2.12 Comparison of recommendations for <u>normal</u> heart rate thresholds within PTTS scoring systems to validated reference ranges



Heart rate thresholds from PTTS systems are plotted against validated reference ranges derived from percentile curves for hospitalised children[185]

Legend (percentile values): —— 99th; - - - - 95th; ····· 90th; —— 50th; ····· 10th; - - - - 5th; —— 1st

2.3.6.2 Respiratory rate

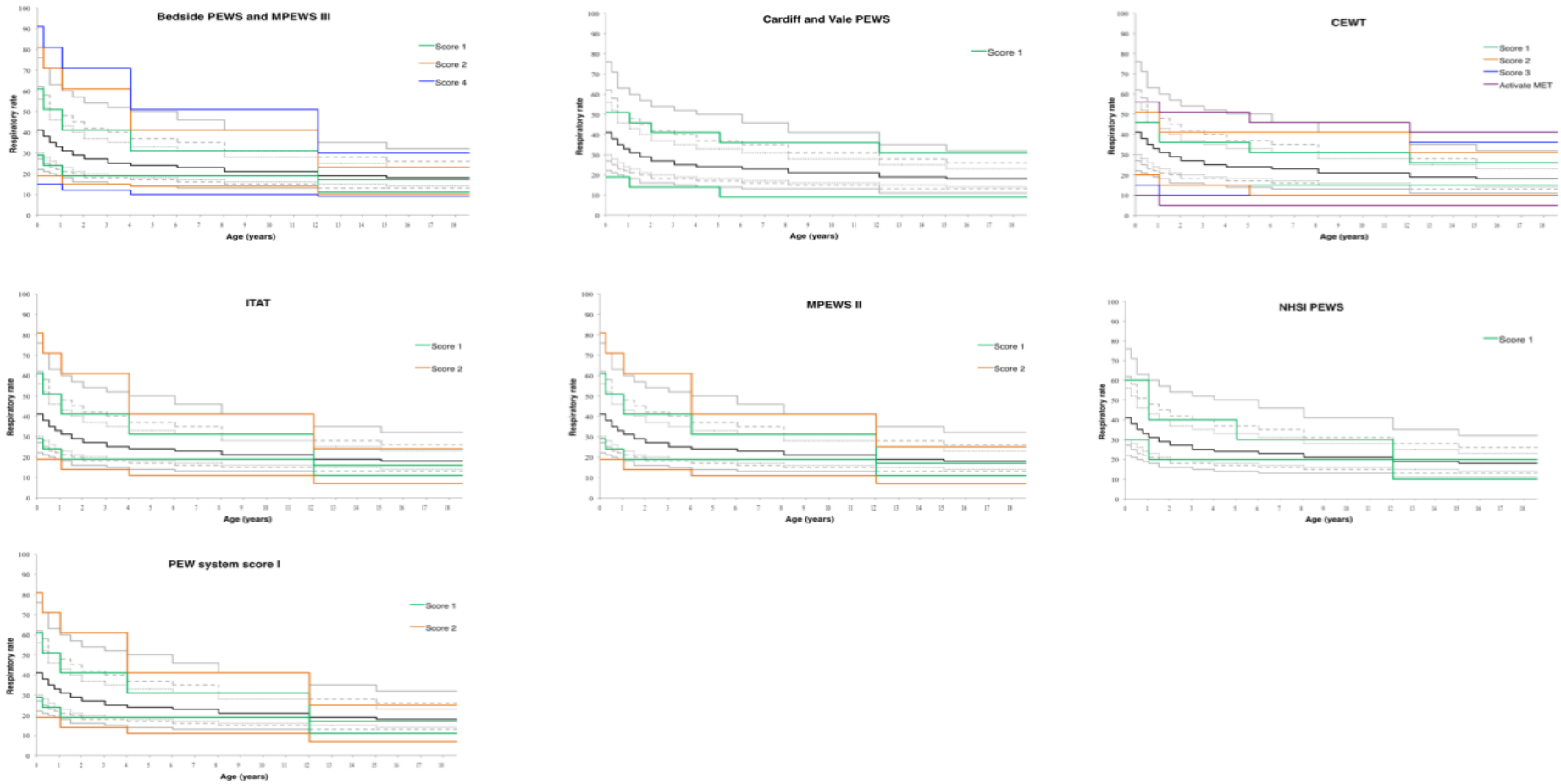
Respiratory rate thresholds also demonstrated variability when compared to evidence-based reference ranges. The eight score-based PTTS had seven separate thresholds (Figure 2.13). Again, differences were often minor. The *Bedside PEWS* 'lower' score of one sat at or around the 50th centile (median) for children aged eight to 12 years, but fell to below the 1st centile for children/young people over 12 years. However, for the same age-ranges the 'upper' score of one sat well above the 99th centile for those aged eight to 12 years, but at or around the 50th centile for older children/young people. Both upper and lower thresholds for respiratory rate demonstrated marked differences between the systems and poor correlation to the percentile-derived reference ranges.[184]

The six trigger systems had three differing thresholds (Figure 2.14). None presented thresholds for low respiratory rate. The thresholds for tachypnea varied when compared to the evidence-based thresholds and there appeared to be little agreement on values.

Four PTTS provided additional guidance on 'normal thresholds' for respiratory rate in infants and children (Figure 2.15). There was little consensus between the four differing PTTS on what they would classify as 'normal'. When compared to the evidence-based thresholds, differences were marked, with no association between percentile threshold and 'normal' ranges.

Overall respiratory rate thresholds within PTTS appear detached from the reference ranges derived from percentile-based values in hospitalised children.

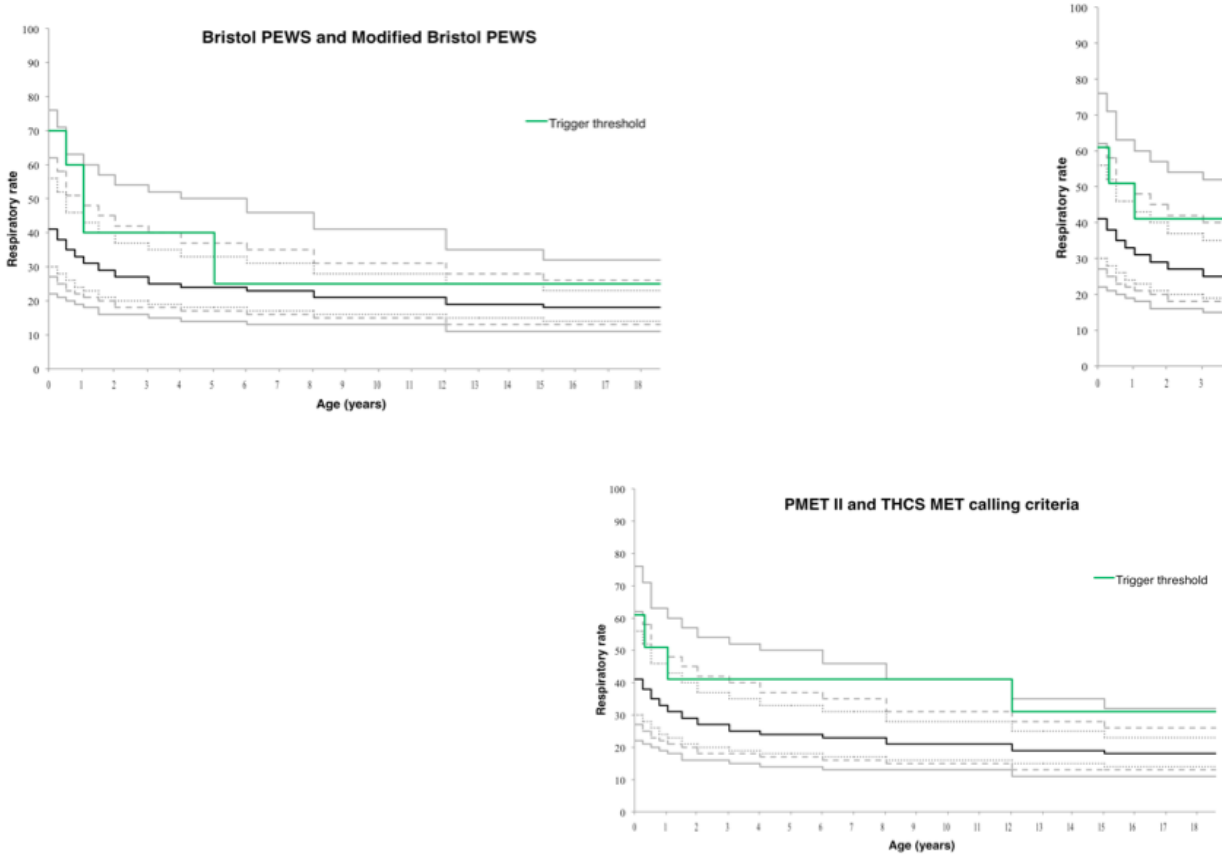
Figure 2.13 Comparison of respiratory rate thresholds within PTTS scoring systems to validated reference ranges



Respiratory rate thresholds from PTTS systems are plotted against validated reference ranges derived from percentile curves for hospitalised children[185]

Legend (percentile values): —— 99th; - - - - 95th; ····· 90th; —— 50th; ····· 10th; - - - - 5th; —— 1st

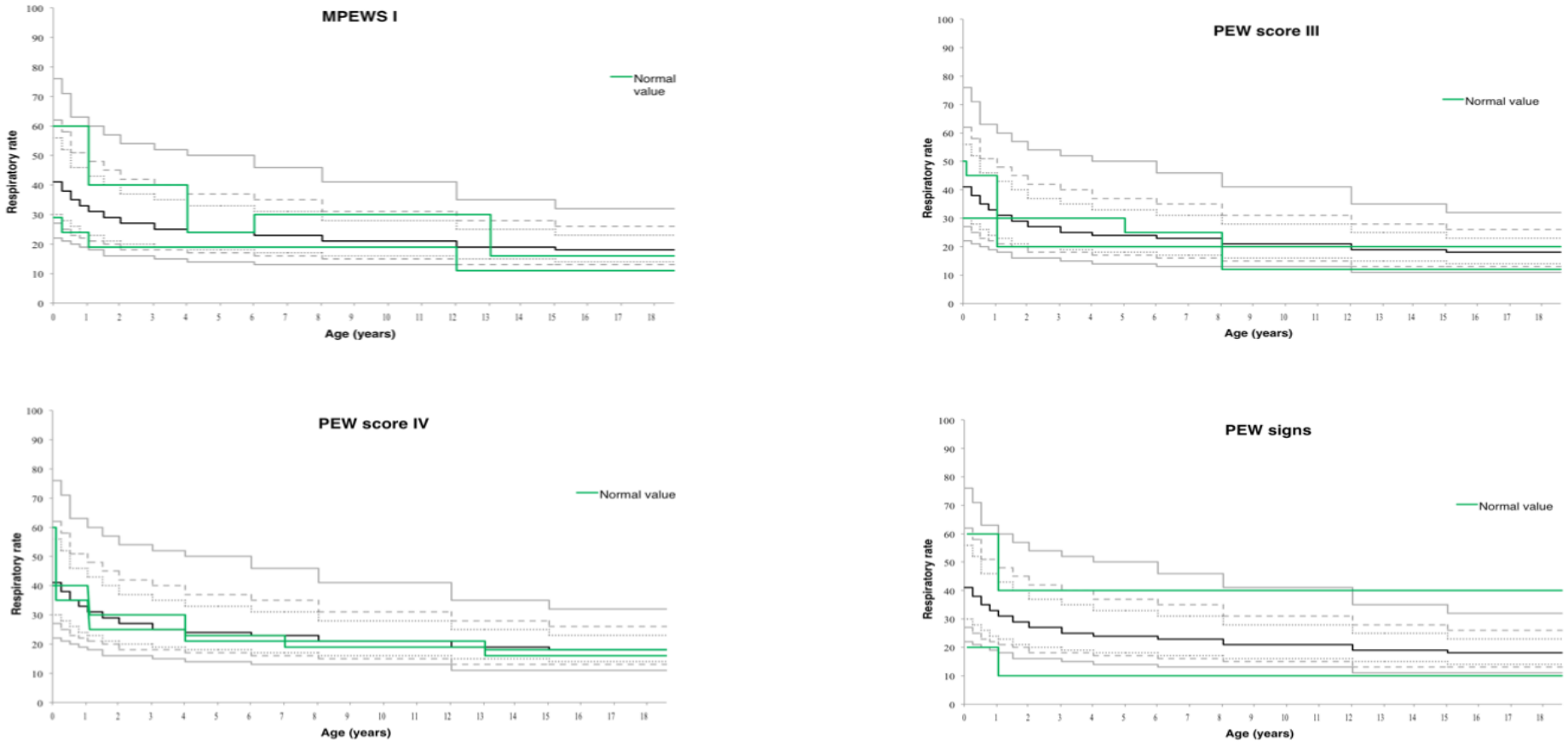
Figure 2.14 Comparison of respiratory rate thresholds within PTTS trigger systems to validated reference ranges



Respiratory rate thresholds from PTTS systems are plotted against validated reference ranges derived from percentile curves for hospitalised children[185]

Legend (percentile values): —— 99th; - - - - 95th; ····· 90th; —— 50th; ····· 10th; - - - - 5th; —— 1st

Figure 2.15 Comparison of recommendations for normal respiratory rate thresholds within PTTS scoring systems to validated reference ranges



Respiratory rate thresholds from PTTS systems are plotted against validated reference ranges derived from percentile curves for hospitalised children[185]

Legend (percentile values): —— 99th; - - - - 95th; ····· 90th; —— 50th; ····· 10th; - - - - 5th; —— 1st

2.3.7 Effect as a single intervention on patient important outcomes

Six studies evaluated PTTS as a single intervention (four studies examined PTTS introduction into hospitals with an established rapid response team[67,118,176,182] and two without[119,169]). Results are shown in Table 2.9. A further 11 studies examined the impact of PTTS as part of a package of interventions, mainly rapid response team implementation (Table 2.10) and are summarised below. Thirteen studies reported diagnostic accuracy (Table 2.11). No randomised controlled trials were identified. Accordingly the level of evidence overall is very low.

2.3.7.1 Death – Very low evidence

The two observational studies[67,169] had small sample sizes and low event rates. Death following unplanned admission to intensive care from the ward demonstrated a relative risk (RR) of 1.28 (95% confidence interval [CI] 0.66-2.52); however, results were not significant. The RR of unexpected death on the ward could not be calculated, as there was only one death in the study population.

2.3.7.2 Cardiac arrest – Very low evidence

Two studies examined cardiac arrest.[118,176] Both studies were severely limited by methodological concerns and RR could not be estimated from the limited data. The RR of cardiac arrest on the ward demonstrated an increase after PTTS implementation (RR 1.32, 95% CI 0.33-5.26), although this was not statistically significant.

2.3.7.3 Respiratory arrest – No evidence

No studies examined the effect of PTTS implementation on respiratory arrest in hospitalised children.

Table 2.9 Evidence profile of PTTS as a single intervention

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Outcome: Death											**Importance: Critical**	
Death after PICU admission from ward	1	OS	not serious	not serious	not serious	not serious[1]	publication bias strongly suspected[2]	17/157 (10.8%)	14/166 (8.4%)	**RR 1.28** (0.66 to 2.52)	**24 more per 1000** (from 29 fewer to 128 more)	⨁◯◯◯ VERY LOW
Unexpected death on ward	1	OS	not serious	not serious	not serious	very serious[1]	publication bias strongly suspected	0/899 (0.0%)	1/1059 (0.1%)	not estimable	not estimable	⨁◯◯◯ VERY LOW
Outcome: Cardiac Arrest											**Importance: Critical**	
Ward arrests/1000 patient days	1	OS	serious[3]	not serious	not serious	serious[4]	none	6/12344 (0.5)	3/8115 (0.4)	**RR 1.32** (0.33 to 5.26)	**1 more per 1000** (from 2 fewer to 16 more)	⨁◯◯◯ VERY LOW
Ward arrests/1000 patient days	1	OS	serious[3]	not serious	not serious	serious[4]	publication bias strongly suspected[2]	0.12	0.61	not estimable	not estimable	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Days between ward cardiac arrests	1	OS	very serious[5]	not serious	not serious	serious[4]	publication bias strongly suspected[2]	1053	299	not estimable	not estimable	⨁◯◯◯ VERY LOW
Outcome: Request for emergency assistance											**Importance: Critical**	
Code blue events/1000 patient days	1	OS	very serious[3]	not serious	serious[8]	not serious	publication bias strongly suspected[2]	0.256	0.293	not estimable	not estimable	⨁◯◯◯ VERY LOW
Outcome: Unplanned transfer to PICU											**Importance: Critical**	
Invasive ventilation after unplanned PICU transfer	1	OS	not serious	not serious	not serious	very serious[1]	publication bias strongly suspected[2]	104/166 (62.7%)	118/157 (75.2%)	**RR 0.83** (0.72 to 0.97)	**128 fewer per 1000** (from 23 to 210 fewer)	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Unplanned transfer from ward to PICU/1000 patient days	1	OS	not serious	not serious	serious [6]	serious [4]	publication bias strongly suspected [2]	102/12344 (8.3)	66/8115 (8.1)	**RR 1.02** (0.75 to 1.38)	**1 more per 10,000** (from 3 fewer to 16 more)	⨁◯◯◯ VERY LOW
Median days of invasive ventilation	1	OS	not serious	not serious	not serious	not serious	publication bias strongly suspected [2]	2	4	not estimable	not estimable	⨁◯◯◯ VERY LOW
Inotropes after unplanned PICU transfer	1	OS	not serious	not serious	not serious	very serious [4]	publication bias strongly suspected [2]	40/166 (24.1%)	50/157 (31.8%)	**RR 0.76** (0.53 to 1.08)	**76 fewer per 1000** (from 25 more to 150 fewer)	⨁◯◯◯ VERY LOW
Median days of inotropes	1	OS	not serious	not serious	not serious	very serious [4]	publication bias strongly suspected [2]	0	0	not estimable	not estimable	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Median days of PICU stay	1	OS	not serious	not serious	not serious	very serious[4]	publication bias strongly suspected[2]	3	5	not estimable	not estimable	⨁◯◯◯ VERY LOW
*Unsafe transfer to centre with PICU /1000 patient days	1	OS	not serious	not serious	serious[6]	serious[4]	none	1/2350 (0.4)	2/842 (2.4)	**RR 0.18** (0.02 to 1.98)	**2 fewer per 1000** (from 2 fewer to 2 more)	⨁◯◯◯ VERY LOW
Transfer to centre with PICU facilities/1000 patient days	1	OS	not serious	not serious	serious[6]	serious[1]	none	19/2350 (8.1)	5/842 (5.9)	**RR 1.36** (0.51 to 3.64)	**2 more per 1000** (from 3 fewer to 16 more)	⨁◯◯◯ VERY LOW
Median PIM2 score	1	OS	not serious	not serious	serious[7]	not serious	publication bias strongly suspected[2]	0.04	0.06	not estimable	not estimable	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Outcome: Need for PICU and/or HDU										**Importance: Critical**		
Unplanned transfer from ward to PICU or HDU	1	OS	not serious	not serious	serious[6]	not serious	publication bias strongly suspected[2]	24/899 (2.7%)	40/1059 (3.8%)	**RR 0.71** (0.43 to 1.16)	**11 fewer per 1000** (from 3 fewer to 16 more)	⨁◯◯◯ VERY LOW
Outcome: Call for urgent assistance										**Importance: Important**		
Urgent call to paediatrician/ 1000 patient days	1	OS	not serious	not serious	serious [8]	serious[1]	none	12/2350 (5.1)	19/842 (22.6)	**RR 0.23** (0.11 to 0.47)	**17 fewer per 1000** (from 12 to 20 fewer)	⨁◯◯◯ VERY LOW
Urgent call to respiratory therapist/1000 patient days	1	OS	not serious	not serious	serious [8]	serious[1]	none	8/2350 (3.4)	8/842 (9.5)	**RR 0.36** (0.14 to 0.96)	**6 fewer per 1000** (from 0 to 8 fewer)	⨁◯◯◯ VERY LOW
RRT call /1000 patient days	1	OS	very serious [3]	serious [9]	serious [8]	not serious	publication bias strongly suspected[2]	5.85	4.88	not estimable	not estimable	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Call to RRT	1	OS	not serious	serious [9]	serious [8]	not serious	publication bias strongly suspected [2]	5/899 (0.6%)	⨁◯◯◯ VERY LOW	**RR 1.47** (0.40 to 5.47)	**2 more per 1000** (from 2 fewer to 17 more)	⨁◯◯◯ VERY LOW
Call to RRT	1	OS	serious [3]	serious [9]	serious [8]	very serious [10]	publication bias strongly suspected [2]	19.4% reduction in RRT activation after PTTS implementation				⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS	No PTTS	Relative (95% CI)	Absolute (95% CI)	
Outcome: Length of hospital stay											**Importance: Important**	
Mean days in hospital	1	OS	not serious	not serious	serious[11]	not serious	publication bias strongly suspected[2]	1.5		not estimable	not estimable	⨁◯◯◯ VERY LOW

Data presented relates to the number of patients unless the metric states otherwise. Outcomes highlighted in blue are statistically significant.

***Unsafe transfer:** Patient requiring intubation, vasoactive drugs or >3 fluid bolus prior to or within first hour in PICU

Abbreviations: **CI:** Confidence interval; **HDU:** High Dependency Unit; **OS:** Observational study; **PICU:** Paediatric Intensive Care Unit; **RR:** Relative risk;

RRT: Rapid Response Team

Key

1. Very low number of events and small sample size therefore results uncertain. Downgrade by 2
2. Single study of small sample size. Considering that PTTS are widely used, the possibility of publication bias is strongly suspected.
3. Implementation study with retrospective data collection, poor definitions of outcome, and inadequate control and reporting of confounding.
4. Low number of events and limited sample size, therefore results uncertain. Downgrade by 2
5. Implementation study with poor definition of outcomes, inadequate control of confounding measures and poor description of outcome measurement.
6. Threshold to transfer to higher level of care can be influenced by numerous factors including capacity, physician preference, parental concern, nurse staffing on both ward and PICU. Therefore indirect measure of patient outcome but only warrants downgrading by 1.
7. Well validated surrogate outcome which is widely used to assess risk of death in PICU, therefore only downgraded by 1.
8. Urgent call to individual or emergency team can be influenced by many factors including nurse staffing levels, nurse skill mix and experience, ward culture, previous experience of emergency situations and training and education. Downgraded by 1.
9. Studies describing rapid response team calls demonstrated differing results with some demonstrating increasing calls and others decreasing calls.
10. No statistical analysis or CI presented so high degree of uncertainty about the results. Downgrade by 2.
11. Length of stay can be influenced by non-patient factors such as nurse staffing, capacity, parental ability, and clinician subjective assessment. Downgrade by 1.

2.3.7.4 Unplanned transfer to intensive care – Very low evidence

Of the three studies[67,119,169] examining unplanned admission to intensive care, one also included admissions to high dependency care[67] and a further study reported transfers to a specialist hospital with intensive care facilities, although it is not known if these children ultimately received intensive care.[119] Results were mixed, with PTTS introduction reported as either increasing or decreasing the risk of transfer.

Surrogate measures of illness severity included the requirement for inotropes and ventilation, PiM2 score and length of intensive care stay. Only the change in the rate of invasive ventilation after unplanned transfer was statistically significant, with a RR of 0.83 (95% CI 0.72-0.97). This was predicted to result in 128 fewer patients requiring invasive ventilation per 1000 PICU transfers.

2.3.7.5 Call for emergency assistance – Very low evidence

Emergency assistance was defined as activation of the code blue or cardiac arrest team. A single study reported a reduction in calls after a PTTS was introduced, but RR could not be calculated as neither the number of calls nor the denominator were reported.[182]

2.3.7.6 Call for urgent assistance – very low evidence

Four studies examined urgent calls for assistance.[67,118,119,182] A single study[119] reported a statistically significant reduction in calls to paediatricians (RR 0.23, 95% CI 0.11-0.47) and respiratory therapists (RR 0.36, 95% CI 0.14-0.96).

2.3.7.7 Length of hospital stay – very low evidence

A single study reported a decreased length of hospital stay (1.5 days pre- versus 1.6 days post-PTTS implementation) but the RR could not be calculated.[182]

2.3.8 Effect as part of a package of interventions on patient important outcomes

Ten observational studies described the introduction of PTTS as part of instigating a rapid response team.[40,139,141-143,152,153,155,179,181] A further study[84] with an established team examined a package of interventions designed to increase situational awareness. Results are summarised in Table 2.10.

Table 2.10 Evidence profile for PTTS as part of a package of interventions

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Outcome: Death								**Importance: Critical**				
Death following PICU transfer/all PICU patients	1	OS	not serious	not serious	not serious	not serious	very strong association[2]	228/5753 (4.0%)	266/4666 (5.7%)	**RR 0.70** (0.59 to 0.83)	**171 fewer per 10,000** (from 97 fewer to 234 fewer)	⨁⨁⨁⨁ HIGH
Death in hospital/ 1000 admissions	4	OS	not serious	not serious	not serious	not serious	strong association[1]	1136/ 207115 (5.5)	1661/ 192862 (8.6)	**RR 0.64** (0.59 to 0.69)	**27 fewer per 10,000** (from 23 fewer to 30 fewer)	⨁⨁⨁◯ MODERATE
Unexpected death on ward/1000 admissions	3	OS	not serious	not serious	not serious	not serious	none	11/151327 (0.1)	37/129679 (0.3)	**RR 0.26** (0.13 to 0.50)	**2 fewer per 10,000** (from 1 fewer to 2 fewer)	⨁⨁◯◯ LOW
Death following PICU transfer/ PICU transfers	4	OS	not serious	not serious	not serious	not serious	none	137/1946 (7.0)	210/2479 (8.5)	**RR 0.83** (0.68 to 1.02)	**144 fewer per 10,000** (from 17 more to 271 fewer)	⨁⨁◯◯ LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Death after PICU readmission/ 1000 hospitals admissions	1	OS	not serious	not serious	not serious	not serious	none	7/55963 (0.1)	16/55469 (0.3%)	**RR 0.43** (0.18 to 1.05)	**2 fewer per 10,000** (from 0 fewer to 2 fewer)	⨁⨁◯◯ LOW
Death during ward emergency/ 1000 patient days	1	OS	not serious	not serious	not serious	not serious	none	0/178151 (0.0)	2/192353 (0.0)	not estimable	not estimable	⨁⨁◯◯ LOW
Death of arrested patients/ arrested patients	1	OS	not serious	not serious	not serious	very serious[3]	none	2/8 (25.0%)	8/16 (50.0%)	**RR 0.50** (0.33 to 1.00)	**250 fewer per 1000** (from 0 fewer to 335 fewer)	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Outcome: Cardiac Arrest							**Importance: Critical**					
Arrest on ward/1000 non-PICU admissions	3	OS	not serious	not serious	not serious	not serious	none	28/145574 (0.2)	40/125013 (0.3)	**RR 0.60** (0.37 to 0.97)	**1 fewer per 10,000** (from 0 fewer to 2 fewer)	⨁⨁◯◯ LOW
Arrest on ward/1000 non-PICU patient days	3	OS	not serious	not serious	not serious	not serious	none	28/363316 (0.1)	35/384655 (0.1)	**RR 0.85** (0.52 to 1.39)	**1 fewer per 10,000** (from 4 fewer to 4 more)	⨁⨁◯◯ LOW
Arrests/1000 hospital admissions	1	OS	not serious	not serious	not serious	not serious	none	15/5471 (2.7)	43/10576 (4.1)	**RR 0.67** (0.38 to 1.21)	**13 fewer per 10,000** (from 9 more to 25 fewer)	⨁⨁◯◯ LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Outcome: Respiratory arrest							**Importance: Critical**					
Ward intubation/ 1000 patient days	1	OS	not serious	not serious	not serious	not serious	none	3/49588 (0.1)	11/48393 (0.2)	**RR 0.27** (0.08 to 0.98)	**2 fewer per 10,000** (from 0 fewer to 2 fewer)	⨁⨁◯◯ LOW
Ward intubation/ 1000 patient discharges	1	OS	not serious	not serious	not serious	not serious	none	3/7503 (0.4)	11/7504 (1.5)	**RR 0.27** (0.71 to 0.98)	**11 fewer per 10,000** (from 0 fewer to 13 fewer)	⨁◯◯◯ VERY LOW
Arrests/1000 patient days	1	OS	not serious	not serious	not serious	not serious	none	4/52494 (0.1)	16/92188 (0.2)	**RR 0.44** (0.15 to 1.31)	**1 fewer per 10,000** (from 1 fewer to 1 more)	⨁⨁◯◯ LOW
Ward intubation/ 1000 non-PICU patient days	1	OS	not serious	not serious	not serious	not serious	none	0.12	0.09	not estimable	not estimable	⨁⨁◯◯ LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Outcome: Cardiac and/or respiratory arrest								**Importance: Critical**				
Arrests/1000 non-PICU admissions	4	OS	not serious	not serious	not serious	not serious	strong association[1]	89/68701 (1.3)	173/91644 (1.9)	**RR 0.69** (0.53 to 0.89)	**6 fewer per 10,000** (from 2 fewer to 9 fewer)	⨁⨁⨁◯ MODERATE
Arrests/1000 discharges	2	OS	serious [4]	not serious	not serious	not serious	strong association[1]	68/19185 (3.5)	176/30065 (5.9)	**RR 0.61** (0.46 to 0.80)	**23 fewer per 10,000** (from 12 fewer to 32 fewer)	⨁⨁⨁◯ MODERATE
Arrests/1000 patient days	3	OS	not serious	not serious	not serious	not serious	none	19/136502 (0.1)	94/243118 (0.4)	**RR 0.36** (0.22 to 0.59)	**2 fewer per 10,000** (from 2 fewer to 3 fewer)	⨁⨁◯◯ LOW
Outcome: Request for emergency assistance								**Importance: Critical**				
Code blue call/1000 non-PICU patient days	1	OS	not serious	not serious	not serious	not serious	none	115/ 178151 (0.6)	102/ 192353 (0.5)	**RR 1.22** (0.93 to 1.59)	**1 more per 10,000** (from 0 fewer to 3 more)	⨁⨁◯◯ LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Code blue call/1000 hospital admissions	1	OS	not serious	not serious	not serious	not serious	none	210/55469 (3.8)	150/55963 (2.7)	**RR 1.41** (1.15 to 1.74)	**11 more per 10,000** (from 4 fewer to 20 more)	⨁⨁◯◯ LOW
Code blue call/1000 patient days	1	OS	very serious[5]	not serious	not serious	not serious	none	88/49588 (1.8)	51/48393 (1.1)	**RR 1.68** (1.19 to 2.38)	**7 more per 10,000** (from 2 more to 15 more)	⨁◯◯◯ VERY LOW
Outcome: Unplanned transfer to PICU								**Importance: Critical**				
Unplanned transfers requiring vasopressors in first 1 hour/ unplanned transfers	1	OS	not serious	not serious	not serious	serious[6]	none	16/936 (1.7%)	41/874 (4.7%)	**RR 0.36** (0.21 to 0.65)	**30 fewer per 1000** (from 16 fewer to 37 fewer)	⨁◯◯◯ VERY LOW
Unplanned ward transfers/ 1000 admissions	2	OS	not serious	not serious	not serious	not serious	none	1178/ 91855 (12.8)	1560/ 160249 (9.7)	**RR 1.32** (1.22 to 1.42)	**31 more per 10,000** (from 21 more to 41 more)	⨁⨁◯◯ LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Unplanned ward transfers/1000 non-PICU patient days	1	OS	not serious	not serious	not serious	not serious	none	936/ 178151 (5.3)	874/ 192353 (4.5)	**RR 1.16** (1.05 to 1.27)	**7 more per 10,000** (from 2 more to 12 more)	⨁⨁◯◯ LOW
Unplanned readmissions from ward/ 1000 admissions	1	OS	not serious	not serious	not serious	not serious	none	200/55469 (3.6)	163/55963 (2.9)	**RR 1.24** (1.01 to 1.52)	**7 more per 10,000** (from 0 fewer to 15 more)	⨁⨁◯◯ LOW
Critical deterioration event/1000 non-PICU patient days	1	OS	not serious	not serious	not serious	not serious	none	281/ 178151 (1.6)	260/ 192353 (1.4)	**RR 1.17** (0.99 to 1.38)	**2 fewer per 10,000** (from 0 fewer to 5 more)	⨁⨁◯◯ LOW
Median PRISM III-12 score on admission	1	OS	not serious	not serious	not serious	not serious	none	0	2	not estimable	not estimable	⨁⨁◯◯ LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Unsafe transfer*/ 10000 non-ICU inpatient days	1	OS	not serious	not serious	not serious	not serious	none	2.4	4.4	not estimable	not estimable	⨁⨁◯◯ LOW
Unplanned transfer requiring vasopressors in first 12 hours/ unplanned PICU transfers	1	OS	not serious	not serious	not serious	serious[6]	none	57/936 (6.1%)	71/874 (8.1%)	**RR 0.75** (0.54 to 1.05)	**20 fewer per 1000** (from 4 more to 37 fewer)	⨁◯◯◯ VERY LOW
Unplanned transfer requiring mechanical ventilation in first 1 hour/ unplanned PICU transfers	1	OS	not serious	not serious	not serious	serious[6]	none	42/936 (4.5%)	45/874 (5.1%)	**RR 0.87** (0.58 to 1.31)	**9 fewer per 1000** (from 13 more to 23 fewer)	⨁◯◯◯ VERY LOW

Metric	Quality assessment							№ of patients		Effect		Quality
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other factors	PTTS as part of RRT	No RRT	Relative (95% CI)	Absolute (95% CI)	
Unplanned transfer requiring mechanical ventilation in first 12 hours/ unplanned PICU transfers	1	OS	not serious	not serious	not serious	serious[6]	none	103/936 (11.0%)	112/874 (12.8%)	**RR 0.86** (0.67 to 1.10)	**18 fewer per 1000** (from 13 more to 42 fewer)	⨁◯◯◯ VERY LOW

Data presented relates to the number of patients unless the metric states otherwise. Outcomes highlighted in blue are statistically significant.

***Unsafe transfer:** Patient requiring intubation, vasoactive drugs or >3 fluid bolus prior to or within first hour in PICU

Abbreviations: CI: Confidence interval; **OS:** Observational study; **PICU:** Paediatric Intensive Care Unit, **RR:** Relative Risk

Key

1. Large effect of relatively rate outcome. Upgraded by 1.
2. Very large effect of relatively rate outcome. Upgraded by 2.
3. Extremely small sample size. Downgraded by 1.
4. One study poorly reported the definition of arrest and both studies inadequately described the risk of confounding. Downgrade by 1.
5. Inadequate definition of code blue call, retrospective data collection, inadequate description of risk of confounding. Downgraded by 2
6. Small sample size. Downgraded by 1.

2.3.8.1 Death – Moderate evidence

Eight studies reported impact on mortality.[139,141-143,152,155,179,181] The pooled results indicate a statistically significant reduction in the risk for death in hospital of 0.64 (95% CI 0.59-0.69), with 31 fewer deaths predicted per 10,000 admissions. Relative risk of death following PICU transfer was reduced at 0.7 (95% CI 0.59-0.83), which equates to 171 (95% CI 97 – 234) fewer predicted deaths per 10,000 PICU patients. There was also a significant reduction in unexpected deaths on the ward (RR 0.26, 95% CI 0.13-0.50), with two fewer predicted deaths per 10,000 admissions after rapid response team and PTTS implementation. These are rare events and hence the absolute effect size is small.

2.3.8.2 Cardiac arrest – Low evidence

Three studies reported the impact of a rapid response team with an embedded PTTS on the rate of cardiac arrest.[142,152,155] Ward cardiac arrests per 10,000 non-PICU admissions were significantly reduced (RR 0.60, 95% CI 0.37-0.97). Unsurprisingly given the low event rates, the predicted absolute reductions are very small, with one fewer predicted death per 10,000 non-PICU ward admissions. Notably, when the RR of arrest was calculated per 10,000 non-PICU patient days, the result was not statistically significant (RR 0.85, 95% CI 0.52-1.39).

2.3.8.3 Respiratory arrest – Low evidence

Requirement for bag-valve-mask ventilation and intubation on the ward were considered under the outcome of respiratory arrest. The three studies[139,142,155] all utilised different metrics. There was a statistically significant reduction in the risk of need for intubation on the ward of 0.27 for events, both per 1000 patient days (95% CI 0.08-0.98) and per 1000 discharges (95% CI 0.71-0.98). Again the absolute effect was small, with two fewer predicted ward intubations per 10,000 patient days (zero fewer to two fewer) and 11 fewer per 10,000 discharges (zero fewer to 13 fewer).

2.3.8.4 Cardiac and/or respiratory arrest – Moderate evidence

Six studies combined the reporting of cardiac and respiratory arrests for three metrics.[139,142,143,153,179,181] All results were statistically significant. The RR of arrest per 10,000 non-ICU admissions was 0.69 (95% CI 0.53-0.89) or six fewer predicted arrests. When reported against patient discharges, an absolute reduction of 23

arrests per 10,000 discharges was estimated (RR 0.61, 95% CI 0.46-0.80). The RR of arrest per 10,000 patient days was also reduced (RR 0.36, 95% CI 0.22-0.59) with an estimated reduction of 23 arrests per 10,000 patient days.

2.3.8.5 Request for emergency assistance – Low evidence

Calls for emergency assistance were reported by three studies[139,155,181] using three metrics. No metric achieved statistical significance.

2.3.8.6 Unplanned transfer to Intensive Care –Very low level evidence

Five studies[40,84,139,155,181] described 10 different metrics relating to the risk of unplanned transfer to PICU. The RR of unplanned transfer requiring vasopressors in the first hour was 0.36 (95% CI 0.21-0.65), with an absolute rate of 30 fewer patients per 1000 unplanned PICU admission. The remaining results did not achieve statistical significance.

2.3.9 Validity – Predictive performance

Seventeen studies[42,59,116,121,137,138,144,154,157,158,162,164,170,172,177,186] examined the predictive performance of PTTS to predict patient important outcomes (Table 2.11). One study[42] reported inaccurate values for sensitivity and specificity and the methodology did not permit accurate calculation.[187] The results were therefore removed from the table. The majority of the remaining 13 studies were retrospective, which increased the risk of bias. PTTS systems were examined across a variety of outcomes and combinations of outcomes.

Table 2.11 Studies reporting predictive performance

Paper	Design	Patients	Outcome measures	System	Score	Sensitivity % (95% CI)	Specificity % (95% CI)	AUROC (95% CI)
Olson[162]	Prospective nested case-control	54 cases 161 controls	Death within 2 days	ITAT	≥ 4	44.0 (31.3-58.5)	86.0 (79.1-90.5)	0.76
Robson[121]	Retrospective case-controlled evaluation of 3 systems	96 cases 96 controls	Code blue	Bedside PEWS	≥8	43.8 (33.8-54.2)	85.4 (76.4-91.5)	0.73
				Bristol PEW tool	≥1	76.3 (66.0-83.9)	61.5 (50.9-71.1)	0.75
				PEWS score I	≥5	86.6 (77.6-92.3)	72.9 (62.7-81.2)	0.85
Duncan[138]	Retrospective case control	87 cases 128 controls	Code blue	PEWS score I	≥5	78.0 (67.8-86.0)	95.0 (88.6-97.6)	0.90
Akre[177]	Retrospective, descriptive	186 cases	Code blue and/or RRS activation	PEW score IV	≥ 4	85.5 (79.4-90.1)		
Fenix[175]	Retrospective cohort study	97 patients	Deterioration event* after non-elective PICU transfer	PEW Score II	≥ 3	80.0	43.0	

Paper	Design	Patients	Outcome measures	System	Score	Sensitivity % (95% CI)	Specificity % (95% CI)	AUROC (95% CI)
Mandell[186]	Retrospective case-controlled	38 cases 151 controls	Unplanned PICU readmission within 48 hours	CH LA PEWS	≥2	76.0	56.0	0.71
Parsharum 2011[116]	Prospective multi-centre case-controlled	686 cases 1388 controls	Urgent PICU admission and/or call to resuscitation team	Bedside PEWS	≥8	57.4 (53.6-61.2)	94.7 (93.3-95.8)	0.87 (0.85-0.89)
McLellan[158]	Retrospective cohort	64 cases (10 arrests, 54 PICU transfers) 248 controls	Unplanned PICU transfer or cardiopulmonary arrest	C-CHEWS	≥ 3	95.3	76.2	0.92
				PEW I	≥ 3	54.7 (41.7-67.2)	86.3 (81.4-90.3)	0.79
Fuijschot[172]	Retrospective cohort	24 cases	Unplanned PICU admission	Bedside PEWS	≥7	64.0	91.0	
				MPEWS III	≥8	67.0	88.0	
Skaletzky[170]	Retrospective case-controlled	100 cases 250 controls	PICU admission	MPEWS I	2.5	62.0 (51.7-71.4)	89.2 (84.5-92.6)	0.81 (0.75-0.86)
Tucker[144]	Prospective, cohort	2979	PICU admission	PEW score II	≥3	90.2 (77.8-96.3)	74.4 (72.8-75.9)	0.89 (0.84-0.94)

Paper	Design	Patients	Outcome measures	System	Score	Sensitivity % (95% CI)	Specificity % (95% CI)	AUROC (95% CI)
Parshuram 2009[154]	Prospective case-controlled validation	60 cases 120 control	Urgent PICU admission without code blue	Bedside PEWS	≥8	82 (69.1-90.1)	93 (86.9-96.9)	0.91 (0.86-0.96)
Agulnik[160]	Retrospective case-controlled	110 cases 220 controls	Unplanned admission to PICU	C-CHEWS	≥ 3	93.6 (86.9-97.2)	88.2 (83.0-92.0)	0.96 (0.93-0.98)
Gawronski[157]	Retrospective case-controlled	19 cases 80 controls	Unplanned PICU transfer, urgent RRS consult, unexpected ward death	Bedside PEW system	≥8	73.7 (48.6-89.9)	98.8 (92.3-99.9)	0.87
Tume[59]	Retrospective cohort	33 cases (PICU) 32 cases (HDU)	Unplanned admission to PICU or HDU	Bristol PEW tool	≥ 1 (HDU)	84.4 (66.5-94.1)		
					≥ 1 (PICU)	87.9 (70.9-96.0)		
				MET activation criteria I	≥ 1 (HDU)	87.5 (70.1-96.0)		
					≥ 1 (PICU)	87.9 (70.9-96.0)		

Paper	Design	Patients	Outcome measures	System	Score	Sensitivity % (95% CI)	Specificity % (95% CI)	AUROC (95% CI)
Edwards 2009[137]	Prospective cohort	1000[1]	PICU/PHDU admission; respiratory/ cardiac arrest**; death**	Cardiff and Vale PEW system	≥2	68.7 (41.5-87.9)	89.9 (87.9-91.7)	0.86 (0.82-0.91)
Edwards 2011[164]	Retrospective cohort study	1000[1]	PICU/PHDU admission; death**	MET activation criteria I	≥1	68.3 (57.7-77.3)	83.2 (83.1-83.2)	0.79 (0.30 -0.84)
Mason[174]	Retrospective cohort study	1000[1]	Adverse outcome (PICU/ PHDU admission, death*)	NHSI PEW system	≥2	62.5 (35.9-83.7)	42.0 (38.9-45.1)	.83 (0.77-0.88)

One study[42] reported incorrect values for sensitivity and specificity and these have been eliminated from analysis

Key: *Deterioration event: Intubation, inotropes, high flow nasal cannula oxygen, non-invasive ventilation and/or aggressive (>60mL/kg) fluid resuscitation within 12 hours of transfer to the PICU

**No respiratory/cardiac arrests or deaths occurred; Values in red were not reported in the paper and have been calculated using available data; [1]Published values were calculated based on the number of observations taken, rather than the number of patients and have re-calculated

Abbreviations: AUROC: Area Under Receiver Operating Characteristic Curve; **C-CHEWS**: Cardiac Children's Hospital Pediatric Early Warning Score; **CI:** Confidence interval; **ITAT**: Inpatient triage, assessment and treatment score; **MET**: Medical Emergency Team; **MPTTS**: Modified Pediatric Track and Trigger Score; **PEW**: Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PHDU:** Paediatric High Dependency Unit; **PICU:** Paediatric Intensive Care Unit; **PMET**: Pediatric Medical Emergency Team **PPV:** positive predictive value; **RRT:** Rapid Response Team; **TCH**: Texas Children's Hospital

2.3.9.1 Death in hospital – very low evidence

A single study of the ITAT system,[162] set in a resource-limited environment, was examined for the ability to predict death in hospital. A significant proportion of children were excluded due to missing data, raising concerns about the risk of bias. AUROC of 0.76 demonstrated reasonable ability to identify children at risk of death within two days.

2.3.9.2 Cardiac arrest – very low evidence

Two case controlled studies were identified,[121,138] of which one compared the validity of three differing systems.[121] Similar levels of sensitivity were seen across the differing systems, but specificity varied. AUROC values ranged from 0.73 to 0.91. Trigger-based system[121] appeared to perform less well than the scoring systems.[121,138]

2.3.9.3 Respiratory arrest – no evidence

No studies evaluated respiratory arrest as a stand-alone outcome.

2.3.9.4 Unplanned transfer to intensive care – very low evidence

Unplanned transfer to PICU was evaluated in four studies[144,154,170,172] of which one specifically excluded patients who had received a code blue call prior to transfer.[154] AUROC ranged from 0.80 (95% CI 0.85-0.89) to 0.90 (95% CI not reported).

2.3.9.5 Unplanned transfer to PICU or HDU – very low evidence

Three studies[59,137,164] examined the composite outcome of transfer to PICU or HDU. Two studies[137,164] used the same data set to validate prospectively and to evaluate retrospectively the ability to predict unplanned transfer, cardiac/respiratory arrest and/or death. However no arrests or deaths occurred so the outcome was limited to unplanned transfer. AUROC ranged from 0.79 (95% CI 0.73-0.84) to 0.86 (95% CI 0.82 - 0.91).

2.3.10 Reliability

Six studies evaluated the inter-rater reliability of six different PTTS (Table 2.12) in a variety of settings. Good to high levels of inter-rater reliability were reported for four studies,[118,119,144,182] with a further study demonstrating excellent inter-rater reliability

at scores of three and above, the first cut-point on the algorithm that required escalation.[158] The remaining study presented the outcomes graphically and reported a consistent improvement over an unspecified period of time.[176] All studies were conducted during the implementation of score-based PTTS but no studies evaluated whether reliability was sustained after implementation. No studies evaluated intra-rater reliability.

Table 2.12 Studies reporting inter-rater reliability

System	Setting	Assessors	Cases assessed	Inter-rater reliability (95% CI)
Bedside PEW system[119]	22 bed ward, community hospital	Frontline nurse and research nurse	793 vital sign documentations	0.90 (0.87- 0.93)
C-CHEWS[158]	41 bed cardiovascular unit	25 frontline nurses and expert nurse	37 patients (87 documented vital signs)	0.5 all scores 1.0 when score ≥ 3
PEW score I[118]	Cardiology/ nephology unit	3 assessors (nurse manager, staff nurse, medical director)	44 cases across 4 assessments	0.9 –0 .95
PEW score II[144]	24-bed medical unit	2 nurses	55 cases	0.92, p <.0001
PEW score III[176]	Haematology/ oncology unit	2 nurses	NS	Increased over time
TCH-PAWS[182]	3 acute care units	58 nurses	NS	0.85 (0.75 –0 .91)

Key: C-CHEWS: Cardiac Children's Hospital Early Warning Score **CI:** Confidence interval; **NS:** Not stated; **PEW:** Paediatric Early Warning; **TCH-PAWS:** Texas Children's Hospital Pediatric Advance Warning System

2.3.11 Calibration

No studies assessed calibration.

2.3.12 Utility

Eight quantitative and two qualitative studies examined the acceptability and usefulness of PTTS to staff (Table 2.13). Nurses were represented in all 10 studies, physicians in eight and respiratory therapists in two. Overall responses were positive, with improved recognition, escalation and communication featuring in a number of studies.

Staff appeared to value the systems and reported improvements in both the detection and escalation of concerns. However one study reported an 'unwillingness' to escalate elevated PTTS by 47% of doctors and 32% of nurses. No study identified PTTS as negatively impacting on patients or staff.

Although a number of PTTS contain criterion to report 'family concern' no studies evaluated the acceptability of PTTS to the children who were undergoing PTTS monitoring and their families.

Table 2.13 Studies reporting acceptability to staff

System	Setting	Methodology	Participants	Main results
Bedside PEWS[119]	Community hospital	Staff survey 3 months before and 2 and 5 months after PTTS implementation using Likert and 100mm visual analogue scale (VAS)	114 frontline nurses and respiratory therapists (61%)	Documentation quality rating increased from a median of 3 (adequate) to 4 (good) post-implementation (p=.007) VAS ratings of documentation, inter-professional communication and apprehensiveness when calling a paediatrician after hours improved after implementation
Bedside PEWS[156]	Children's hospital	Electronic survey (Likert scale) on medical ward with and without PTTS	35 nurses (46% return), 17 physicians (81% return)	Nurses on PTTS ward reported significantly greater ability to identify early signs of deterioration (4.43 vs 3.9, p<.04) and greater ability to escalate concern (4.52 vs 3.0, p<.01) than non-PTTS ward staff Physicians reported that more nurses on PTTS ward were able to communicate concerns about deteriorating child than non-PTTS ward (4.18 vs 3.67, p<.05). No physicians indicated that the PTTS was unhelpful
Bristol PEWS[188]	University hospital	Chart audit and questionnaire	Medical and nursing staff (n not stated)	Staff lacked confidence in the PTTS
CEWT[67]	University hospital	Pre- and post staff survey on interventional study on education and PTTS introduction	Pre: 7 medical officers and 58 nurses (63.1% return) Post: 2 medical officers and 24 nurses (53.1%)	Increase in self-reported confidence in assessment (90.2% vs 100%, p=.269) and ease in determining if the child was deteriorating (80.5% vs 100%, p=.159)

System	Setting	Methodology	Participants	Main results
MET activation criteria I[166]	Children's hospital	Likert based electronic survey on attitudes and barriers to established paediatric RRS	280 nurses, 127 doctors	RRS was highly valued by 85% nurses and 83% doctors. However 47% doctors and 32% nurses reported unwillingness to activate RRS when the PTTS criterion were breeched. 30% doctors and 15% nurses reported that delay in activating the RRS was because they did not appreciate how sick the patient was
Modified Bristol PEWS[69]	Children's hospital	Survey of ward nurses	122 nurses (64% Registered nurses, 20% charge nurse, 8% student nurse, 7% care assistant)	62% felt PTTS helped them pick up seriously ill children earlier. 43% had triggered the PTTS in the last month and 80% felt it helped them get appropriate management for the child. 51% of nurses felt medical staff did not take PTTS seriously enough.
Modified PEWS II[79]	Children's hospital	Semi-structured interviews with staff who had recently cared for patients with false-positive and false-negative PTTS	27 nurses and 30 physicians	Four major themes: 1: PTTS facilitate patient safety by alerting staff to concerning changes, prompting them to think critically about the possibility of deterioration 2: PTTS provide less experienced nurses with helpful age-based reference ranges for vital signs 3: PTTS serve as concrete evidence to empower nurses to escalate care 4: PTTS may not be helpful for children with altered baseline physiology and neurological deterioration
PEW score I[39]	Children's hospital	Staff survey	33 staff (medical and surgical ward)	80% reported that PTTS improved their confidence in recognising the child at risk of deterioration

System	Setting	Methodology	Participants	Main results
PEW Score II[83]	Children's hospital	Seven role-specific focus groups on situational awareness. Constant comparison analysis	10 charge nurses, 8 bedside nurses, 3 respiratory nurses, 10 resident physicians	PTTS was identified by all 6 nurse focus groups as contributing to situational awareness of the deteriorating child PTTS was not identified by resident physicians as contributing to situational awareness of the deteriorating child
PEW Score III[176]	Children's hospital	Staff survey	Nurses (29%) and house officers (36%)	Percentage of nurses who agreed or strongly agreed with the following: PTTS made it easier to know what to do when a child was deteriorating (60%) PTTS made it easier to get help when taking care of patients (80%) PTTS had positively impacted the care given to children (60%) Percentage of physicians who agreed or strongly agreed with the following: Calls regarding changes to patient clinical status were appropriate in frequency (62%) PTTS kept them better informed (62%) PTTS resulted in consistent and prompt care (75%) PTTS had positively impacted the care given to children on the unit (38%) and children who were deteriorating (74%) PTTS had prevented codes (57%)

Key: C-CHEWS: Cardiac Children's Hospital Paediatric Early Warning Score; **CEWT:** Children's Early Warning Tool; **MET:** Medical Emergency team; **NS:** Not stated; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **RRS:** Rapid Response System; **VAS:** Visual analoge scale

2.4 **Discussion**

Paediatric track and trigger systems are now an established part of care for children in hospital. Most paediatric centres report using them.[43] There is striking diversity in the components, thresholds and efficacy of the systems. The *Paediatric Early Warning System Score I*[138] remains the most complex, with nineteen parameters. By contrast, the *Paediatric Early Warning Score I*[39,118] and its derivatives[48,144,170,177,180,182] have far fewer parameters (three to five). However, these 'simpler' systems are constituted from parameters which have three to four sub-parts requiring assessment. For example, the 'cardiovascular' parameter in the *Paediatric Early Warning Score I* requires assessment of skin colour, capillary refill time and heart rate, whilst the 'respiratory' parameter combines respiratory rate, oxygen therapy, tracheal tug and other signs of respiratory effort. Within these 'simpler' systems clinicians often had to make independent judgments of the 'normal' values for heart rate and respiratory rate. It is also unclear what score they should assign if the clinical features identified were spread across two or more 'sub-scores'. Therefore it may be that the superficially more complex systems containing objective and unambiguous scoring frameworks may be simpler for clinicians to use.

Although vital signs appeared frequently, comparison to evidence-based thresholds for heart rate and respiratory rate[184] revealed marked variation between different PTTS systems. No system had consistent thresholds when mapped against the centile-derived reference ranges and some had thresholds that crossed the 50th centile, indicating that activation/escalation would occur with a 'normal' vital sign value. Others had thresholds that sat well outside the 1st or 99th centile, representing extreme levels of derangement. Most age-dependent PTTS grouped children into five age-categories, which may account for the 'bluntness' of the thresholds when compared to those derived from percentile curves.

The evidence to support the clinical utility of PTTS is variable. Implemented without a rapid response team, PTTS did not demonstrate statistically significant relative reduction in cardiac or respiratory arrest, or mortality. A single study in a specialist children's hospital demonstrated a reduction in the rate of invasive ventilation after unplanned admission to PICU (RR 0.83, 95% CI 0.72 – 0.97). The study predicted that PTTS implementation would result in 128 fewer patients requiring ventilation per 1000 unplanned ward to PICU transfers. A separate study set in a community

hospital reported a relative reduction in risk of urgent calls to both physician and respiratory therapists, with a predicted absolute reduction of 17 and six fewer calls per 1000 patient days respectively. However it is unclear whether low rates of urgent calls is a desirable outcome that ultimately benefits patients.

When implemented as part of a rapid response team, PTTS demonstrated more positive results and the evidence overall was of moderate quality. This would support the ethos of the safe system framework,[33] where improvements in the management of the deteriorating child are likely to emerge through attention to the system of care rather than implementation of any one single intervention. There was a statistically significant reduction in the relative and absolute risk of death in hospital, death on the ward and death following PICU transfer. Childhood mortality remains a rare but devastating event. The contributing factors are complex, but the failure to recognise serious illness and correctly interpret physical signs correctly has been cited as a significant factor.[1] This review demonstrates the potential of PTTS and associated interventions to reduce the number of in-hospital deaths by an estimated 31 cases per 10,000 hospital admissions. Given the rarity of childhood death, this is a significant improvement.

PTTS as part of a package of interventions also had a positive impact on cardiac and respiratory arrests on the ward. When examined separately the evidence was low level, however studies that combined the outcome were of moderate quality. Again, the events are relatively rare and although a significant reduction was seen in the RR, the predicted absolute effect was low, with only one fewer predicted cardiac arrests on the ward per 10,000 non-ICU admissions, and 11 fewer ward intubations per 10,000 discharges. In 2009 the short-term financial cost per event was estimated at £3884 for cardiac arrest and £3569 for respiratory arrest.[189] The emotional cost, particularly for children and their families, cannot be overestimated.

Unplanned transfer to the PICU generally increased post-rapid response team implementation, but studies did not achieve statistical significance. Only the metric of unplanned PICU transfers requiring vasopressors within the first hour was statistically significant, however the effect was not sustained and at 12 hours post-transfer there was no difference between the groups.

Many of the metrics used to assess the outcomes did not achieve statistical significance. The relatively low incidence of these events means that many years of

data are required to achieve studies with sufficient statistical power, prompting calls for valid, yet pragmatic measures to be adopted.[168]

There is low level evidence of the predictive validity of PTTS in detecting children at risk of cardiopulmonary arrest or admission to a higher level of care. There remains very low evidence about the ability to predict mortality. The evidence arises from the single centre study in a resource limited setting. This may simply reflect the study power issue with relatively low rates of unexpected deaths in hospital in developed countries.

Scoring systems are generally used with a decision-algorithm, which indicates the appropriate action to be taken for the PTTS score. This facilitates a graded response, where low scores prompt review by the nurse in charge of the ward and high scores require referral to a senior clinician. However, effective use requires appropriate assessment of the degree of risk indicated for each score. To date, no studies have analysed the calibration of score-based PTTS, therefore it is unclear whether the decision-algorithms advocated by differing PTTS scores are appropriate for the degree of risk. Despite this, the evidence on validity suggests that score-based PTTS may be more effective than trigger-based systems.

2.4.1 Limitation of the systematic review

This updated systematic review was restricted to published PTTS and it is highly likely that there are many more unpublished systems in clinical practice that may have undergone local evaluation and examination. There is a potential risk of bias through non-publication of studies with equivocal or negative results (publication bias).[190]

Most studies have been conducted in specialist children's hospitals and the results may have limited applicability to secondary care settings due to the different mix of patients and staffing.

2.4.2 Implications for practice

The initial systematic review highlighted the lack of evidence to support PTTS. Validity, utility and reliability were largely unknown. More robust research was called for before more widespread adoption.[4] Over the course of the PhD process the

situation has improved. The evidence is stronger for PTTS as part of a package of interventions. This may reflect the complexities of healthcare delivery and support the approach advocated by the safe system framework.[33] Management of complex conditions is rarely resolved by a single intervention, and this may explain the popularity of packages of interventions or 'care bundles'.[191,192]

There remains no consensus on what type of PTTS should be implemented, or on the constituent parameters. Score-based systems may have benefits over trigger systems. They offer the opportunity to implement a graded response, which may be a better use of resources and expertise. This may be most relevant in centres without access to a rapid response team. Score-based systems have also had more extensive evaluation and demonstrated better sensitivity. Currently the *Bedside PEWS* has been the most intensively evaluated. This score was developed and tested in a single tertiary centre, but has undergone several further evaluations in other settings and is currently being tested in a multi-centre, international cluster-randomised trial in 22 hospitals.[10] As such, it appears to be the most appropriate choice for centres looking to implement a PTTS.

2.5 Conclusion

This chapter has contributed to the body of knowledge of PTTS through a rigorous and systematic examination the literature. The low overall level of evidence on PTTS has been highlighted. Most studies have failed to demonstrate that PTTS have a positive impact on clinical outcomes. The reasons for this are complex but validity, reliability and utility require further research. Validity and particularly predictive performance remain largely unknown. Only 14 of the 33 identified systems have undergone evaluation of predictive performance and performance between differing PTTS was only compared in a single study. Pooled analysis was largely not possible because of the different outcome and metrics that were evaluated.

The next chapter will compare the predictive validity of 18 PTTS and explore whether performance can be improved by the addition of evidence based heart and respiratory rate thresholds.

Chapter 3 Validity: an observational study of 18 paediatric track and trigger systems in a paediatric hospital

3.1 Introduction

In the previous chapter the literature on paediatric track and trigger systems (PTTS) was systematically reviewed. Gaps were identified in the evidence for validity, particularly predictive performance. In this chapter performance of 18 PTTS will be compared to determine if performance varies. Recently published evidenced-based thresholds for heart and respiratory rate have been proposed as offering potential to improve existing PTTS. They may also offer the opportunity to adapt the adult *National Early Warning Score*[146] *(NEWS)* to a paediatric population, with possible benefits in terms of staff training, improved communication and greater synergy between paediatric and adult services. Therefore the performance of the *NEWS* in a paediatric population will also be evaluated. Examining the performance of PTTS has the potential to inform decision-making regarding the choice of PTTS. Selection of a high performing PTTS may improve the 'recognition of deterioration' component of the safe system framework.[33]

A retrospective case-control methodology was selected as this allowed comparison between and across multiple PTTS without interfering with patient care. As validity is largely unknown this was appropriate to protect patients whilst conducting the research. It also allowed comparison to be made on the basis of clinical signs and observations that had been documented without knowledge of the resulting PTTS score.

3.2 Aim

The aim of this study was to compare the performance of PTTS in predicting critical deterioration in a UK tertiary referral children's hospital.

A secondary aim was to examine if any limitations in the performance of these PTTS could be improved by substitution of evidence-based thresholds derived from percentile curves for heart and respiratory rate.[185]

3.2.1 Hypothesis

H1: Predictive validity, as assessed by the area under the receiver operator characteristic curve (AUROC), varies between differing PTTS

H2: The current PTTS in clinical use, the *Children's Early Warning Score (CEWS)*, has significantly worse performance that other published PTTS

H3: Predictive validity of PTTS, as assessed by the AUROC, can be improved by substitution of percentile-derived thresholds for heart and respiratory rate

3.2.2 Setting

The studies reported in Chapters three to five took place in a tertiary specialist children's hospital in central London. There are in excess of 50 different paediatric clinical specialties. The hospital receives in excess of 240,000 visits per year (in-patient admissions and out-patient visits). Most children have complex and/or rare health problems which are life-threatening or life limiting.

There were 25 wards at the time of data collection for the studies. Two wards were exclusively for international and private patients and had a range of specialities. The remaining wards admitted children from a small number of related sub-specialities. There were no 'general paediatric wards'. Where multiple specialities co-existed on a single ward, these were closely related, for example neurology and neurosurgery and gastroenterology, endocrinology and metabolic medicine. Although children were often seen by multiple teams and differing professionals they were cared for on the ward associated with their 'primary specialist'. As such, wards were considered a proxy match for diagnostic specialty.

At the time of the study standard protocols were in place for recording and documenting of vital signs, which nurses were informed of at induction and yearly intervals thereafter. Medical staff were received information on the PTTS on induction and were also updated at yearly intervals. The PTTS protocol mandated recording of a full set of vital signs within two hours of the start of the 12-hour shift. Elevated PTTS scores required repeat vital sign recording after 30 minutes. On-going frequency of recording was at the discretion of the bedside nurse.

3.3 Methods

A retrospective case-control study design was chosen as this was the most appropriate methodology to compare multiple differing PTTS without exposing patients to unnecessary risk. A cohort methodology was considered, however given the relatively small number of critical deterioration events per year this would exceed the resources available both in terms of researcher time and PhD duration if results were to be statistically significant. A two-year retrospective study would yield approximately 300 cases, which was considered sufficient by a statistician to demonstrate significant results at a p value of <.05.

3.3.1 Selection of Paediatric Track and Trigger Systems

As different PTTS were going to be compared based on existing data, not all of the PTTS identified in the systematic review (Chapter 2) were suitable for inclusion in this study.

A number of PTTS required knowledge of the patient's baseline vital signs or included subjective assessments; these were excluded. Components of the remaining systems were reviewed to confirm that they could be extracted from the healthcare records. Criteria for data extraction were developed for included parameters (Table 3.2) together with the weighting framework for scoring systems. Minor inconsistencies such as overlapping age bandings were modified in a consistent manner to facilitate score calculation. These modifications can be seen at Appendix 1. The *NEWS* has been recommended by the Royal College of Physicians for use across adult services in the National Health Service (NHS).[193] This was included to evaluate whether there was potential to adapt this tool for use with children. As this system was designed to identify deterioration in adults, evaluation of the unmodified *NEWS* was restricted to children aged 12 years and over. The local hospital's unvalidated PTTS (*CEWS*) was also included.

3.3.2 The Children's Early Warning Score

The PTTS in use at the time of the study was the *Children's Early Warning Score* or *CEWS*. This was an age-dependent scoring system which was developed locally based on the Advanced Paediatric Life Support Guidance.[15] It had six component parameters: temperature, heart rate, blood pressure, respiratory rate,

consciousness measured using the AVPU scale (Alert - Responding to Voice - Responding to Pain - Unresponsive), and oxygen saturation.

Vital signs were assessed by the bedside nurse and the values documented on the *CEWS* chart. Each vital sign parameter had an allocated section on the *CEWS* chart, with the exception of heart rate and blood pressure, which were charted in the same section. Temperature, respiratory rate, heart rate and blood pressure were charted on a graphical scale, whilst AVPU and oxygen saturation were entered into a table.

Each component parameter was then allocated a score from zero up to four (Appendix 2.1). The score was dependent on the degree of abnormality, with higher scores indicating a greater degree of variance from the 'normal' thresholds described in the APLS guidance.[15] The parameters of temperature, oxygen saturation and AVPU were assessed against a standardised scoring matrix regardless of the child's age. Heart rate, respiratory rate and blood pressure were assessed against one of four age-dependent scoring matrixes. Age ranges were in line with APLS recommendations: up to one year, one year to four years, five years to 11 years and 12 years and over.[173,194] As the vital sign CEWS scores were embedded in the observation chart, there were four versions of the observation charts, one for each age-range. In addition, the chart had sections for recording the vital sign monitoring plan and presence of supplemental oxygen therapy. An example of the *CEWS* observation charts can be seen at Appendix 2.1.

Each vital sign parameter was entered onto the chart and the individual parameter sub-score determined. Parameter sub-scores were then combined to produce the overall *CEWS* score.

3.3.3 CEWS escalation plan

The overall *CEWS* score was linked to an escalation plan identifying the action to be taken (Appendix 3). Higher scores indicated greater physiological derangement. This is purported to be associated with increasing risk of critical deterioration and prompted increasingly swift and more senior action.

Scores of zero or one were considered to indicate a child at low risk of deterioration, with vital sign parameters at or close to normal values. No action was required as part of the response. Scores of 2-4 were considered to indicate medium risk. This

prompted the vital sign parameters and PTTS score to be repeated and the child reviewed by a senior clinician. Scores at or above five were considered to indicate high risk. Vital sign parameters should be repeated and the child promptly reviewed by a senior clinician and specialist personnel from the intensive care outreach team.

The intensive care outreach team comprised a senior doctor and senior nurse experienced in paediatric critical care. Both members of the team were required to attend children with a *CEWS* score of five and above. However staff were aware that they could call the intensive care outreach nurse at any time if they had concerns or questions about the child's condition. Both the nurse and doctor were members of the hospital's clinical emergency team, which would be activated for an actual or imminent respiratory or cardiac arrest.

3.3.4 Participants

Patient's who suffered a critical deterioration event were designated 'cases' (Table 3.1). Case patients were identified from the Paediatric Intensive Care Audit Network database (PICANet),[195] the hospital resuscitation database and cross-referenced against intensive care admission records. Patients present on the ward for less than two hours before the event were excluded as this was considered the minimum time for the child to be assessed, clinical signs recorded and action to be taken. Each case patient was matched with a single control, present on the same ward at the same time. Wards were considered a proxy match for diagnostic speciality.

Table 3.1 Conditions constituting critical deterioration

Condition	Definition
Cardiac arrest	Chest compressions administered for absent or poor pulse
Respiratory arrest	Rescue breaths administered via mouth-to-mouth, bag-valve-mask or emergency intubation on ward
Unplanned admission to critical care	An admission that was not expected and is therefore classed as an emergency. Includes children who are admitted from the operating room where surgery is not the main reason for admission (e.g. child who is taken to the anaesthetic room for emergency intubation due to difficult airway)
Unexpected death	Death on the ward without the presence of a 'do not attempt resuscitation' (DNAR) order or end of life care pathway

3.3.4.1 Inclusion criteria

Participants were admitted to the hospital between the 1st January 2011 and 31st December 2012.

3.3.4.2 Exclusion criteria

To ensure at least one set of observations could be extracted, control patients present on the ward for less than 24 hours were excluded, with the exception of wards classified as providing short stay/day case care where the threshold was four hours. Patients who suffered a critical deterioration event within the following 48 hours and/or having a 'do not attempt resuscitation order' were excluded.

3.3.4.3 Matching procedure

The ward at the time of each case patient's critical deterioration event was identified. If the event took place outside of the ward, such as in x-ray, the 'home ward' where the child was currently nursed was used.

Eligible participants present on the ward at that time were identified from the hospitals registration system and sorted into order of age. The child closest in age to the case patient was identified. The healthcare record was then examined and the CEWS chart for the previous 48-hours was identified. If healthcare records were unavailable or the relevant vital sign record was missing, the patient was excluded

and a new control was sought using the same procedure. Patients previously entered into the study were eligible to act as a control.

3.3.5 Ethical issues

This study was assessed by the hospital's clinical audit department and was designated a service evaluation project. As such the study was considered exempt from approval from a Research Ethics Committee and the local clinical research committee. The project was registered with the clinical audit department (registration number 1489).

3.3.6 Data extraction:

Clinical data were extracted from the healthcare record of case patients for a period of 48 hours before the critical deterioration event. Data from controls were extracted for the same 48-hour period. Data were extracted using a standardised pro-forma. Vital signs were extracted as continuous variables. Respiratory effort was assessed retrospectively as mild, moderate or severe using standardised criteria.[196] Dichotomous variables were assessed using criteria in Table 3.2.

Data were collected by the candidate (588 participants) and a prospective medical student working under the candidate's supervision (20 participants).

Table 3.2 Data extraction criteria

Variable	Descriptor	Value
Abnormal airway (not tracheostomy)	Documented structural abnormality or admission for investigation of persistent stridor	0 (No), 1 (Yes)
Acquired or congenital heart disease	Documented diagnosis	0 (No), 1 (Yes)
Apnoea	Documentation of the terms 'apnoea', 'breath holding', 'respiratory arrest'	0 (No), 1 (Yes)
AVPU	Documented value	Continuous value
Blood gas values	Documented value	Continuous value
Capillary refill time	Documented value	Continuous value
Cardiac arrest	Requirement for cardiac compressions and/or defibrillation.	0 (No), 1 (Yes)
Central venous line	Presence of any central venous line	0 (No), 1 (Yes)
Clinically tiring/ impending or complete airway obstruction	Documentation of exhaustion, tiring, or outreach review for severe respiratory distress	0 (No), 1 (Yes)
Convulsion	Documented convulsion +/- administration of rescue anticonvulsants	0 (No), 1 (Yes)
Cyanotic heart disease	Diagnosis of cyanotic heart lesion which had not been corrected	0 (No), 1 (Yes)
Diabetic ketoacidosis	Documented actual or differential diagnosis	0 (No), 1 (Yes)
Gastrostomy	Excludes oro- or naso-gastric tube	0 (No), 1 (Yes)
Heart rate	Documented value	Continuous value
Home oxygen	Evidence of home oxygen therapy immediately before admission	0 (No), 1 (Yes)
Hyperkalaemia>6.0	Documented potassium value of greater than 6	0 (No), 1 (Yes)
Long term ventilation	Diagnosis of long term ventilation/CPAP or admission to LTV ward	0 (No), 1 (Yes)
Medication sub-score	Number of prescribed medications, not individual doses	Continuous value
Meningococcus	Documented actual or differential diagnosis of meningococcus or presence of purpuric rash	0 (No), 1 (Yes)
Nebulised adrenaline	Administration of adrenaline nebuliser	0 (No), 1 (Yes)

Variable	Descriptor	Value
Nebulisers	Documentary evidence of continuous nebulisers or greater than 3 nebulisers in one hour	0 (No), 1 (Yes)
Number of specialities	Documentary evidence of review by differing speciality during data extraction period	0 (No), 1 (Yes)
Oxygen therapy	Documented value as fraction of inspired oxygen or percentage	Continuous value
Oxygen saturation	Documented value	Continuous value
Parental concern	Documentary evidence of parental concern/anxiety/worry	0 (No), 1 (Yes)
Persistent vomiting post-surgery	3 or more vomits in the 4 hours post-surgery	0 (No), 1 (Yes)
Pre-transplant	Evidence of presence on transplant list or pre-transplant work-up	0 (No), 1 (Yes)
Pulses	Documentary evidence of poor peripheral pulses	0 (No), 1 (Yes)
Respiratory arrest	Requirement for bag-value-mask or intubation on the ward	0 (No), 1 (Yes)
Respiratory effort	Documentary evidence of increased respiratory effort classified according to adapted WHO criteria[196]	Mild=1, Moderate =2, Severe/ apnoea=3
Respiratory rate	Documented value	Continuous value
Severe cerebral palsy	Documented diagnosis	0 (No), 1 (Yes)
Severe developmental delay, neuro /neuromuscular	Documented diagnosis. Excludes mild developmental delay	0 (No), 1 (Yes)
Signs of shock	Documentation of the terms 'shocked', 'mottled', 'poor perfusion'	0 (No), 1 (Yes)
Staff concern	Documentary evidence of healthcare professional concern/anxiety/worry, or request for review by nurse in charge or medical staff	0 (No), 1 (Yes)
Stridor/airway threat	Any documentation of stridor or threatened airway	0 (No), 1 (Yes)
Systolic blood pressure	Documented value	Continuous value
Temperature	Documented value	Continuous value
Tracheostomy	Presence of tracheostomy	0 (No), 1 (Yes)

Variable	Descriptor	Value
Transplant	Any organ transplant, bone marrow or stem cell transplant	0 (No), 1 (Yes)
Unresolved pain	Persistent pain requiring referral to acute pain service	0 (No), 1 (Yes)

If unclear, parameter scored as 0

3.3.6.1 Data entry

Data were electronically checked for internal consistency and manually checked for accuracy. Inconsistencies were resolved by reviewing the data extraction proforma and the healthcare records.

3.3.6.2 Paediatric Track and Trigger System score calculation

A recording of one or more vital signs was considered as an observation data set. Using the formulas function in Excel, the scores for each parameter within each PTTS were calculated for each observation data set. If the system contained overlapping thresholds these were modified so the calculated score would be at the lesser rather than the greater value. The most common modification was the addition of 'greater than' or 'less than' before a threshold. A summary of modifications made to the age-ranges for each PTTS can be seen at Appendix 1. If any of the observations required to complete the score were missing these were presumed to be normal (score zero), consistent with clinical practice at the time.

For score-based systems the individual parameter scores were calculated and then summed and this value represented the total PTTS score. For trigger systems, each parameter was considered as scoring one if breeched or zero if not. Trigger systems were considered to have been activated if one or more parameters were breeched (i.e. if the score was one or above). In order to assess if trigger systems might function significantly better as a score-based system the individual parameter scores were also summed. This value was considered to be the total PTTS score when the system was assessed as a scoring system.

3.3.6.3 Modifying PTTS with percentile values

Each PTTS system was modified to incorporate percentile derived thresholds for heart and respiratory rate. Percentile values were available for the 1st, 10th, 50th, 90th

and 99th percentile for healthy children and the 1st, 5th, 10th, 50th, 90th, 95th and 99th percentile for hospitalised children.

Modification followed a standardised procedure. Five weighting frameworks for the PTTS were identified. These were matched with the available centile thresholds. Values between the 10th and 90th percentile were considered to be 'normal' and therefore assigned a weighting of '0'. The 99th percentile was considered grossly abnormal and assigned the highest weighting. Remaining weightings were then distributed across the available percentile thresholds. If the number of weighting thresholds exceeded the number of available percentile values the higher weighting was excluded, on the basis that it was preferable to under rather than over score. The total PTTS score and trigger activation for these modified PTTS were then calculated according to the process described in Section 3.3.6.2.

The percentile values assigned to the weighting framework can be seen in Table 3.4 and Table 3.4.

Table 3.3 Framework to identify the appropriate percentile value (healthy children) to be applied to the respiratory and heart rate parameter score dependent on the PTTS weighting framework

Percentile value	Weighting framework within PTTS				
	0,1,2,3	0,1	0,1,2	0,1,2,4	0,1,2,3,4
99th	3	1	2	4	4
90th	1	0	1	1	1
Values in between	0	0	0	0	0
10th	1	0	1	1	1
1st	3	1	2	4	4

The range of weighting scores for heart and respiratory rate are matched with the weighting framework. The heart and respiratory rate thresholds for each given score are then modified using the identified percentile value[184]

Table 3.4 Framework to identify the appropriate percentile value (hospitalised children) to be applied to the respiratory and heart rate parameter score dependent on the PTTS weighting framework

Percentile value	Weighting framework within PTTS				
	0,1,2,3	0,1	0,1,2	0,1,2,4	0,1,2,3,4
99th	3	1	2	4	4
95th	2	1	1	2	2
90th	1	0	1	1	1
Values in between	0	0	0	0	0
10th	1	0	1	1	1
5th	2	1	1	2	2
1st	3	1	2	4	4

The range of weighting scores for heart and respiratory rate are matched with the weighting framework. The heart and respiratory rate thresholds for each given score are then modified using the identified percentile value[184]

3.4 Data analysis

Analysis was performed using SPSS and r (www.cran.r-project.org). Characteristics of cases and controls were compared with the Mann Whitney U-test for continuous variables and Chi-squared for categorical variables.

The maximum observed value for each PTTS for each patient in the 48 hours before the event was used in the comparison. The final hour of data before the deterioration event in the case patient was censured to establish if the PTTS could identify critical deterioration with at least one hour's notice. The AUROC were calculated for each PTTS and the PTTS were ranked from highest to lowest AUROC value.

To assess if published systems demonstrated better performance the AUROC of each PTTS was then compared to the local PTTS (the *CEWS*). The AUROC values were transformed into a z-score. Z-scores indicate the number of standard deviations above or below the area under the curve of the *CEWS.*[197] Standardising the AUROC values in this way facilitates meaningful comparison between the

differing systems. A z-score of zero would indicate no difference. A z-score of one would indicate a value that is one standard deviation greater, whilst a z-score of -1 indicates one standard deviation less than the AUROC value of the *CEWS.* The AUROC values were compared using the Delong's test for correlated curves.[198] As this would result in multiple comparisons of the AUROC, significance testing was adjusted with Bonferroni's correction to avoid type I errors.[199] Type I errors result in the rejection of the null hypothesis when there is no significant difference in the performance of the PTTS.[200] p-values <.0025 were therefore considered significant. The process was repeated to compare the highest ranked PTTS to the remaining systems.

3.4.1.1 Trigger systems

The performance of trigger systems was primarily assessed at a score of one. However to assess if trigger systems had significantly better performance when they functioned as a scoring system, AUROC were compared using the method described above.

3.4.1.2 Modification of PTTS with percentile values

The AUROC of PTTS after modification of thresholds with percentile values for heart and respiratory rate were calculated and the significance of the difference assessed pairwise between each PTTS and its modified version using the analysis described above.

3.4.1.3 Performance measures

Measures of performance, such as sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio positive test and likelihood ratio negative test were calculated for each PTTS.

Trigger-based PTTS systems are amenable to comparison as values are calculated on the same threshold, namely the breeching of a single 'trigger' which is equivalent to a score of one. However score-based systems result in a range of scores, each with differing values for the performance indicators. As the range of scores within differing PTTS systems varies, this can make comparison of the performance indicators between differing PTTS challenging.

In order to compare the performance of differing score-based PTTS, it was necessary to select the scoring threshold for comparison in a uniform manner. Previous studies have described the calculation of an 'optimal score'.[133] This is the scoring threshold which results in the maximum value for the sum of the sensitivity and specificity. Although the optimal score facilitates comparison between differing PTTS systems and demonstrates the maximum combined value for sensitivity and specificity, it may not be a clinically appropriate threshold which would be used in practice. However it does offer a way to compare differing PTTS systems in a uniform manner.

The optimal score for each scoring system was identified,[137] and the sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio positive test and likelihood ratio negative test were calculated. The numbers of case and control patients who would be correctly and incorrectly identified at this threshold were calculated.

3.4.1.4 Time from optimal score to event

For case subjects who triggered the optimal score the time from the first recorded optimal score to the event was calculated. The median time was calculated with the inter quartile range.

3.5 Results

3.5.1 Eligible systems

The systematic review in chapter two identified 33 PTTS. Nine contained parameters requiring subjective assessment, six required knowledge of the baseline vital signs and one inadequately described the component parameters: these were excluded from further analysis. Seventeen PTTS remained. Systems with the same name were numbered in order of publication to distinguish between them (Table 2). In order to evaluate whether the national system for adults could be adapted to predict deterioration in children, the *NEWS* was also included. To evaluate performance against the current system in use the local unpublished system (*CEWS*) was also evaluated. This resulted in 18 paediatric and one adult system for comparative evaluation.

3.5.1.1 Characteristics and component parameters

Thirteen PTTS were categorised as '*scoring'* and six as '*trigger'* systems. The number of component parameters varied from three to 19. Some systems combined two or more variables within a single parameter, for example oxygen therapy and saturation values. Forty variables either alone or in combination were identified, as shown in Table 3.2.

3.5.1.2 Vital signs

Vital signs featured prominently in all systems. All 19 include heart and respiratory rate, 15 included oxygen saturation (78.9%) and 12 blood pressure (63.2%). Temperature was a component of only seven systems (36.8%). Thirteen had age-specific criteria for one or more vital signs embedded in the PTTS. Five provided supplemental guidance on age-specific 'normal values'. Five weighting frameworks were identified across the 13 scoring systems with four PTTS also incorporating additional points for risk factors. Differences between systems were often minor. The maximum scores varied from seven to 32.

Table 3.5 Key characteristics and parameters of the PTTS

System	PTTS characteristics				Parameters (scored using weighting framework)																Additional risk factors	Weighting framework
					Vital signs						Concern		Other parameters									
Name, first citation	Score or trigger	Maximum score	Age ranges	Parameters (n)	Heart rate	Respiratory rate	Oxygen saturation	Systolic BP	Capillary refill time	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Airway threat	Oxygen therapy			
Bedside PEWS[154]	S	26	5	7	✓	✓	✓	✓	✓									✓		✓			0,1,2,4
Bristol PEW tool[42]	T	13	1	14	✓	✓	✓[1]		✓		✓					✓	✓			✓	Apnoea ±bradycardia; DKA; clinically tiring or complete airway obstruction; hyperkalaemia; nebulised adrenaline; signs of shock (e.g. poor perfusion, ± low BP); suspected meningococcus		Trigger
Cardiff and Vale PEWS[137]	S	8	5	8	✓	✓	✓	✓			✓					✓		✓	✓	✓			0, 1
Children's Early Warning Tool [67]	S	24	4	9	✓	✓	✓	✓	✓	✓						✓		✓		✓			0,1,2,3
ITAT[162]	S	8	5	4	✓	✓	✓			✓													0,1,2
MET AC I[40]	T	9	5	9	✓[1]	✓	✓	✓			✓					✓	✓	✓	✓		Cardiac/respiratory arrest; apnoea or cyanosis		Trigger

System	PTTS characteristics				Parameters (scored using weighting framework)																Additional risk factors	Weighting framework
					Vital signs						Concern		Other parameters									
Name, first citation	Score or trigger	Maximum score	Age ranges	Parameters (n)	Heart rate	Respiratory rate	Oxygen saturation	Systolic BP	Capillary refill time	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Airway threat	Oxygen therapy			
MET AC III[141]	T	9	5	9	✓[1]	✓	✓	✓			✓	✓				✓	✓	✓	✓		Cardiac/respiratory arrest; apnoea or cyanosis		Trigger
Modified Bristol PEWS[169]	T	15	5	16	✓[1]	✓[2]	✓		✓		✓					✓	✓				Apnoea ±bradycardia; Clinically tiring or complete airway obstruction; Hyperkalaemia; Marked increased work of breathing; Nebulised adrenaline (or no improvement); pH <7.2, Poor perfusion, ± low BP, large central/peripheral temp gradient; Unresolved pain on current anagesia therapy		Trigger
MPEWS I[170]	S	9	1	3	✓	✓			✓				✓	✓	✓					✓			0,1,2,3

System	PTTS characteristics				Parameters (scored using weighting framework)																Additional risk factors	Weighting framework
					Vital signs						Concern		Other parameters									
Name, first citation	Score or trigger	Maximum score	Age ranges	Parameters (n)	Heart rate	Respiratory rate	Oxygen saturation	Systolic BP	Capillary refill time	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Airway threat	Oxygen therapy			
MPEWS II[79]	S	26	5	18	✓	✓	✓	✓	✓	✓						✓		✓		✓	CVL; IV bolus fluid or blood product within past 4 hours	Abnormal airway or positive pressure ventilation; Active acquired/congenital heart disease or history of heart surgery; Home oxygen; Pre/post any transplant; Gastrostomy or jejunostomy tube; Previous ICU admission; Severe developmental, neurological or neuromuscular disease	0,1,2
MPEWS III[172]	S	28	5	8	✓	✓	✓	✓	✓	✓								✓		✓			
NHSI PEWS[173]	S	7	4	7	✓	✓					✓	✓				✓		✓		✓	Stridor or apnoea		0,1
PEW score III[176]	S	10	1	4	✓	✓			✓			✓	✓	✓	✓					✓			0,1,2,3

System	PTTS characteristics				Parameters (scored using weighting framework)																	Additional risk factors	Weighting framework
					Vital signs						Concern		Other parameters										
Name, first citation	Score or trigger	Maximum score	Age ranges	Parameters (n)	Heart rate	Respiratory rate	Oxygen saturation	Systolic BP	Capillary refill time	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Airway threat	Oxygen therapy			
PEW score IV[177]	S	13	1	4	✓	✓			✓				✓	✓	✓					✓		15 minute nebulisers or vomiting post-op	0,1,2,3
PEW system score I[138]	S	32	5	19	✓	✓	✓	✓	✓	✓						✓				✓		>3 medical specialities involved in care; abnormal airway (not tracheostomy); CVL; gastrostomy; home oxygen; medication score; previous admission to ICU; severe cerebal palsy; transplant recipient	0,1,2,3
PMET triggers II[181]	T	7	5	7	✓	✓	✓[1]	✓			✓	✓				✓	✓			✓			Trigger
THCS MET criteria[183]	T	7	1	7	✓	✓	✓[1]	✓	✓		✓					✓	✓	✓	✓	✓	Poor peripheral pulses, mottled extremities		Trigger

System	PTTS characteristics				Parameters (scored using weighting framework)																Additional risk factors	Weighting framework
	Vital signs										Concern		Other parameters									
Name, first citation	Score or trigger	Maximum score	Age ranges	Parameters (n)	Heart rate	Respiratory rate	Oxygen saturation	Systolic BP	Capillary refill time	Temperature	Staff concern	Parent concern	Respiratory	Behaviour	Cardiovascular	Consciousness	Seizure	Respiratory distress	Airway threat	Oxygen therapy		
CEWS (local PTTS)	S	21	4	6	✓	✓	✓	✓		✓						✓						0,1,2,3,4
NEWS (adult)	S	20	1	7	✓	✓	✓	✓		✓						✓				✓		0,1,2,3

Key: Indicators combined within a single parameter are presented in coloured text / ✓. All studies are single centre unless otherwise stated. [1] Separate parameters for children with and without cyanotic heart disease; [2] following one bolus of 10mls/kg fluid

Abbreviations: AC: Activation criteria; **BP:** Blood pressure; **CEWS:** Children's Early Warning Score **CVL:** Central venous line; **DKA:** Diabetic ketoacidosis; **ICU:** Intensive Care Unit; **ITAT:** Inpatient triage, assessment and treatment score; **IV:** Intravenous; MET: Medical Emergency Team; **MPEWS:** Modified Pediatric Early Warning Score; **NEWS:** National Early Warning Score; **NHSI:** NHS Institute; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET:** Pediatric Medical Emergency Team; **SVT:** Super ventricular tachycardia; **THSC:** Toronto Hospital for Sick Children

3.5.2 Patient characteristics

Three hundred and nineteen critical deterioration events were identified. In eight episodes the patient was present on the ward for less than two hours, leaving 311 eligible critical deterioration events in 237 patients. Fourteen case patient records were missing, leaving a case sample of 297 events in 224 patients. Two hundred and forty-four control patients were identified for the 311 events.

In total, 13551 observations sets were performed, 8360 on cases and 5191 on controls. The median number of observation sets per patient per day was 13 for cases and six for controls. Only 36.4% of observation sets contained the five vital sign parameters and assessment of consciousness required for complete recording of the local PTTS.

Case patients were more likely to be female (56.3% vs 46.3%, p=.009), have been admitted as an emergency (64.6% vs 39.2%, p=<.01) and have a longer hospital stay (median 57.1 vs 35.9 days, p=<.01). Mortality was also higher for case patients at 24 hours, 30 days and hospital discharge. A summary of patient characteristics is shown in Table 3.6.

Table 3.6 Patient characteristics (each patient episode)

Characteristic	Cases (n=297) n (%)	Controls (n=311) n (%)	P value
Male Female	130 (43.8%) 167 (56.3)	167 (53.7) 144 (46.3)	.018[a]
Age 0-<6 months 6 months-<1 year 1-4 years 5-11 years 12-<19y	 70 (23.6) 41 (13.8) 101 (34.0) 54 (18.2) 31(10.4)	 66 (21.2) 47 (15.1) 108 (34.7) 62 (19.9) 28 (9.0)	.888[b]
Gestation below 37 weeks	60 (20.1)	48 (15.4)	.152[a]
Weight, median, (interquartile range)	10.4kg (1.71-87.00)	11.1kg (2.10-94.20)	.668[b]

Characteristic	Cases (n=297) n (%)	Controls (n=311) n (%)	P value
Number of previous same hospital admissions			
0	150 (50.5)	145 (46.6)	.946[b]
1-5	66 (22.2)	92 (29.6)	
6-10	29 (9.8)	27 (8.7)	
11 – 20	20 (6.7)	26 (8.4)	
21 – 50	25 (8.4)	16 (5.2)	
>50	7 (2.4)	5 (1.6)	
Number of previous PICU admissions (excluding this admission)			
0	247 (83.1)	276 (88.7)	.061[b]
1	32 (10.8)	20 (6.4)	
2	15 (5.1)	4 (1.3)	
3 - 5	1 (0.3)	5 (1.6)	
>5	2 (0.7)	6 (1.9)	
Number of previous PICU admissions (this admission)			
0	185 (62.3)	238 (76.5)	<.001[b]
1	75 (25.2)	55 (17.7)	
2	17 (5.7)	14 (4.5)	
3 - 5	14 (4.7)	4 (1.3)	
>5	6 (2.0)	0 (0.0)	
Admitting specialty			
Medical	186 (62.6)	205 (65.9)	.19[a]
Surgical	57 (19.2)	66 (21.2)	
Intensive Care	54 (18.2)	40 (12.9)	
Type of admission			
Elective	105 (35.4)	189 (60.8)	<.001[a]
Emergency	192 (64.6)	122 (39.2)	
Specialty at event			
Medical	228 (76.8)	237 (76.2)	1.0[a]
Surgical	69 (23.2)	74 (23.8)	

Characteristic	Cases (n=297) n (%)	Controls (n=311) n (%)	P value
Critical deterioration event classification			
PICU transfer	186 (62.6)	0	N/A
Respiratory Arrest	84 (28.3)	0	
Cardiac Arrests	27 (9.1)	0	
Death on ward	0 (0)	0	
Reason for event			
Respiratory	176 (59.3)	0	N/A
Cardiovascular	67 (22.6)	0	
Neurological	38 (12.8)	0	
Other	16 (5.4)	0	
Length of stay in days median, (interquartile range)	57.1 (21.0 – 122.0)	35.9 (12.8 – 89.4)	0.001[b]
Outcome			
Alive at 24 hours	279 (93.9)	311 (100%)	<.001[a]
Alive at 30 days	246 (82.8)	308 (99.0)	<.001[a]
Alive at discharge	220 (74.1)	301 (96.8)	<.001[a]

Key: [a]Chi-squared; [b]Mann-Whitney U test

Abbreviations: PICU: Paediatric intensive care unit

One hundred and eighty six (62.6%) critical deterioration events were categorised as unplanned transfers to the PICU, 84 (28.3%) as respiratory arrests and 27 (9.1%) as cardiac arrests. 31 patients remained on the ward after a cardiac or respiratory arrest. Six patients died before transfer to intensive care**.**

3.5.3 Performance of systems

3.5.3.1 Overall predictive performance

The predictive performance across the differing PTTS varied (Table 3.7 and Table 3.8). When placed in rank order the *Cardiff and Vale Paediatric Early Warning System (PEWS)* had the highest AUROC at 0.89 (95% confidence interval [CI] 0.86-0.91). The *Bristol PEWS* had the lowest at 0.62 (95% CI 0.58-0.67). When evaluated across children of all ages the adult *NEWS* had an AUROC of 0.72 (95% CI 0.67-0.76), which was less than all the paediatric scoring systems. When

comparison was restricted to children of 12 years and over, performance improved to give an AUROC of 0.78 (0.67-0.91). The local PTTS (*CEWS*) was ranked 9th with an AUROC of 0.79 (95% CI 0.75-0.82).

Table 3.7 Comparative performance against the CEWS for scoring systems

Scoring systems	AUCROC (95% CI)	z-score	p-value
Cardiff and Vale PEWS	0.89 (0.86-0.91)	-7.12	<.001
Bedside PEWS	0.88 (0.85-0.91)	-6.49	<.001
Modified PEWS III	0.87 (0.85-0.90)	-5.88	<.001
CEWT	0.85 (0.82-0.88)	-6.49	<.001
Modified PEWS II	0.85 (0.82-0.88)	-3.30	<.001
PEWS III	0.83 (0.80-0.86)	-2.63	.009
NHSI PEWS	0.82 (0.79 - 0.86)	-2.10	.036
PEWS system score I	0.82 (0.78-0.85)	-1.58	.114
PEWS IV	0.79 (0.75-0.82)	-0.11	.909
CEWS	0.79 (0.75-0.82)	N/A	N/A
NEWS (12 years and above)	0.78 (0.67-0.91)	0.04	.968
ITAT score	0.77 (0.74-0.81)	0.75	.453
Modified PEWS I	0.74 (0.70-0.78)	2.10	.036
NEWS (all ages)	0.72 (0.67-0.76)	3.46	.001

z-score values calculated by Dr Samiran Ray

Performance was assessed by calculation of the AUROC. Systems were then ranked and performance was compared to the local PTTS (CEWS) using the Delong's test for correlated curves. z-scores represent comparison of mean values. Significance testing was adjusted for the multiple comparisons of AUROC with Bonferroni's correction, meaning p-values <.0025 were considered significant.

Abbreviations: AUROC: Area under the receiver operator characteristic curve; **CEWS:** Children's Early Warning Score; **CEWT**: Children's Early Warning Tool; **CI:** Confidence interval; **ITAT:** Inpatient triage, assessment and treatment score; **NEWS:** National Early Warning Score; **NHSI:** NHS Institute; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System

Trigger systems had lower AUROC values, which would be expected from a dichotomous system (Table 3.8). Four trigger systems demonstrated similar performance with an AUROC value of 0.71 to 0.73. The remaining two systems had considerably worse performance, with an area under the curve value of 0.62. The majority of trigger systems would be outperformed by the adult *NEWS* without any modifications

Table 3.8 Comparative performance against the CEWS for trigger systems

Trigger systems	AUCROC (95% CI)	z-score	p-value
THSC MET calling criteria	0.73 (0.69-0.77)	3.02	.003
MET activation criteria I	0.71 (0.70-0.75)	4.18	<.001
MET activation criteria III	0.71 (0.70-0.75)	4.18	<.001
PMET triggers II	0.71 (0.67 – 0.75)	4.40	<.001
Modified Bristol PEWS	0.62 (0.58-0.67)	8.16	<.001
Bristol PEWS	0.62 (0.58-0.67)	8.27	<.001

z-score values calculated by Dr Samiran Ray

Performance was assessed by calculation of the AUROC. Systems were then ranked and performance was compared to the local PTTS (CEWS) using the Delong's test for correlated curves. z-scores represent comparison of mean values. Significance testing was adjusted for the multiple comparisons of AUROC with Bonferroni's correction, meaning p-values <.0025 were considered significant.

Abbreviations: AUROC: Area under the receiver operator characteristic curve; **CI:** Confidence interval; **MET:** Medical Emergency Team; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET**: Pediatric Medical Emergency Team; **THSC:** Toronto Hospital for Sick Children

3.5.3.1 Comparative performance against the local PTTS (CEWS)

The AUROC curve for each PTTS was compared to local *CEWS* (AUROC 0.79) (Table 3.7). The z-scores varied from -7.12 to 8.27. Nine systems demonstrated better performance and nine had worse performance. When results were adjusted with Bonferroni's correction five performed significantly better than the *CEWS*.

The receiver operator characteristic (ROC) curve of the highest ranked PTTS was plotted against the ROC curve of the *CEWS* (Figure 3.1). The 95% confidence

interval for the *Cardiff and Vale PEWS* is in blue, the *CEWS* in pink. There was no overlapping of the confidence intervals.

Figure 3.1 Comparison of the receiver operator characteristic curve of the highest performing PTTS and the local PTTS

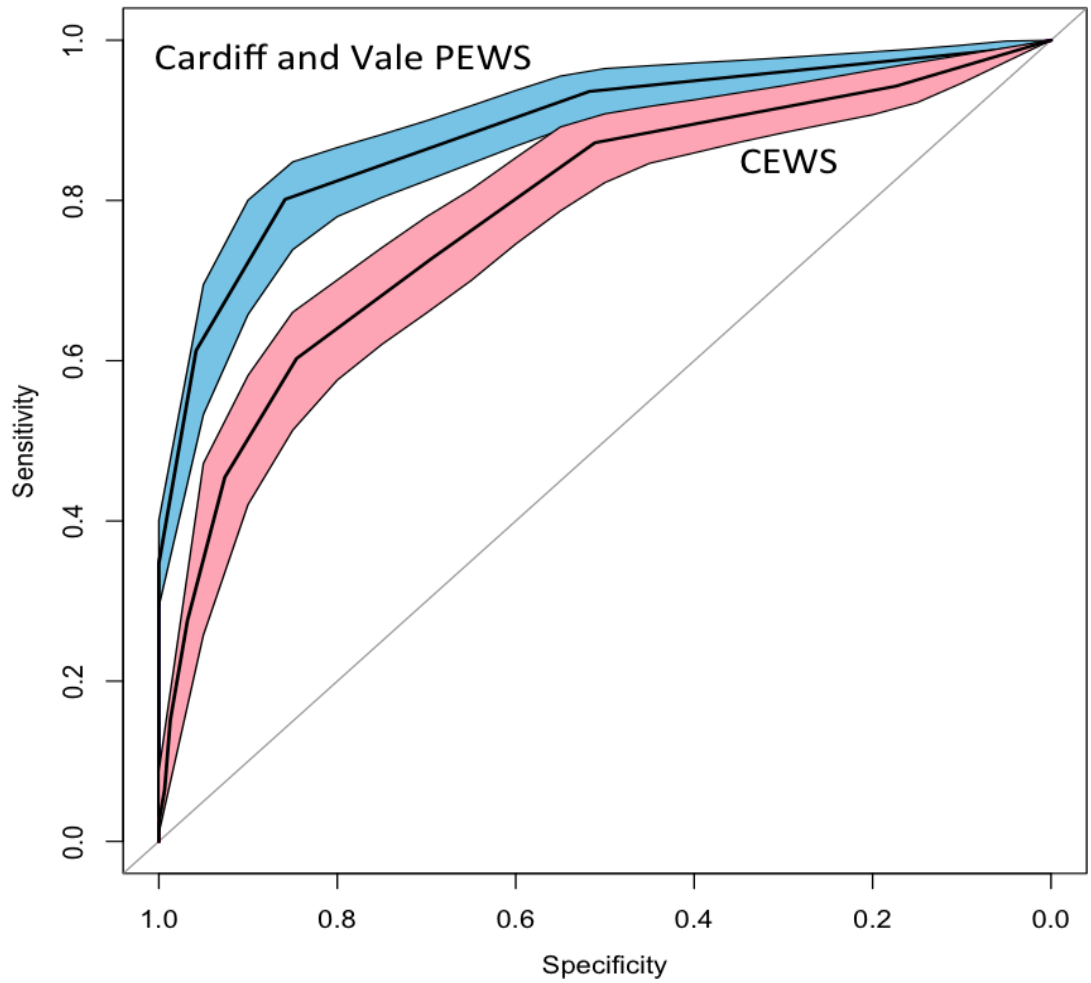


Figure created by Dr. Samiran Ray.

The receiver operator characteristic curve of the local system (CEWS, AUROC 0.79) was compared to the highest performing system (Cardiff and Vale PEWS, AUROC 0.89). Shaded areas represent the 95% confidence intervals.

Key: AUROC: Area under the receiver operator characteristic curve; **CEWS:** Children's Early Warning Score; **PEWS:** Paediatric Early Warning System

3.5.3.2 Comparative performance against the highest performing PTTS (Cardiff and Vale PEWS)

The AUROC for each PTTS was compared to the PTTS with the largest value, the *Cardiff and Vale PEWS* (AUROC 0.89). The comparative performance of scoring systems is seen in Table 3.9 and trigger systems in Table 3.10. The z-scores for

scoring systems varied from 0.72 to 9.10 and for trigger systems from 9.31 to 16.01. The difference in area under the curve of the *Bedside PEWS* and the *Modified PEWS III* was not statistically significant. As such, the performance of these three systems could be considered equivalent.

Table 3.9 Comparative performance of PTTS scoring systems against the highest AUROC-ranked PTTS

Scoring systems	AUCROC (95% CI)	z-score	p-value
Cardiff and Vale PEWS	0.89 (0.86-0.91)	N/A	N/A
Bedside PEWS	0.88 (0.85-0.91)	0.72	.47
Modified PEWS III	0.87 (0.85-0.90)	1.58	.11
Modified PEWS II	0.85 (0.82-0.88)	2.87	.004
CEWT	0.85 (0.82-0.88)	3.21	.001
PEWS III	0.83 (0.80-0.86)	4.06	<.001
PEWS system score I	0.82 (0.78-0.85)	4.42	<.001
NHSI PEWS	0.82 (0.79 - 0.86)	4.52	<.001
PEWS IV	0.79 (0.75-0.82)	6.00	<.001
CEWS	0.79 (0.75-0.82)	7.12	<.001
NEWS (12 years and above)	0.78 (0.67-0.91)	1.58	0.12
ITAT score	0.77 (0.74-0.81)	7.12	<.001
Modified PEWS I	0.74 (0.70-0.78)	8.06	<.001
NEWS (all ages)	0.72 (0.67-0.76)	9.10	<.001

z-score values calculated by Dr Samiran Ray

Performance was assessed by calculation of the AUROC. Systems were then ranked and performance was compared to the highest ranked PTTS (Cardiff and Vale PEWS) using the Delong's test for correlated curves. z-scores represent comparison of mean values. Significance testing was adjusted for the multiple comparisons of AUROC with Bonferroni's correction, meaning p-values <.0025 were considered significant.

Abbreviations: AUROC: Area under the receiver operator characteristic curve; **CEWS:** Children's Early Warning Score; **CEWT**: Children's Early Warning Tool; **CI:** Confidence interval; **ITAT:** Inpatient triage, assessment and treatment score; **NEWS:** National Early Warning Score; **NHSI:** NHS Institute; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System

For 14 of the remaining 15 systems there was a statistically significant difference in performance compared to the *Cardiff and Vale PEWS* when results were adjusted with Bonferroni's correction for multiple comparisons.

Table 3.10 Comparative performance of PTTS trigger systems against the highest AUROC-ranked PTTS

Trigger systems	AUCROC (95% CI)	z-score	p-value
THSC MET calling criteria	0.73 (0.69-0.77)	9.31	<.001
MET activation criteria I	0.71 (0.70-0.75)	10.70	<.001
MET activation criteria III	0.71 (0.70-0.75)	10.70	<.001
PMET triggers II	0.71 (0.67 – 0.75)	10.82	<.001
Modified Bristol PEWS	0.62 (0.58-0.67)	16.02	<.001
Bristol PEWS	0.62 (0.58-0.67)	16.11	<.001

z-score values calculated by Dr Samiran Ray

Performance was assessed by calculation of the AUROC. Systems were then ranked and performance was compared to the highest ranked PTTS (Cardiff and Vale PEWS) using the Delong's test for correlated curves. z-scores represent comparison of mean values. Significance testing was adjusted for the multiple comparisons of AUROC with Bonferroni's correction, meaning p-values <.0025 were considered significant.

Abbreviations: AUROC: Area under the receiver operator characteristic curve; **CI:** Confidence interval; **ITAT:** Inpatient triage, assessment and treatment score; **MET:** Medical Emergency Team; **NHSI:** NHS Institute; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET**: Pediatric Medical Emergency Team; **THSC:** Toronto Hospital for Sick Children

3.5.3.3 Modification of trigger systems into scoring system

Trigger systems were modified to perform as a scoring system by summation of all the scores from each parameter. The AUROC curve was then calculated at all possible scores. Performance of this modified system was then compared to assess whether performance improved significantly.

All six trigger systems performed significantly better when functioning as a scoring system. Performance of the *Medical Emergency Team (MET) activation criteria I* and *MET activation criteria III* both matched the third ranked PTTS. Performance of the two lowest ranked trigger systems was significantly improved.

Table 3.11 Modification of trigger system to score-based system

PTTS	Trigger –based AUROC (95% CI)	Score -based AUROC (95% CI)	z-score	p value
THSC MET calling criteria	0.73 (0.69-0.77)	0.84 (0.81-0.87)	10.69	<.001
MET activation criteria I	0.71 (0.70-0.75)	0.87 (0.84-0.89)	12.90	<.001
MET activation criteria III	0.71 (0.70-0.75)	0.87 (0.84-0.89)	12.90	<.001
PMET triggers II	0.71 (0.67 – 0.75)	0.85 (0.82-0.88)	11.89	<.001
Bristol PEWS	0.62 (0.58-0.67)	0.85 (0.82-0.88)	16.44	<.001
Modified Bristol PEWS	0.62 (0.58-0.67)	0.86 (0.84-0.89)	17.12	<.001

z-score values calculated by Dr Samiran Ray

Performance of each trigger-based PTTS was assessed by calculation of the AUROC. Systems were then modified to a score-based system by aggregating the score of the component parameters. The performance of each modified score-based PTTS was compared to its unmodified trigger-based partner using the Delong's test for correlated curves. z-scores represent comparison of mean values. Significance testing was adjusted for the multiple comparisons of AUROC with Bonferroni's correction, meaning p-values <.0025 were considered significant.

Abbreviations: AUROC: Area under the receiver operator characteristic curve; CI: Confidence interval; **MET:** Medical Emergency Team; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET**: Pediatric Medical Emergency Team; **THSC:** Toronto Hospital for Sick Children

3.5.3.4 Comparative performance at the optimal score

The optimal score for score-based PTTS varied from two for the *NHS Institute PEWS* (maximum score of seven) to nine for the *PEWS system score I* (maximum score of 32). The adult *NEWS* had an optimal core of 10 (maximum score). Trigger-based systems were all assessed at a score of one or greater. Sensitivity, specificity, positive predictive value (PPV), negative predictive vale (NPV) and positive and negative likelihood ratio for the optimal score are reported in Table 3.12.

Trigger systems demonstrated better sensitivity (range 0.90 (95% CI 0.86-0.93) to 0.96 (95% CI 0.93-0.98)) than scoring systems (range 0.46 (95% CI 0.40-0.51) to 0.83 (95% CI 0.78-0.87)), but worse specificity (range 0.28 (95% CI 0.23-0.34) to 0.56 (95% CI 0.50-0.61)) versus 0.65 (95% CI 0.60-0.71) to 0.91 (95% CI 0.87-0.94)).

3.5.3.5 Time from detection to critical deterioration event

Paediatric track and trigger systems demonstrated the ability to detect children at risk of critical deterioration a significant time before the event. Median time from optimal score to the critical deterioration event ranged from 17 hours (interquartile range [IQR] 6.8-35.7) to 39.5 hours (IQR 17.4-46.6) for patients correctly identified by scoring systems (Table 3.12). Longer times were demonstrated by trigger systems: 27.9 hours (IQR 13.7-42.4) to 39.8 (IQR 23.8-46.2), possibly reflecting the increased sensitivity.

The system with the highest AUROC had a median time from optimal score to the event of 26.60 hours. The local *CEWS* performed slightly worse at 21.05 hours.

Table 3.12 Performance at optimal score

PTTS (AUROC rank)	Optimal score/ max score	Case patients (n=297)		Control patients (n=311)		Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR +ve (95% CI)	LR –ve (95% CI)	Median hours to event (IQR)
		TP	FN	FP	TN							
Scoring systems												
Cardiff and Vale PEWS (1)	3/8	238	59	44	267	0.80 (0.75-0.84)	0.86 (0.81-0.89)	0.84 (0.80-0.88)	0.82 (0.77-0.86)	5.66 (4.28-7.49)	0.23 (0.18-0.29)	26.60 (11.57-42.19)
Bedside PEWS (2)	6/26	215	82	35	276	0.72 (0.67-0.77)	0.89 (0.85-0.92)	0.86 (0.81-0.90)	0.77 (0.72-0.81)	6.43 (4.67-8.86)	0.311 (0.26-0.37)	26.25 (13.94-43.29)
Modified PEWS III (3)	7/28	204	93	28	283	0.69 (0.63-0.74)	0.91 (0.87-0.94)	0.88 (0.83-0.92)	0.75 (0.71-0.80)	7.63 (5.31-10.95)	0.34 (0.29-0.41)	21.61 (12.42-40.10)
Modified PEWS II (4)	6/26	228	69	63	248	0.83 (0.78-0.87)	0.71 (0.66-0.76)	0.73 (0.68-0.78)	0.81 (0.76-0.85)	2.85 (2.38-3.42)	0.25 (0.19-0.32)	36.57 (16.57-46.00)
CEWT (4)	4/24	245	52	90	221	0.77 (0.72-0.81)	0.80 (0.75-0.84)	0.78 (0.73-0.83)	0.78 (0.73-0.83)	3.79 (3.01-4.77)	0.29 (0.24-0.36)	37.66 (22.39-44.74)
PEWS III (6)	3/10	247	50	99	212	0.83 (0.78-0.87)	0.68 (0.63-0.73)	0.71 (0.66-0.76)	0.81 (0.76-0.85)	2.61 (2.20-3.10)	0.25 (0.19-0.32)	24.00 (11.23–44.13)
NHSI PEWS (7)	2/7	247	50	108	203	0.83 (0.78-0.87)	0.65 (0.60-0.71)	0.70 (0.65-0.74)	0.80 (0.75-085)	2.40 (2.04-2.81)	0.26 (0.20-0.33)	29.90 (14.57-43.63)

PTTS (AUROC rank)	Optimal score/ max score	Case patients (n=297)		Control patients (n=311)		Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR +ve (95% CI)	LR –ve (95% CI)	Median hours to event (IQR)
		TP	FN	FP	TN							
PEWS system score I (7)	9/32	207	90	78	233	0.70 (0.64-0.75)	0.75 (0.70-0.80)	0.73 (0.67-0.78)	0.72 (0.70-0.77)	2.78 (2.26-3.42)	0.40 (0.34-0.48)	39.50 (17.43-46.57)
PEWS IV (9)	4/13	181	116	50	261	0.61 (0.55-0.67)	0.84 (0.79-0.88)	0.78 (0.72-0.83)	0.69 (0.64-0.74)	3.79 (2.89-4.96)	0.47 (0.40-0.54)	26.00 (11.75-41.58)
CEWS (9)	4/21	179	118	48	263	0.60 (0.54-0.66)	0.85 (0.80-0.88)	0.80 (0.73-0.84)	0.69 (0.64-0.74)	3.91 (2.96-5.15)	0.47 (0.41-0.54)	21.05 (10.38-40.12)
NEWS [12 years and above] (11)	10/20	21	10	4	24	0.68 (0.49-0.83)	0.86 (0.66-0.95)	0.84 (0.63-0.95)	0.71 (0.52-0.84)	4.74 (1.85-12.13)	0.38 (0.22-0.63)	37.63 (27.50-44.08)
ITAT score (12)	3/8	202	95	82	229	0.68 (0.62-0.73)	0.74 (0.68-0.78)	0.71 (0.65-0.76)	0.71 (0.65-0.76)	2.58 (2.11-3.16)	0.43 (0.37-0.51)	28.95 (14.70-43.96)
Modified PEWS I (13)	4/9	135	162	31	280	0.46 (0.40-0.51)	0.90 (0.86-0.93)	0.81 (0.74-0.87)	0.63 (0.59-0.68)	4.56 (3.19-6.51)	0.61 (0.55-0.67)	17.00 (6.75-35.68)

PTTS (AUROC rank)	Optimal score/ max score	Case patients (n=297)		Control patients (n=311)		Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR +ve (95% CI)	LR –ve (95% CI)	Median hours to event (IQR)
		TP	FN	FP	TN							
Trigger systems												
THSC MET calling criteria (14)	≥1 triggers	267	30	138	173	0.90 (0.86-0.93)	0.56 0.50-0.61)	0.66 (0.61-0.71)	0.85 (0.79-0.90)	2.03 (1.78-2.31)	0.18 (0.13-0.26)	27.90 (13.74-42.37)
MET activation criteria I (15)	≥1 triggers	276	21	158	153	0.93 (0.89-0.96)	0.49 (0.44-0.55)	0.64 (0.59-0.68)	0.88 (0.82-0.92)	1.83 (1.63-2.05)	0.14 (0.10-0.22)	33.87 (18.76-45.52)
MET activation criteria III (15)	≥1 triggers	276	21	158	153	0.923 (0.89-0.96)	0.49 (0.44-0.55)	0.64 (0.59-0.68)	0.88 (0.82-0.92)	1.83 (1.63-2.05)	0.14 (0.10-0.22)	33.92 (18.76-45.52)
PMET triggers II (15)	≥1 triggers	273	24	157	154	0.92 (0.88-0.95)	0.50 (0.44-0.55)	0.64 (0.59-0.68)	0.87 (0.80-0.68)	1.82 (1.62-2.04)	0.16 (0.11-0.24)	33.25 (16.90-45.42)
Modified Bristol PEWS (18)	≥1 triggers	286	11	223	88	0.96 (0.93-0.98)	0.28 (0.23-0.34)	0.56 (0.52-0.61)	0.90 (0.81-0.94)	1.34 (1.25-1.45)	0.13 (0.07-0.24)	39.83 (23.82-46.25)
Bristol PEWS (18)	≥1 triggers	285	12	223	88	0.96 (0.93-0.98)	0.28 (0.23-0.34)	0.56 (0.52-0.61)	0.88 (0.80-0.93)	1.34 (1.24-1.44)	0.14 (0.08-0.25)	39.73 (23.45-46.25)

The PTTS are ordered by rank performance based on the AUROC. Values for sensitivity, specificity, PPV, NPV and likelihood ratio are presented for the optimal score.

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Optimal score is the maximum value for sensitivity plus specificity. Median time calculated from case patient's achieving optimal score/trigger
Results for the NEWS are only presented for children of 12 years and above (31 cases, 29 controls).

Abbreviations: AUROC: Area under the receiver operator characteristic curve; **CI:** Confidence interval; **FP:** False positive; **FN:** False negative; **IQR:** Interquartile range; **ITAT:** Inpatient triage, assessment and treatment score; **LR +ve;** Positive likelihood ratio; **LR –ve:** Negative likelihood ratio; **MET:** Medical Emergency Team**; NEWS:** National Early Warning System; **NHSI:** NHS Institute; **NPV:** Negative predictive value; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET**: Pediatric Medical Emergency Team; **PPV:** Positive predictive value; **THSC:** Toronto Hospital for Sick Children; **: TP:** True positive; **TN**: True negative

3.5.3.6 Modification with percentile based thresholds

The AUROC was calculated for each PTTS after the heart and respiratory rate thresholds had been modified with percentile based values for both hospitalised (Table 3.4) and healthy children (Table 3.3). The AUROC values, together with the z-score and values are presented in Table 3.13. All values are adjusted for Bonferroni's correction.

The substitution of percentile-based heart and respiratory rate values for healthy children improved the AUROC value for three systems and decreased the AUROC for two. Performance of the two lowest ranked PTTS was significantly improved. None of the AUROC values of the modified systems were greater than the three highest ranked unadjusted PTTS. Although the AUROC increased for the adult *NEWS*, the difference was not statistically significant. Performance of the remaining 13 systems did not reach statistical significance.

The substitution of percentile-based values for hospitalised children improved the performance of five PTTS and only decreased performance in one system. The two lowest performing PTTS again demonstrated significant improvement in AUROC. The *NHS Institute PEWS* performance improved significantly, matching the AUROC of the Modified PEWS III (ranked third). Performance of the adult *NEWS* did not significantly improve.

Table 3.13 Performance of modified PTTS

PTTS	Unadjusted	Modified (healthy children)			Modified (hospitalised children)		
	AUROC (95%CI)	AUROC (95%CI)	z-score	p-value	AUROC (95%CI)	z-score	p-value
Cardiff and Vale PEWS	0.89 (0.86-0.91)	0.73	8.37	<.001	0.88	0.48	.633
Bedside PEWS	0.88 0.85-0.91)	0.86	2.72	.007	0.88	0.01	.990
Modified PEWS III	0.87 (0.85-0.90)	0.85	2.77	.006	0.86	1.01	.313

PTTS	Unadjusted	Modified (healthy children)			Modified (hospitalised children)		
	AUROC (95%CI)	AUROC (95%CI)	z-score	p-value	AUROC (95%CI)	z-score	p-value
CEWT	0.85 (0.82-0.88)	0.83	2.22	.026	0.85	0.00	.997
Modified PEWS II	0.85 (0.82-0.88)	0.75	5.06	<.001	0.76	4.76	<.001
PEWS III	0.83 (0.80-0.86)	0.81	1.11	.266	0.81	0.86	.391
NHSI PEWS	0.82 (0.79 - 0.86)	0.85	-2.63	.008	0.86	-3.22	.001
PEWS system score I	0.82 (0.78-0.85)	0.80	1.12	.264	0.85	-1.99	.047
PEWS IV	0.79 (0.75-0.82)	0.80	-0.48	.634	0.85	-4.67	<.001
CEWS	0.79 (0.75-0.82)	0.76	1.30	.194	0.80	-1.49	.137
ITAT score	0.77 (0.74-0.81)	0.76	1.36	.173	0.79	-1.13	.258
Modified PEWS I	0.74 (0.70-0.78)	0.84	-4.99	<.001	0.85	-5.55	<.001
THSC MET calling criteria	0.73 (0.69-0.77)	0.68	2.86	.004	0.68	3.03	.003
NEWS (all ages)	0.72 (0.67-0.76)	0.75	-1.83	.070	0.76	-2.39	.017
MET activation criteria I	0.71 (0.70-0.75)	0.68	1.81	.070	0.68	2.07	.039
MET activation criteria III	0.71 (0.70-0.75)	0.68	1.81	.070	0.68	2.07	.039
PMET triggers II	0.71 (0.67–0.75)	0.68	1.68	.093	0.68	2.01	.045

PTTS	Unadjusted	Modified (healthy children)			Modified (hospitalised children)		
	AUROC (95%CI)	AUROC (95%CI)	z-score	p-value	AUROC (95%CI)	z-score	p-value
Modified Bristol PEWS	0.62 (0.58-0.67)	0.70	-5.44	<.001	0.71	-5.19	<.001
Bristol PEWS	0.62 (0.58-0.67)	0.70	-5.37	<.001	0.71	-5.05	<.001

z-score values calculated by Dr Samiran Ray

Performance of each PTTS was assessed by calculation of the AUROC. Systems were then modified by substitution of the heart and respiratory rate threshold derived from percentile based for healthy children (seen at Table 3.3) and hospitalised children (seen at Table 3.4) and the AUROC calculated. The performance of each modified PTTS for healthy and hospitalised children was compared to its unmodified partner using the Delong's test for correlated curves. z-scores represent comparison of mean values. Significance testing was adjusted for the multiple comparisons of AUROC with Bonferroni's correction, meaning p-values <.0025 were considered significant.

Values in red indicate a significant decrease in performance. Values in green represent a significant improvement in performance.

Abbreviations: AUROC: Area under the receiver operator characteristic curve; **CI:** Confidence interval; **MET:** Medical Emergency Team; **PEW:** Paediatric/Pediatric Early Warning; **PEWS:** Paediatric/Pediatric Early Warning System; **PMET**: Pediatric Medical Emergency Team; **THSC:** Toronto Hospital for Sick Children

3.6 Discussion

This study compared the predictive ability of 18 PTTS and one adult track and trigger system. Track and trigger systems are an important component supporting the detection of deterioration within the safe system framework.[33] Although no system demonstrated excellent performance, eight might be considered as good predictors, nine as useful and two poor.[201] Score-based systems consistently outperformed trigger systems. Larger number of parameters did not appear to improve performance: for instance the two lowest ranked systems had 16 and 14 parameters respectively compared to eight parameters for the highest ranked system. As part of a system, the choice of PTTS may be important in identification of the deteriorating hospitalised child.

The *Cardiff and Vale PEWS*, *Bedside PEWS* and *Modified PEWS III* performed better than the other PTTS. There were no clear defining features that identified why these systems significantly outperformed their competitors. Score weighting differed, with the *Cardiff and Vale PEWS* using a weighting of zero or one, and the *Bedside* and *Modified III PEWS* using the more complex zero, one, two, four weighting. All three systems included heart and respiratory rate, oxygen saturation and blood pressure. The *Cardiff and Vale PEWS* did not include capillary refill time but did incorporate staff concern, conscious level and airway threat. The *Modified PEWS II* only differed from the *Bedside PEWS* by the additional scoring of temperature, but this did not significantly alter its performance.

At the optimal score, scoring systems demonstrated poorer sensitivity, but superior specificity than trigger systems, which may reduce false alerts and build clinician confidence. Using the two-year data from this study, the highest AUROC-ranked trigger system (*THSC MET calling criteria*) would correctly identify 29 more patients than the highest AUROC-ranked scoring system (the *Cardiff and Vale PEWS*) at the optimal score. However 94 additional false alerts would result. This would significantly increase clinician workload, potentially incur greater financial costs and may create ‘alarm fatigue’ and increase response times.[202]

Lowering the scoring thresholds improves sensitivity, creating additional opportunities to intervene and potentially improve outcome.[203] The ability to select the threshold which balances sensitivity and specificity most appropriate to the local environment gives scoring systems some advantages. However they are more

complex to use, carrying the risk of inaccurate calculation [49,94] and inappropriate response.[54,204]

When trigger systems were modified to function as a scoring system, their performance improved significantly. All six modified trigger systems had an AUROC of above or equal to 0.85. Although modification in this way introduces additional complexity into the calculation of the PTTS, the significant improvement in the overall performance, particularly the reduction in false alerts, would appear to justify this modification.

The current local system (*CEWS*) performed moderately, ranked ninth overall despite being developed by local clinicians, using local data and local expertise. It was considerably out-performed by systems externally validated in similar and differing populations. The receiver operator characteristic curve shows no overlapping of the 95% confidence intervals, illustrating the significance of the differences between the curves. Using the two-year data from this study, the highest AUROC-ranked PTTS would correctly identify 59 more patients who subsequently suffered a critical deterioration event than the *CEWS* at the optimal score. This represents a significant number of opportunities to intervene and potentially improve the outcome. Only four additional false alerts would result, with minimal impact on clinician workload.

Incorporation of evidence based thresholds for heart and respiratory rate did not deliver the expected benefits. Although the inclusion of percentile thresholds from hospitalised children out-performed those derived from healthy children, neither improved the performance of the top-ranked systems. Given the additional complexity that these thresholds would introduce, their inclusion into current published PTTS cannot, at this time, be recommended.

All PTTS demonstrated the ability to identify deteriorating children at an early stage. Median hours from optimal score to critical deterioration event varied from 17.0 to 39.5 hours and from 27.9 to 39.8 hours for trigger systems. This is longer than previous study findings for comparable scoring thresholds[177] and demonstrates that both scoring and trigger systems can act as an important ‘early warning’ to front line staff of children at risk of critical deterioration.

3.6.1 Limitations

Values for PTTS were retrospectively calculated from existing documentation. There was no way to verify the accuracy of the documented vital sign values and other observations. Administration of a fluid bolus could not be reliably extracted affecting three PTTS.[42,79,138] Missing values were considered to be 'normal' (score 0) and this may underestimate PTTS performance. Data sets were frequently incomplete however inadequate vital sign monitoring has been frequently reported even when staff are actively prompted by researchers.[67,117]

Significance testing for comparison between the different systems was adjusted with Bonferrioni's correction for multiple comparisons. This may be considered a conservative approach, resulting in equivocal findings where differences may exist.[199] However only two systems, the *Children's Early Warning Tool* and the *Modified PEWS II*, demonstrated equivocal results.

The framework for percentile-based modification of PTTS was developed using a pragmatic approach. As such the choice of weightings may not have been optimal, which could have affected the results.

The optimal score was used to facilitate comparison of performance measures between differing PTTS systems. However scoring thresholds for use in clinical practice are selected by clinicians to balance the benefits, risks, workload and available resources. As such this may not be the most appropriate threshold for this evaluation.

At the time of the study the *CEWS* was in clinical use and as such was used by staff to inform their decision-making. All other PTTS were retrospectively evaluated based on available data and could not inform the clinical decision-making of staff. As such, if the *CEWS* was performing effectively, its use may have prompted staff to intervene and the resulting actions may have prevented or modified a critical deterioration event. This would have decreased the sensitivity of the *CEWS* and as such, the performance of the *CEWS* may have been underestimated.

The study was conducted in a tertiary specialist children's hospital. The critical deterioration event rate was high when compared to reports from other specialist children's hospitals. Other settings may require alternative response strategies at differing scoring thresholds. Different results may also be seen for different

outcomes and combinations of outcomes. Greater standardisation of reporting and consensus on pragmatic measures to evaluate PTTS and other similar interventions would facilitate meaningful comparison and collaborative research.[168]

3.7 Conclusion

Recognition of the deteriorating child is an important component of the safe system framework.[33] However there is considerable variation in the performance of published PTTS and as such the choice of PTTS may be an important factor in the performance of the overall system and in the child's outcome. The three top-ranked systems demonstrated similar performance and could be recommended for hospitals seeking to introduce or revise their PTTS. Trigger based systems performed poorly overall and although proponents cite simplicity as a justification for their selection, their low AUROC values would appear to out-weigh this. However it remains unclear what factors determine optimum performance across the PTTS. More complex systems did not necessarily demonstrate improved performance.

We have no reason to believe our situation is unique and it is likely that many other locally developed un-validated PTTS would demonstrate similar sub-optimal performance if rigorously evaluated.[36] The high and increasing number of published and unpublished PTTS raises concerns that paediatrics may be following a similar path to that of adult track and trigger systems, with multiple poorly validated systems with unknown predictive power.

The choice of PTTS may be an important factor in determining outcome. On the basis of this study, three systems could be recommended: the *Cardiff and Vale PEWS*, the *Bedside PEWS* and the *Modified PEWS III*. Trigger systems cannot, at this time, be advocated due to their poor predictive performance. Modification of existing systems with percentile based heart and respiratory rate thresholds did not deliver the expected benefits and therefore further research is required to determine if they have a place within PTTS.

The next chapter will explore if the accuracy and completeness of PTTS scoring affects the utility of PTTS in the clinical setting.

Chapter 4 Reliability: an observational study of the accuracy and completeness of paediatric track and trigger system documentation and compliance to a monitoring and escalation protocol

4.1 Introduction

Research on paediatric track and trigger systems (PTTS) has largely concentrated on diagnostic accuracy, using retrospective data to assess whether the system can accurately discriminate between children who are clinically deteriorating from those who are not. Relatively few studies have examined how healthcare practitioners use PTTS in clinical practice. Evidence from patient safety incidents suggests that they are not always used optimally.[33] This may have implications for the recognition of deterioration and response to deterioration components of the safe system framework.[33]

This chapter reports the real-world use of PTTS by clinical staff. Firstly how compliance to a protocol may be assessed will be discussed, and why the 'all-or-nothing' approach was selected will be examined. The study methodology will then be described, specifying and justifying the standards used to assess monitoring and escalation compliance. The results of PTTS completeness, accuracy and frequency will be presented before a discussion of the findings.

4.1.1 Background

For PTTS to function effectively they need to be used as designed. This means that observation sets should be complete so all parameters can be scored effectively. Scores should be calculated correctly. This requires selection of the correct chart for the child's age, allocation of the correct sub-scores for each parameter and correct summation of these sub-scores to produce a total PTTS score. Finally PTTS need to be acted upon through adherence to the escalation protocol for elevated scores. Although performing each of these steps appears, on the surface at least, to be simple, there is evidence that recording and calculating track and trigger scores involves a complex relationship between clinical decision-making, human error and external factors such as chart design.[49,72,205,206] Steps can be omitted or incorrectly performed, and this can affect the accuracy of the score.

Numerous studies have highlighted deficiencies in the use of track and trigger systems in adult clinical practice as highlighted in section 1.2.10. Major areas of concern include missing, incomplete and inaccurate scoring and failure to follow the recommended plan for escalation. Although the research on PTTS tools is less developed, it is reasonable to assume that they may suffer from similar flaws in use, given the similarities in their form and function.

Effective track and trigger systems require adherence to a protocol. A number of studies of adult patients have assessed the performance of both novel and established track and trigger systems.[49,111] These previous studies have predominantly assessed performance in two ways: 'item-by item measurement', where each item is reported separately as a percentage, (e.g. 80% of patients had a PTTS value recorded twice per day), or as a 'composite measure' where performance is reported as a ratio of the elements achieved, (e.g. all patients achieved three out of the four required care elements).[207] In the current study compliance has been assessed using an 'all or nothing' approach.[207] This approach is particularly relevant when care is composed of differing and often interlinked steps. Using PTTS as an example, a full observation set (step 1) is accurately taken (step 2) at the required frequency (step 3). A corresponding PTTS score is calculated (step 4), but the value is incorrect. The nurse correctly follows the escalation plan (but for the incorrect value) (step 5), and the patient receives the required response (step 6). However despite five of the six steps being correctly executed, the process is flawed. The steps are inter-linked and the process requires reliable execution of each step to achieve the desired outcome. As such, when assessing the monitoring and escalation of PTTS, all or nothing measures are considered more appropriate than item-by-item or composite measures.

Within the 'all-or-nothing' approach, compliance to all the specified elements of the protocol is required to achieve the standard. There is no 'credit' for partial compliance. Whilst this inevitably produces far lower levels of compliance, it more closely reflects wishes and desires of patients and families and reportedly drives clinicians to achieve improvements in care.[207]

4.1.1.1 The local PTTS protocol for monitoring and escalation

The local PTTS protocol set out the minimum standards derived from recommendations of national reports and professional consensus.[3,5,6,33,51] All nurses and medical staff were informed of these standards on induction and thereafter at

yearly updates. The protocol was available on each ward and could be accessed via the hospital intranet. The protocol was designated as a policy rather than a guideline. As such staff were mandated to adhere to the protocol unless there were clear contra-indications to its use, which would need to be documented and reported.

At the time of the study the PTTS protocol required blood pressure to be documented once per day. All other vital sign parameters had to be recorded at least once per nursing shift. This equated to once every 12-hours as a standard shift pattern was in operation at the time.

The protocol directed that a PTTS score should be completed with each vital sign parameter recording. Where a vital sign parameter value fell on the border between two differing sub-scores, the protocol stated that the lower sub-score value should be used.

A hospital-wide escalation protocol was in place which identified the action to be taken for each PTTS score (Appendix 3).

4.2 Methods

This was an observational study examining the real-world use of PTTS by clinicians. The aim was to explore whether PTTS are used as intended and to examine the compliance to a monitoring and escalation protocol. As outlined in chapter three, a case-controlled methodology was selected. A cohort methodology was considered but discarded due to the large number of participants required to capture sufficient data on the management of elevated PTTS values. This would have exceeded the resources available to the PhD candidate. A 2-year retrospective study was considered adequate to demonstrate statistically significant findings at a p value of <0.05 as it would yield approximately 600 participants (300 cases and 300 controls). This would facilitate sufficient number of patients with ‘normal’ and ‘elevated’ PTTS scores to allow meaningful analysis.

4.2.1 Ethical issues

This study was assessed by the hospital’s clinical audit department and was designated a service evaluation project. As such the study was considered exempt from approval from a Research Ethics Committee and the local clinical research

committee. The project was registered with the clinical audit department (registration number 1489).

4.2.2 Participants

Patients entered into the validity study described in Chapter three also participated in this study. Patients who suffered a critical deterioration event were designated ‘cases’ using the criteria previously described in section 3.3.4. Cases were matched with a single control present on the same ward at the same time. Wards were considered a proxy match for diagnostic speciality.

Inclusion and exclusion criteria were identical for both studies and have previously been described in section 0 and 3.3.4.2. Case patients were matched with the control patient closest in age to them, as outlined in 3.3.4.3.

4.2.3 Criteria for compliance

Standards for compliance were developed based on the recommendations within the PTTS protocol and the PTTS escalation protocol (Appendix 3). The protocol dictated that elevated PTTS values must be repeated within 30 minutes. Although no time-limit for attendance by a clinician or intensive care outreach team was explicitly set within the escalation protocol, a period of one hour from documented score to attendance was considered reasonable, given that PTTS alert staff to clinical deterioration.

It was recognised that there may also be a delay between the recording of vital signs and PTTS documentation. Repeat PTTS recording and escalation may need to be balanced against other important patient-related tasks such as toileting and administering analgesia. Documentation of findings will always be secondary to patient assessment and intervention. To acknowledge this, the standard for compliance required repeat recording within one hour and escalation within two hours.

4.2.3.1 Compliance to the monitoring protocol

Ten standards were developed to assess adherence to the monitoring protocol. Compliance required all ten standards to be met for each 12-hour period. If a patient was ‘not available’ for any single 12-hour period, they were regarded as achieving compliance for that period.

The ten standards for monitoring were:

1. Use of the correct PTTS chart for the child's age
2. Presence of a monitoring plan on the PTTS chart
3. At least one temperature value recorded every 12 hours
4. At least one heart rate value recorded every 12 hours
5. At least one respiratory rate value recorded every 12 hours
6. At least one assessment of consciousness* recorded every 12 hours
7. At least one systolic blood pressure value recorded every 24 hours
8. At least one oxygen saturation value recorded every 12 hours
9. At least one PTTS value recorded every 12 hours
10. At least one accurate PTTS value calculated from a full set of observations recorded every 12 hours

*Consciousness was measured by assessment on the AVPU scale (alert – responds to voice -responds to pain – unresponsive).

4.2.3.2 Compliance to the escalation protocol

Eight standards were developed to assess adherence to the escalation protocol, one for a score of two (standard 1), two standards for a score of three (standards 2 and 3), two standards for a score of four (standards 4 and 5) and three for a score of or above five (standard 6-8). Scores below two did not require escalation.

Within each 12-hour period, the first PTTS value of two, three, four and five or more was identified. The time to the relevant escalation standard (repeat PTTS score, escalation to a senior clinician, escalation to the intensive care outreach team) was calculated. If the relevant action was achieved within one hour for repeat PTTS recording and two hours for clinician or outreach review the standard was considered to have been met for that 12-hour period. Patients who did not achieve a PTTS score of two or more within a given 12-hour period were considered compliant for that period with regards to escalation.

The eight standards for escalation were:

1. For the first recorded PTTS score of two, repeat recording of a full set of observations and a correctly calculated PTTS value within 60 minutes

2. For the first recorded PTTS score of three, repeat recording of a full set of observations and a correctly calculated PTTS value within 60 minutes
3. For the first recorded PTTS score of three, escalation to a senior clinician within 120 minutes
4. For the first recorded PTTS score of four, repeat recording of a full set of observations and a correctly calculated PTTS value within 60 minutes
5. For the first recorded PTTS score of four, escalation to a senior clinician within 120 minutes
6. For the first recorded PTTS scores ≥5, repeat recording of a full set of observations and a correctly calculated PTTS value within 60 minutes
7. For the first recorded PTTS scores ≥5, escalation to a senior clinician within 120 minutes
8. For the first recorded PTTS scores ≥5, escalation to the intensive care outreach team within 120 minutes

4.2.4 Data extraction

Vital sign and PTTS data were extracted from healthcare documents for the 48-hours prior to the critical deterioration event for case patients and the corresponding 48-hour period for the matched controls. The documented values for the component vital sign parameters, PTTS vital sign parameter sub-score, total PTTS scores and the age-range of the PTTS chart used were extracted using a standardised pro-forma. Evidence of a request for or an actual senior clinician and/or intensive care outreach review was also extracted.

Data were assigned to the date and time noted on the healthcare record. Where a value for date and/or time was not recorded, this was estimated using other indicators (such as the activation of a cardiac arrest team) or through calculation of the median of the documented values at either side. For example, if the entry before the missing value was timed at 12:00 and after at 14:00, the missing value would be assigned to 13:00.

4.2.5 Data analysis

Data were entered into a Microsoft Excel database developed by the candidate.

To facilitate analysis, data were allocated to an hour of the day, with the time of each value apportioned to the hour of the time value recorded. For example, if a time value of 08:59 was recorded, the hour of the day would be calculated as 8.

Data were also allocated to the hour before the critical deterioration event. For example if the critical deterioration event occurred at 10:30, values recorded from 09:30 to 10:29 were considered to have occurred in hour zero and those recorded from 08:30 to 09:29 were allocated to the period one hour before the event and so on. For controls, the time of the critical deterioration event was considered to be the event time of their matched case patient. All values for the hour of the day and the hour to event were calculated using formulas in Excel.

Completeness of observation sets was calculated using the 'COUNTIF' function in Excel. An observation set was considered to be complete if there was simultaneous recording of all component PTTS parameters together with a total PTTS score.

To assess PTTS score accuracy, values were recalculated in Excel using the available vital sign parameter values. Formulas were developed by the candidate to accurately determine the correct chart for the child's age based on date of birth and date of vital sign parameter documentation. Individual component parameter sub-scores were calculated using the 'IF' functions within Excel. Component sub-scores were combined using the 'SUM' function to generate an accurate Excel-derived total PTTS score. Missing component vital sign parameters were presumed to be normal (score 0), consistent with clinical practice at the time and the methodology of previous studies.[116,121]

A PTTS score was considered to be accurate when the documented total PTTS score matched the Excel-generated PTTS score. Comparison was undertaken using the pivot table function in Excel. Where the documented and Excel-generated score, although different, would have led to the same escalation, the incorrectly documented score was classed as not clinically significant. Where the incorrectly documented score resulted in a different escalation pathway from that indicated by the Excel-generated score, the score was classed as clinically significant.

Inaccurate PTTS scores were classified according to the reason:

- incorrect chart for child's age
- incorrect sub-score for one or more component vital sign parameters
- incorrect summation of the excel-derived sub-scores or
- a combination of two or more inaccuracies.

Completeness and accuracy were compared across different nursing shifts, days of the week and low (0-1) medium (2-4) and high (≥5) scores for cases and controls. Analysis was facilitated using the pivot table function in Excel.

Compliance was assessed for each 12-hour period before the critical deterioration event (0-11 hours, 12-23 hours, 24-35 hours, 36-47 hours). The 12-hour assessment period corresponded with the length of a ward nurse's shift, facilitating assessment against the standards in the PTTS protocol. A patient was considered to be 'available for PTTS assessment' if they were present on the ward for any part of the relevant 12-hour period. A patient was considered 'unavailable for PTTS assessment' if they were missing from the ward for the entire 12-hour period because, for example, they were in the operating theatre, on home leave, or had not, as yet, been admitted to hospital.

Compliance to the 10 monitoring and eight escalation standards was assessed for each 12-hour period using the pivot table function. Achievement of the required standard or absence of the patient for the entire 12-hour data period were considered to indicate compliance.

Overall compliance was assessed using an 'all or nothing' assessment. This required each patient to have achieved compliance for each of the eight escalation standards at the first presentation of the elevated PTTS score. This 'all or nothing' approach was then applied to the composite standards for monitoring (10 elements) and escalation (8 elements). Failure to achieve the required standard for any one element would be considered as an overall failure to meet the required care standard.

Compliance to each monitoring and escalation standard was analysed across the entire 48-hour study period and the final 12-hour period before the critical deterioration event. Comparisons were drawn between cases and controls across these two periods to evaluate if compliance improved closer to the critical deterioration event, as the signs of deterioration may be more marked.

4.2.5.1 Statistical analysis

Data were analysed using Microsoft Excel, SPSS and Vasser Stats. Descriptive statistics were calculated, including counts, means, medians and percentages. Statistical significance was assessed by chi squared or fishers exact test for

categorical data and Mann-Whitney U test for continuous data. A value of p<.05 was considered to be significant for all comparisons.

4.3 Results

4.3.1 Patient characteristics

Three hundred and nineteen critical deterioration events were identified. In eight episodes the patient was present on the ward for less than two hours, leaving 311 eligible critical deterioration events in 237 patients. Fourteen case patient records were missing, leaving a case sample of 297 events in 224 patients. A total of 244 control patients were identified for the 311 events.

Case patients were more likely to be female (56.3% vs 46.3%, p=.018), have been admitted as an emergency (64.6% vs 39.2%, p<.001) and have a longer hospital stay (median 57.1 vs 35.9 days, p<.01). In-hospital mortality was also higher for case patients at 24 hours and 30 days, and at hospital discharge (p=<.001). A summary of patient characteristics is shown in Table 3.6.

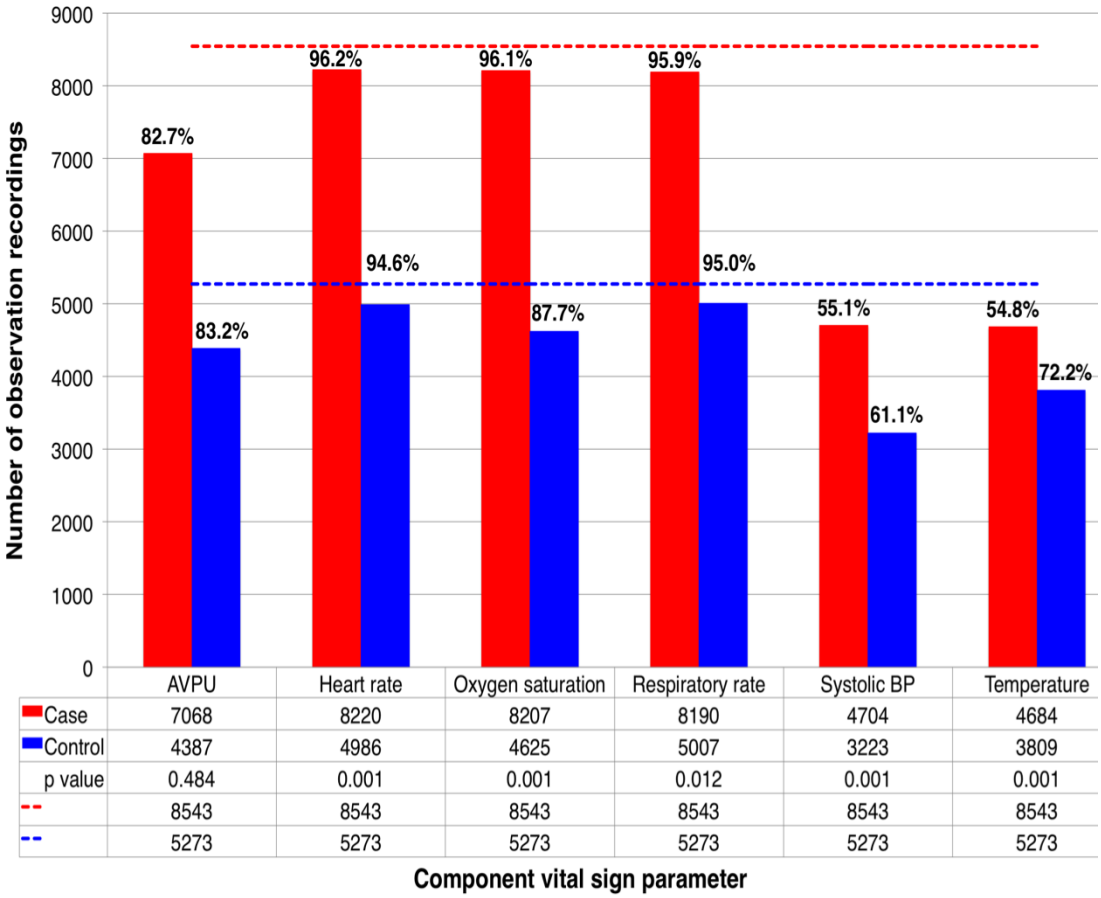
Of the 297 critical deterioration events 186 (62.6%) were classified as PICU transfers, 84 (28.3%) as respiratory arrests and 27 (9.1%) cardiac arrests. Thirty-one patients remained on the ward after a cardiac or respiratory arrest. Six patients could not be resuscitated after a cardiac arrest and died before transfer to intensive care.

4.3.2 Overall frequency of vital sign recording

In total 13,816 observations sets were performed. A greater numbers of observation sets were performed on cases (8543, 61.8%) compared to controls (5273, 38.2%). The median number of observation sets per patient per day was 12 (interquartile range [IQR] 6-19) for cases and six (IQR 6-8) for controls.

The frequency of recording of the component vital sign parameters varied (Figure 4.1). Heart rate, oxygen saturation and respiratory rate were recorded more frequently than other parameters. They were present in the observation sets of more than 95% of case patients and 85% of controls. A comparison of cases and controls revealed a significantly higher presence in the observation sets of case patients compared to controls. The difference was highly significant for heart rate and oxygen saturation (p <.001) and significant for respiratory rate (p= .012).

Figure 4.1 Proportion of observation sets with a value recorded for AVPU, heart rate, oxygen saturation, respiratory rate, systolic blood pressure and temperature for cases and controls



	AVPU	Heart rate	Oxygen saturation	Respiratory rate	Systolic BP	Temperature
Case	7068	8220	8207	8190	4704	4684
Control	4387	4986	4625	5007	3223	3809
p value	0.484	0.001	0.001	0.012	0.001	0.001
--	8543	8543	8543	8543	8543	8543
--	5273	5273	5273	5273	5273	5273

[Footnotes on next page]

Key: The total number of observation sets for cases and controls are shown by the red and blue dashed line.

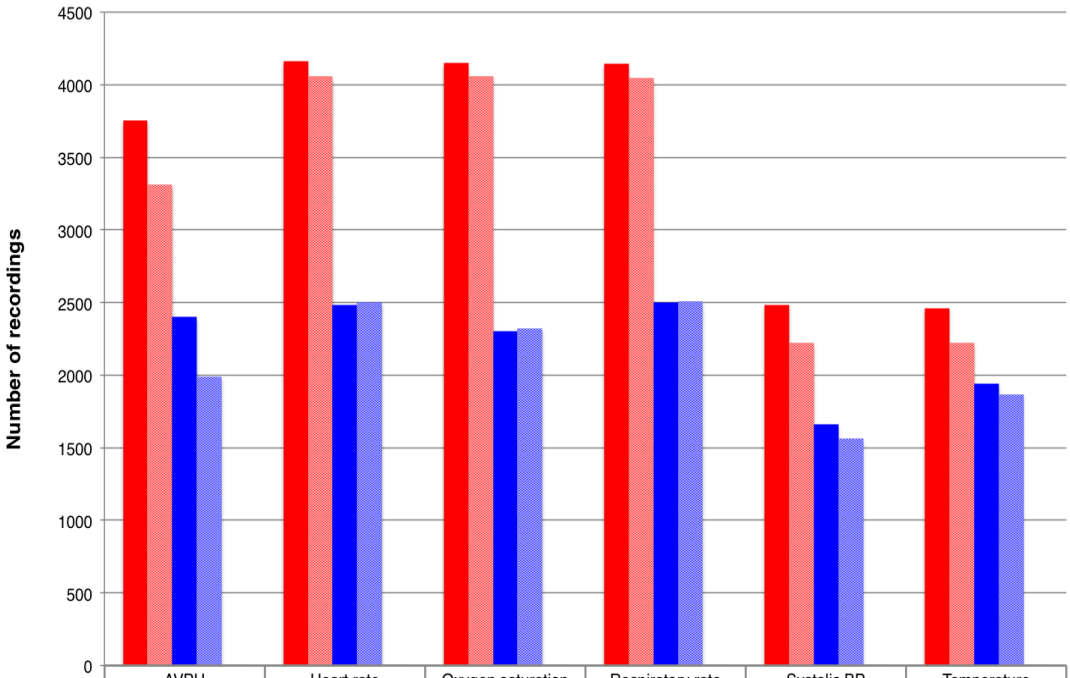
Percentages above each bar represent the total number of observation sets of cases and controls which contain the component vital sign parameters.
p values represent the comparison of component vital sign parameter recordings for cases versus controls (chi-squared)

By contrast, the observation sets of controls more frequently contained a value for temperature (72.2% vs 54.8%, p <.001) and systolic blood pressure (61.1% vs 55.1%. p <.001). There was no difference in the proportion of case patient observation sets with an AVPU value compared to controls (82.7% vs 83.2%, p=0.484).

4.3.2.1 Frequency of component vital signs for day and night shift

More observation sets were recorded during the day shift (08:00- 19:59) compared to the night shift (20:00 – 07:59). Case patients had more day-time recordings of all parameters. Controls had slightly more recordings of heart rate, oxygen saturation and respiratory rate at night, but a greater number of AVPU, oxygen saturation and temperature recordings in the day. For each vital sign parameter, comparison of the number of day and night-time recording across cases and controls revealed no significant differences (Figure 4.2).

Figure 4.2 Frequency of component vital signs parameters documentation during the day and night-time



	AVPU	Heart rate	Oxygen saturation	Respiratory rate	Systolic BP	Temperature
Case (day shift)	3755	4164	4148	4147	2481	2462
Case (night shift)	3313	4056	4059	4043	2223	2222
Control (day shift)	2399	2485	2302	2503	1659	1942
Control (night shift)	1988	2501	2323	2504	1564	1867
p value	0.104	0.362	0.435	0.471	0.267	0.148

Component vital sign parameter

Values represent the total number of vital sign values recording during the day (08:00-19:59) and night shift (20:00-07:59).

Key: p values denote significance of recoding of component vital sign values of cases and controls on the day and night shift (chi-squared)

4.3.2.2 Completeness of observation sets

Only 4957 (35.9%) observation sets contained a complete set of component vital sign parameters with a concurrent PTTS score. The remainder did not, and as such were considered to be incomplete. Case patient's had a significantly lower proportion of observation sets that were complete when compared to controls (32.9% vs 40.7%, p <.0001).

4.3.3 Accuracy and completeness of PTTS scoring

4.3.3.1 Correct, incorrect and missing PTTS scores

The distribution of documented PTTS values for each given Excel-derived PTTS value can be seen in Figure 4.3. The number of observation sets for each documented PTTS value are seen in the 'Total' column on the right, whilst the number of observation sets for each correctly calculated score are seen in the row at the bottom of Figure 4.3

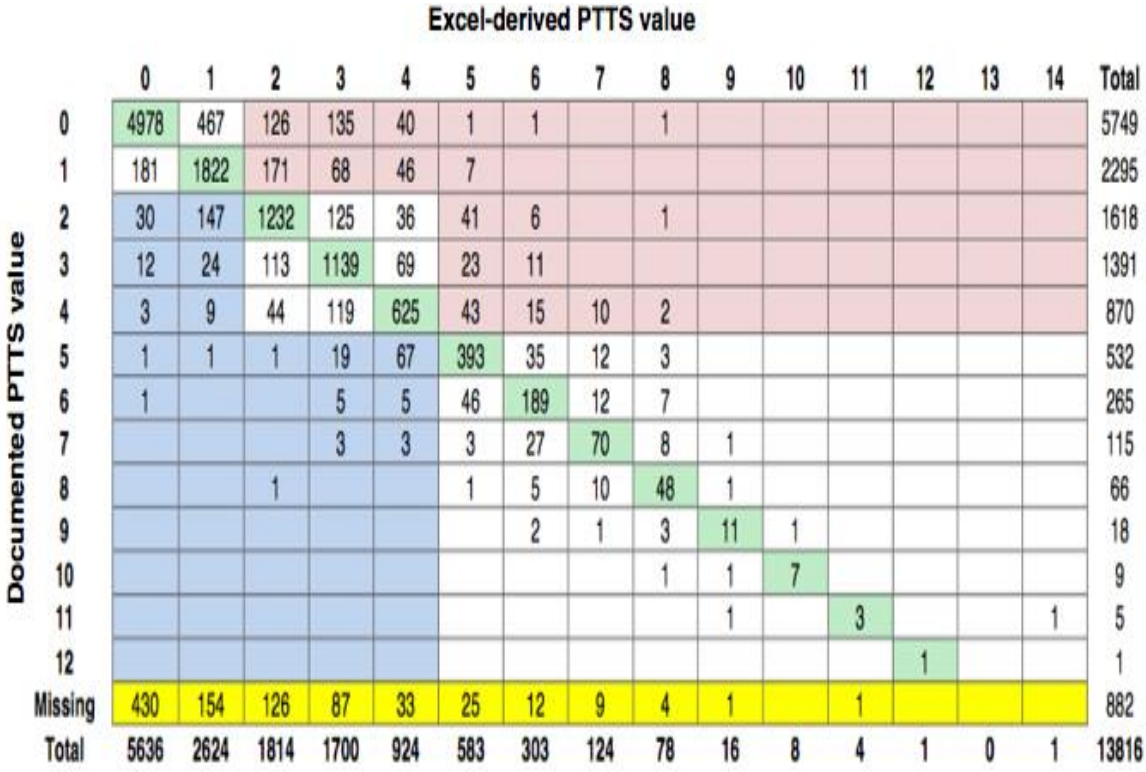
Observation sets with no documented PTTS value are highlighted in yellow. Observation sets where the documented PTTS score matches the Excel-derived score were considered to be accurate and are highlighted in green. Observation sets where the two values did not match were considered to be inaccurate. Values in the top right-hand side of the figure - where the documented PTTS is less than the Excel-derived score - were classified as under-scored. Values in the bottom left of the figure - where the documented PTTS score exceeds the Excel-derived score - were classified as over-scored. Scoring errors which would have led to activation of a different escalation pathway were considered clinically significant and are shaded blue for over-scoring and red for under-scoring errors.

Overall 10,518 (76.1%) observation sets had a PTTS score that was accurately calculated, 2416 (17.5%) were considered inaccurate and 882 (6.4%) were missing (Figure 4.3).

The distribution of correct, incorrect and missing PTTS score for case patients is seen in Figure 4.4. There were 6250 (73.2%) observation sets with a correctly calculated PTTS score. Errors were present in 1673 sets (19.6%) and 620 (7.3%) had no concurrent PTTS value.

Control patients had a higher proportion of accurate PTTS scores (4268, 80.9%) as seen in Figure 4.5. Errors in PTTS scoring were less frequent (743, 14.1%) and fewer observation sets were missing a documented PTTS value (262, 5.0%). When cases and controls were compared, the differences in the proportion of accurate scores ($p < .0001$), scoring errors ($p < .0001$) and missing PTTS values ($p < .0001$) were highly significant.

Figure 4.3 Correct, incorrect and missing PTTS scores (all patients)



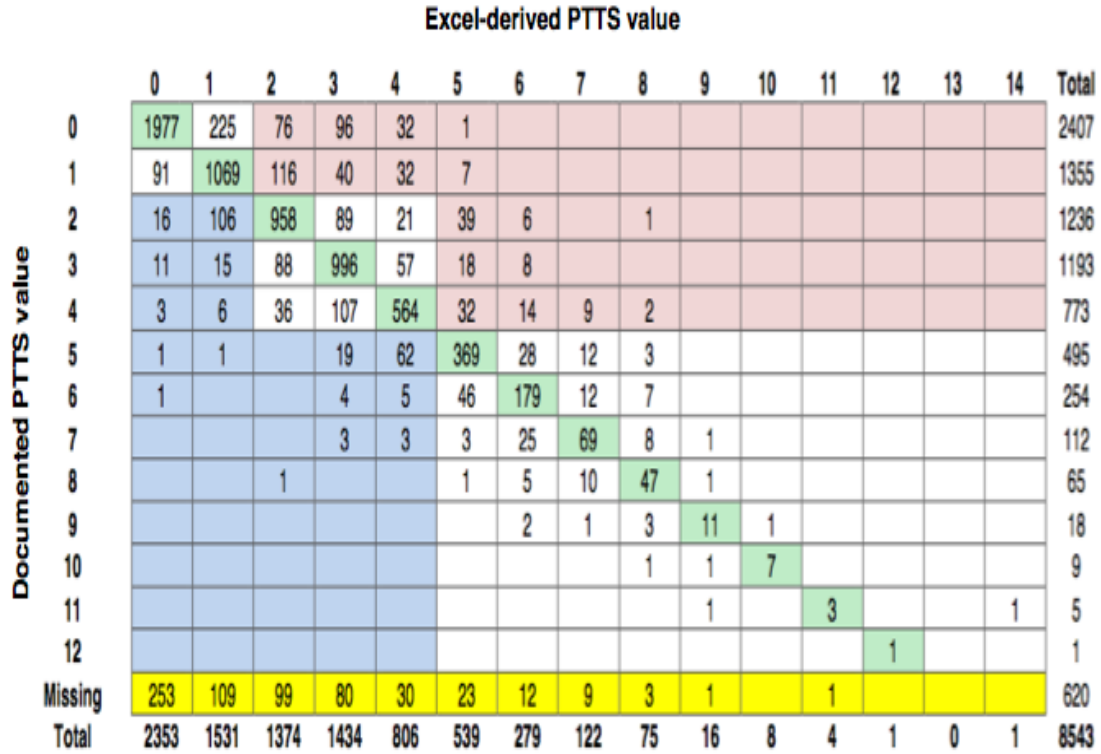
Documented PTTS value \ Excel-derived PTTS value	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
0	4978	467	126	135	40	1	1		1							5749
1	181	1822	171	68	46	7										2295
2	30	147	1232	125	36	41	6		1							1618
3	12	24	113	1139	69	23	11									1391
4	3	9	44	119	625	43	15	10	2							870
5	1	1	1	19	67	393	35	12	3							532
6	1			5	5	46	189	12	7							265
7				3	3	3	27	70	8	1						115
8			1			1	5	10	48	1						66
9							2	1	3	11	1					18
10									1	1	7					9
11										1		3			1	5
12													1			1
Missing	430	154	126	87	33	25	12	9	4	1		1				882
Total	5636	2624	1814	1700	924	583	303	124	78	16	8	4	1	0	1	13816

PTTS values of 0-1 required no escalation. PTTS values of 2-4 and 5 or greater had differing escalation pathways.

The Excel-derived PTTS score was plotted against the documented PTTS score. The framework represents the number of observation sets for each documented PTTS score at the relevant excel-derived PTTS.

Green represents observation sets where the excel-derived and documented PTTS matched and was therefore considered to be accurate
Yellow indicates observation sets where no PTTS value was documented and the PTTS was considered to be missing
Blue indicates observation sets where the Excel-derived score was greater than the documented PTTS score and would have resulted in different escalation pathways (clinically significant under-score)
Red indicates observation sets where the Excel-derived score was less than the documented PTTS score and would have resulted in different escalation pathways (clinically significant under-score)
White indicates observation sets where the Excel-derived and documented PTTS score differed but the resultant escalation pathways matched (non-clinically significant error)

Figure 4.4 Correct, incorrect and missing PTTS scores (case patients)



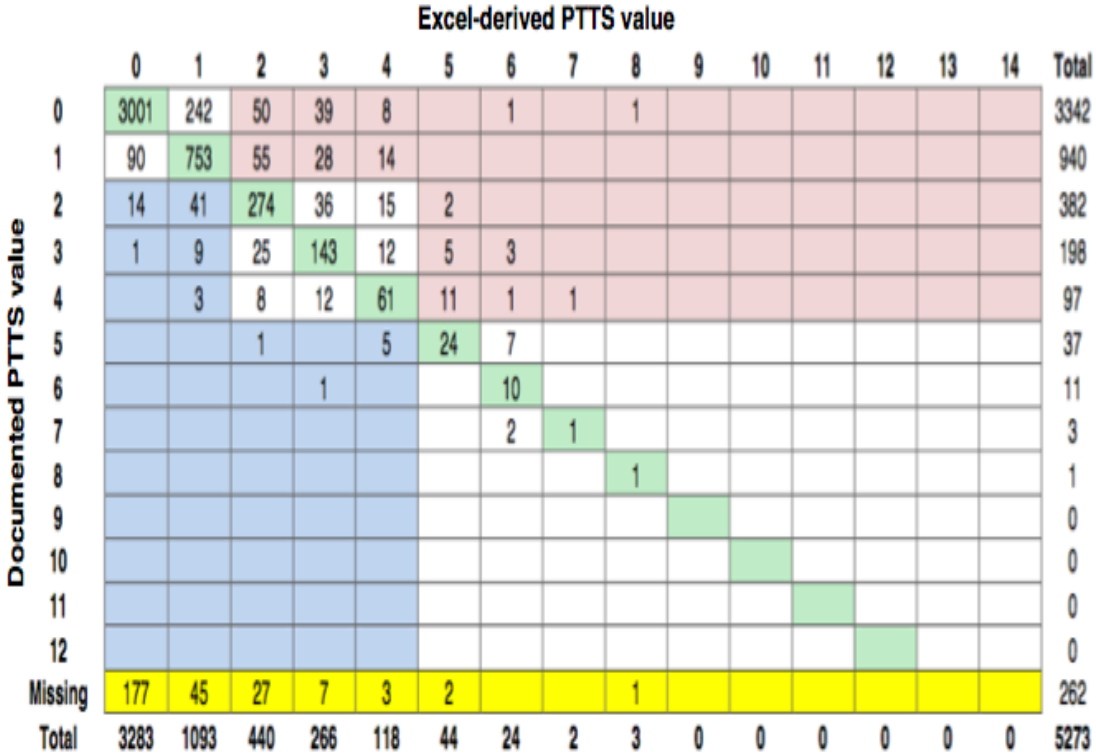
Documented PTTS value	Excel-derived PTTS value															
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
0	1977	225	76	96	32	1										2407
1	91	1069	116	40	32	7										1355
2	16	106	958	89	21	39	6		1							1236
3	11	15	88	996	57	18	8									1193
4	3	6	36	107	564	32	14	9	2							773
5	1	1		19	62	369	28	12	3							495
6	1			4	5	46	179	12	7							254
7				3	3	3	25	69	8	1						112
8			1			1	5	10	47	1						65
9							2	1	3	11	1					18
10									1	1	7					9
11										1		3			1	5
12													1			1
Missing	253	109	99	80	30	23	12	9	3	1		1				620
Total	2353	1531	1374	1434	806	539	279	122	75	16	8	4	1	0	1	8543

PTTS values of 0-1 required no escalation. PTTS values of 2-4 and 5 or greater had differing escalation pathways.

The Excel-derived PTTS score was plotted against the documented PTTS score. The framework represents the number of observation sets for each documented PTTS score at the relevant excel-derived PTTS.

Green represents observation sets where the excel-derived and documented PTTS matched and was therefore considered to be accurate
Yellow indicates observation sets where no PTTS value was documented and the PTTS was considered to be missing
Blue indicates observation sets where the Excel-derived score was greater than the documented PTTS score and would have resulted in different escalation pathways (clinically significant under-score)
Red indicates observation sets where the Excel-derived score was less than the documented PTTS score and would have resulted in different escalation pathways (clinically significant under-score)
White indicates observation sets where the Excel-derived and documented PTTS score differed but the resultant escalation pathways matched (non-clinically significant error)

Figure 4.5 Correct, incorrect and missing PTTS scores (control patients)



Documented PTTS value \ Excel-derived PTTS value	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
0	3001	242	50	39	8		1		1							3342
1	90	753	55	28	14											940
2	14	41	274	36	15	2										382
3	1	9	25	143	12	5	3									198
4		3	8	12	61	11	1	1								97
5			1		5	24	7									37
6				1			10									11
7							2	1								3
8									1							1
9																0
10																0
11																0
12																0
Missing	177	45	27	7	3	2			1							262
Total	3283	1093	440	266	118	44	24	2	3	0	0	0	0	0	0	5273

PTTS values of 0-1 required no escalation. PTTS values of 2-4 and 5 or greater had differing escalation pathways.

The Excel-derived PTTS score was plotted against the documented PTTS score. The framework represents the number of observation sets for each documented PTTS score at the relevant excel-derived PTTS.

Green represents observation sets where the excel-derived and documented PTTS matched and was therefore considered to be accurate
Yellow indicates observation sets where no PTTS value was documented and the PTTS was considered to be missing
Blue indicates observation sets where the Excel-derived score was greater than the documented PTTS score and would have resulted in different escalation pathways (clinically significant under-score)
Red indicates observation sets where the Excel-derived score was less than the documented PTTS score and would have resulted in different escalation pathways (clinically significant under-score)
White indicates observation sets where the Excel-derived and documented PTTS score differed but the resultant escalation pathways matched (non-clinically significant error)

4.3.3.2 The direction of scoring error

Comparison of PTTS errors in cases and controls revealed a higher proportion of scoring errors for case patients and these were predominantly underscored, rather than over-scored (p <.0001).

Table 4.1 The proportion of observation sets with an under and over-scoring error expressed as a percentage of the total observation sets of cases and controls

	Cases (n = 8543)	Controls (n =5273)	p value
Underscored	994 (11.6%)	531 (10.1%)	<.0001
Over-scored	679 (7.9%)	212 (4.0%)	

p value represent comparison of observation sets which were under and over-scored for cases and controls (Chi squared)

While most scoring errors would not have resulted in a different escalation pathway, 888 (10.3%) PTTS values for case patients and 449 (8.5%) for controls should have indicated a different escalation pathway. In both groups, the majority were under-scored and as such, could have resulted in a failure to appropriately escalate a deteriorating patient.

4.3.3.3 The effect of the day of the week and nursing shift on scoring errors

When considered as a proportion of the total number of observation sets recorded on a weekday versus a weekend, there was a decrease in PTTS errors on a weekend for cases (9.5% vs 8.2%, p =.031) and an increase for controls (4.8% vs 7.5%, p = .0002).

Comparison between observation sets recorded on the day and night shift revealed an increased proportion of errors on the day shift for both cases (25.4% vs 22.3%, p <.001) and controls (15.0% vs 13.2%, p= .037).

4.3.3.4 Errors and omissions at low, medium and high PTTS scores

Errors and omissions in cases and controls were assessed across low (0-1), medium (2-4) and high (>=5) PTTS scores (Table 4.2). There was an increase in scoring errors with higher scores for both cases (p <.0001) and controls (p <.0001). Conversely the proportion of missing PTTS values decreased as PTTS scores

increased (p <.0001) in controls. There was no statistical difference in the proportion of missing scores at differing scoring thresholds for controls (p= .737).

When the error rates between the two groups were compared for differing scores, case patients had a higher error rate for low scores (p<.0001) but a lower error rate for medium (p <.0001) and high risk scores (p =.0026).

Table 4.2 The prevalence of errors and missing PTTS scores for low, medium and high scores

PTTS score	Cases	p value	Controls	p value
PTTS score errors				
Low **Medium** **High**	476/3899 (12.2%) 887/3665 (24.2%) 311/1046 (29.7%)	<.0001[a]	400/4376 (9.1%) 309/824 (37.5%) 34/73 (46.6%)	<.0001[a]
Missing PTTS scores				
Low **Medium** **High**	377/3899 (9.7%) 259/3665 (7.1%) 49/1046 (4.7%)	<.0001[a]	222/4376 (5.1%) 37/824 (4.5%) 3/73 (4.1%)	.737

Errors and missing scores are considered as a proportion of the total number of recorded observation sets at low (0-1), medium (2-4) and high scores (≥5)

4.3.3.5 Reason for PTTS score inaccuracy

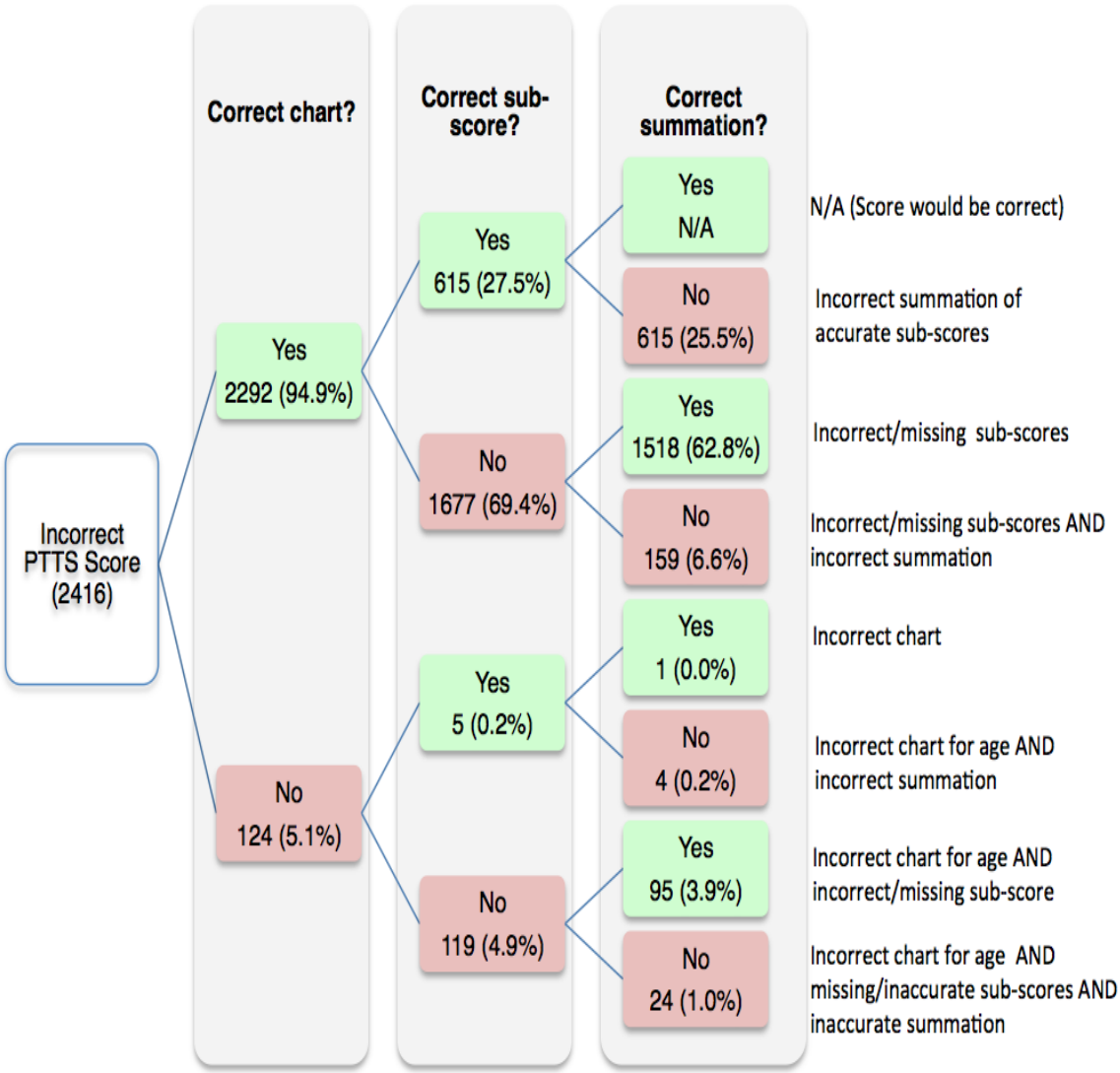
Analysis of the 2416 errors to identify the cause revealed that 124 (5.1%) observation sets were documented on a chart that was the wrong age for the patient (Figure 4.6). This error largely resulted in the incorrect sub-score for one or more of the vital sign parameters in 199 observation sets (4.9%).

Errors were frequently associated with inconsistencies in the sub-scoring of one or more vital sign parameters (74.3%). Overall 1796 (62.8%) erroneous observation sets had a missing or incorrectly scored parameter sub-score. Errors appeared to be particularly prevalent around boundaries between scores.

Errors were also common in the summation of the parameter sub-scores to produce the total PTTS score. A total of 802 (33.3%) erroneous observation sets had errors in summation.

Incorrect or missing parameter sub-scores was the most prevalent reason for errors (62.8%), followed by incorrect summation of these sub-scores (25.5%). These accounted for 88.3% of total errors. A total of 159 (6.6%) observation sets contained both types of errors. A small number of observation sets (24, 1.0%) contained all three types of error.

Figure 4.6 Reason for PTTS inaccurate scores



Values and percentages represent the number of observation sets with each type of error for cases and controls combined.

4.3.3.6 Direction of inaccurate scores

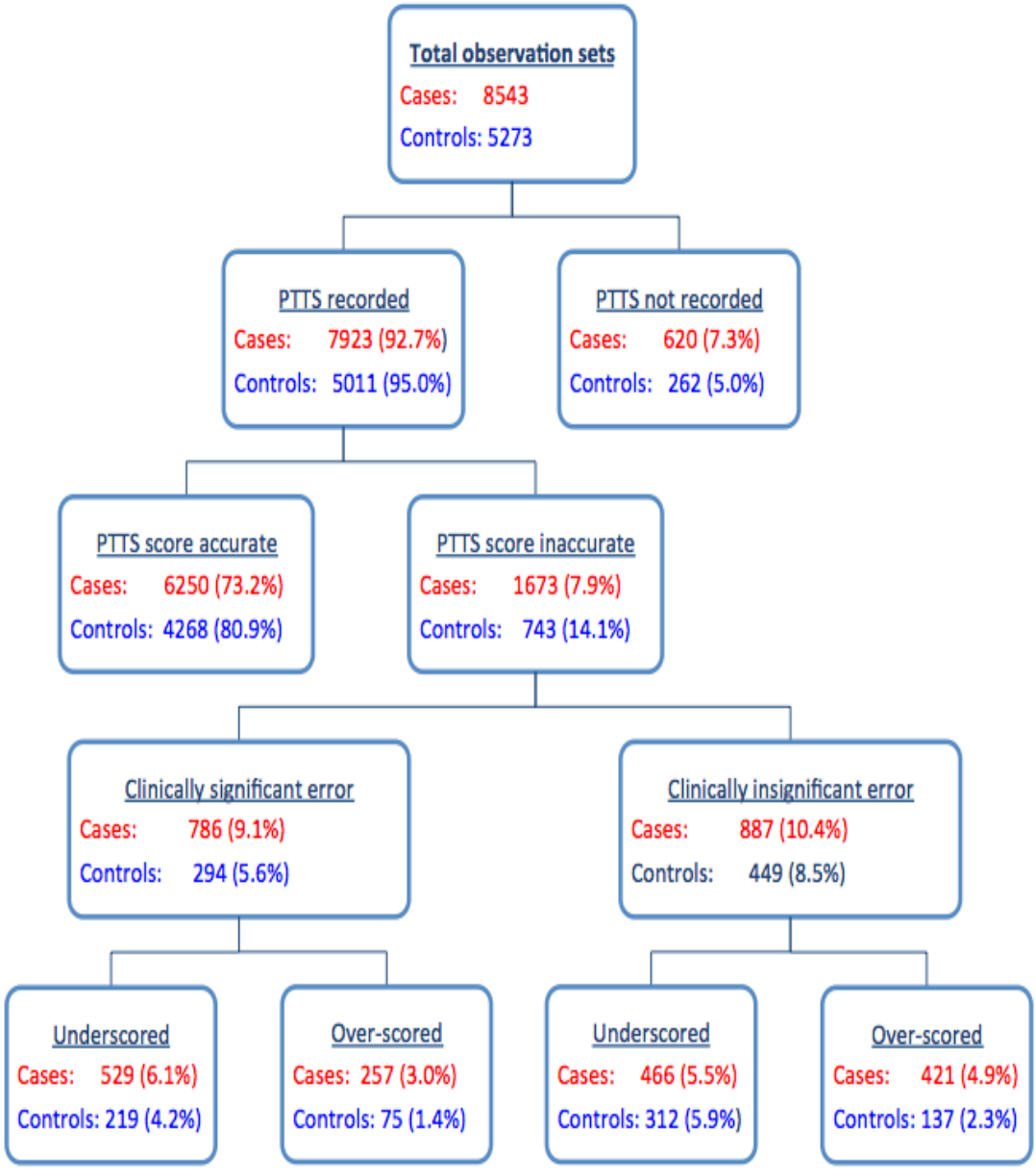
A summary of the direction of the scoring errors can be seen in Figure 4.7. Of the 2416 errors overall, 1673 occurred in case patients and 743 in controls. When errors were considered as a proportion of the total number of observation sets of cases (n=8543) and controls (n=5273), case patients also had a significantly higher proportion of erroneous scores (19.4% versus 14.1%, p <.0001).

4.3.3.7 Clinical implication of PTTS score inaccuracy

Overall 1080 (7.8%) PTTS errors would have indicated a different escalation pathway and, as such, were considered clinically significant. More observation sets were underscored (748, 5.4%), with just 332 (2.4%) classed as over-scored. A higher absolute number of clinical significant errors occurred in the observation sets of case patients (786) compared to controls (294) and this was significant when considered as a proportion of their total observation sets (9.2% vs 5.6%, p <.0001).

Erroneous PTTS scores (n=2416) were predominantly under- rather than over-scored (1526, 11.0% versus 890, 6.4%). The tendency to under rather than over-score was seen in PTTS values that were both clinically significant and clinically insignificant. There were statistically significant differences between cases and controls for errors that were clinically significant (p= .027) and clinically insignificant (p <.01) (Figure 4.7).

Figure 4.7 Direction and potential impact of inaccurate scores



Key: Values represent the number of observation sets within each category for cases (red) and controls (blue).

Percentages are presented separately to allow comparison between the two groups

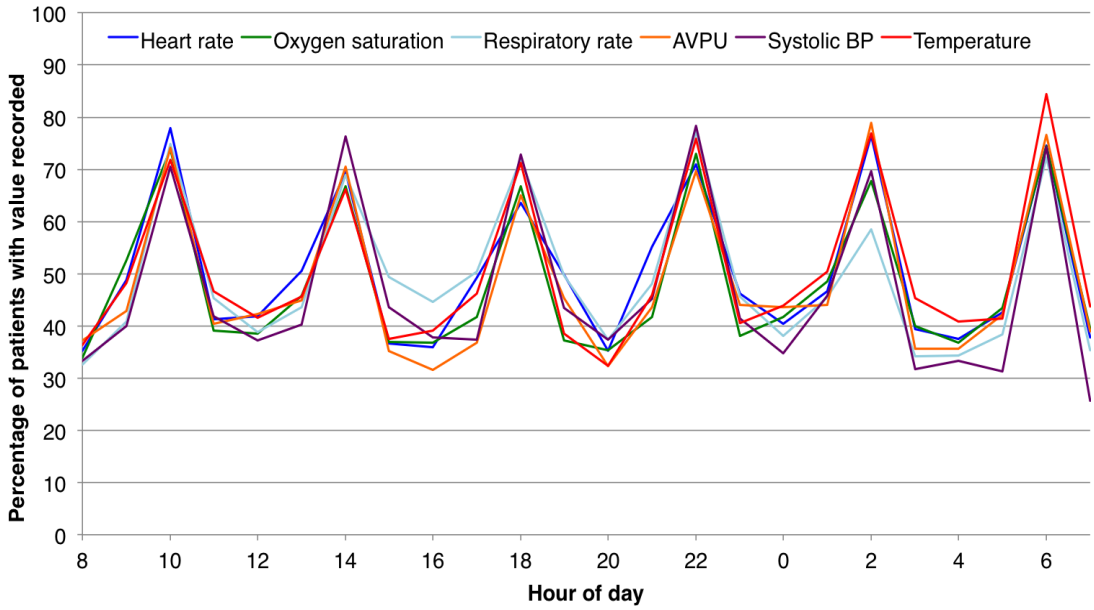
4.3.4 PTTS monitoring for individual patients

To evaluate the efficiency of PTTS monitoring for individual patients, the frequency, completeness and accuracy of PTTS for both cases and controls were assessed. Values were calculated as a percentage of the total number of patients who were available for PTTS assessment.

4.3.4.1 Observation recording by hour of day

Although the pattern of vital sign parameter recording varied throughout the day, there were peaks in the frequency of recording at 4-hourly periods (Figure 4.8). A regular pattern appeared, which corresponded with the traditional pattern of vital sign recording at 2, six and 10 o'clock.

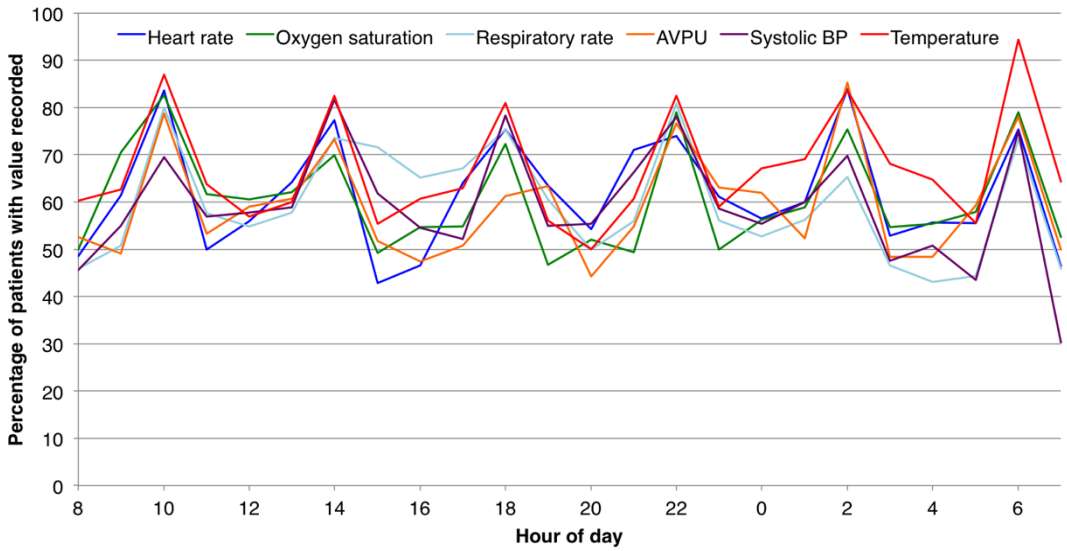
Figure 4.8 Proportion of patients with a vital sign parameter recorded for each hour of the day



Values are a percentage of the total number of patients who were available for vital sign recording within that hour of the day

However comparison of the pattern of recording in case and control patients reveals differences in their frequency. Case patients had more frequent recordings of vital sign parameters overall. There were more frequent recording of values in-between the 4-hourly observation sets (Figure 4.9), with around half of patients having a value recorded in any one hour of the day.

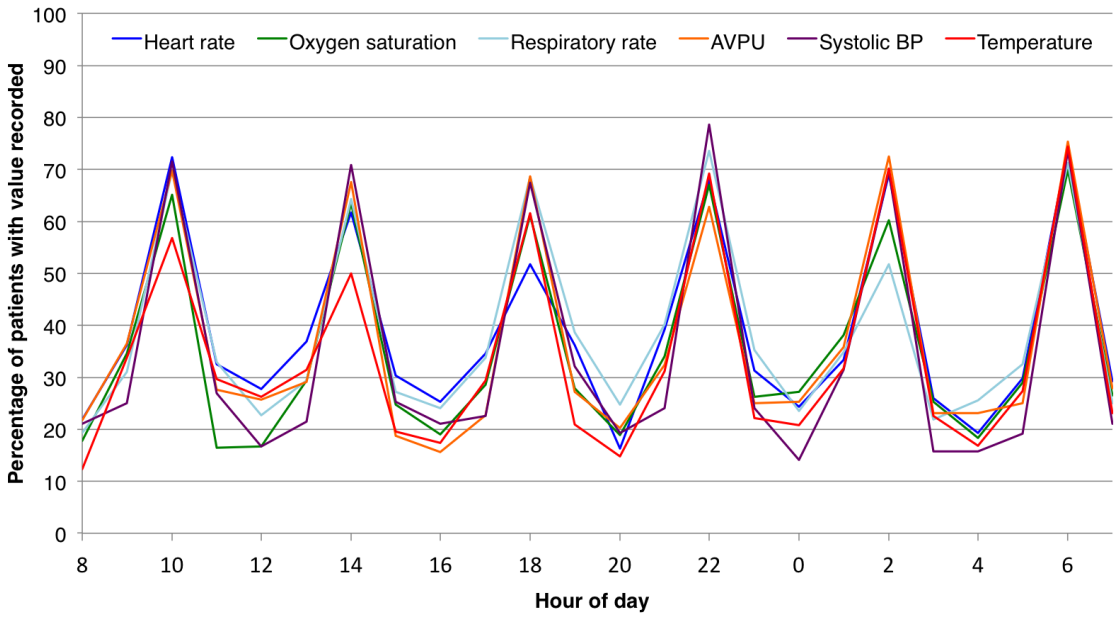
Figure 4.9 Proportion of case patients with a vital sign parameter recording by hour of the day



Values are a percentage of the total number of case patients who were available for vital sign recording within that hour of the day

By contrast, control patients maintained a pattern of four-hourly observation recording, with far fewer patients having values recorded between these times (Figure 4.10). Around 70% of patients had a vital sign recorded at four-hour periods. This fell to below 30% for hours outside of two, six and 10 o'clock.

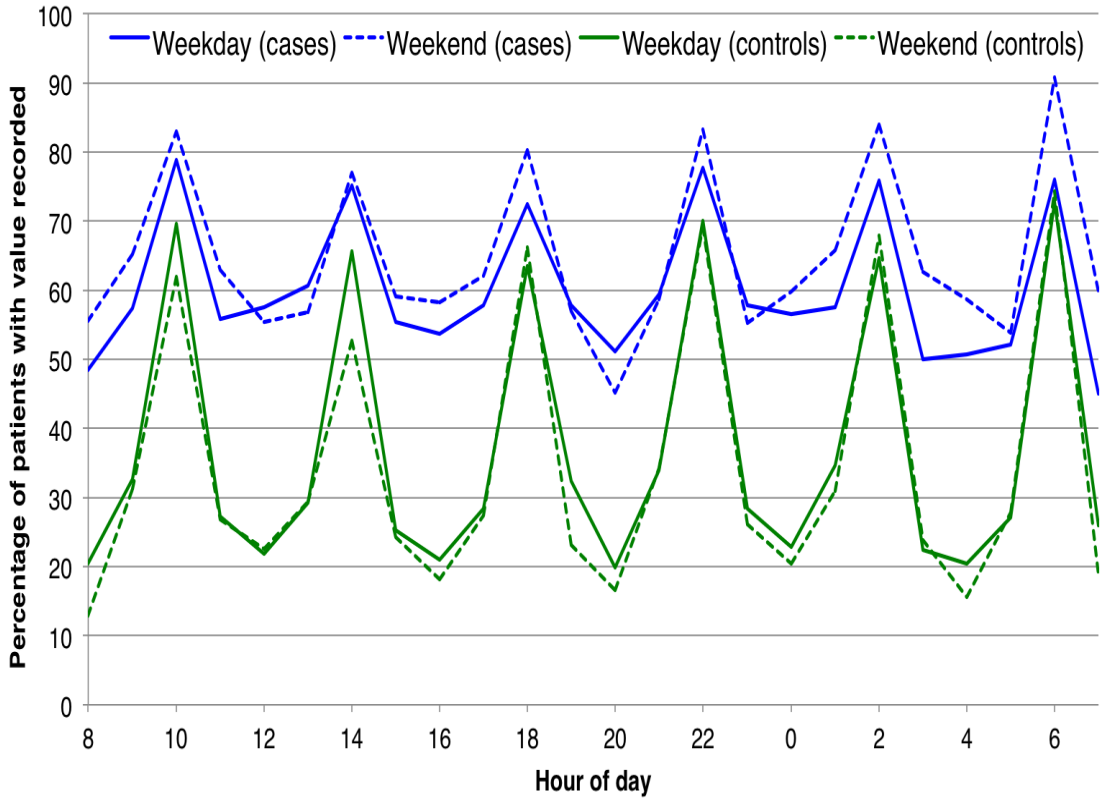
Figure 4.10 Proportion of control patients with a vital sign parameter recording by hour of the day



Values are a percentage of the total number of control patients who were available for vital sign recording within that hour of the day

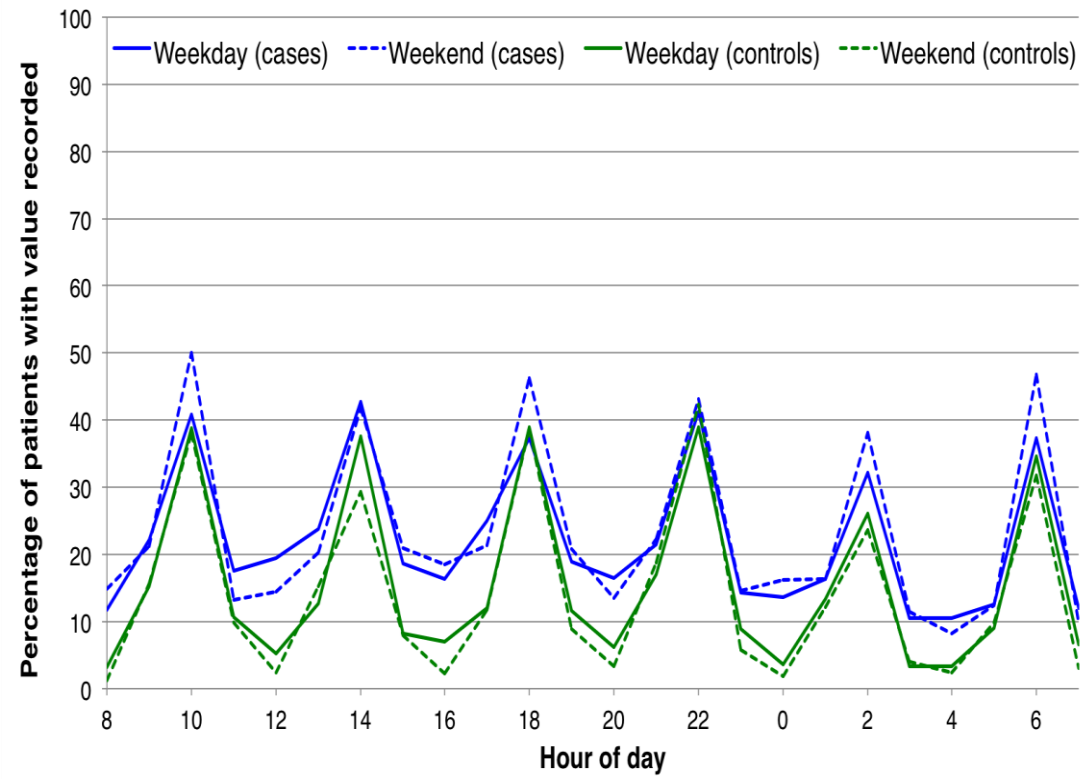
The pattern of vital sign parameter recording on weekdays and at the weekend was examined for all observation sets (Figure 4.11) and only those observation sets that were complete (Figure 4.11). Whilst patterns were similar for complete observation sets of case and control patients, there was a marked difference in the pattern of when observation sets were assessed.

Figure 4.11 <u>All</u> observation sets of cases and controls: weekends versus weekdays



Values are a percentage of the total number of case and control patients who were available for vital sign recording within that hour of the day

Figure 4.12 Complete observation sets of cases and controls: weekends versus weekdays

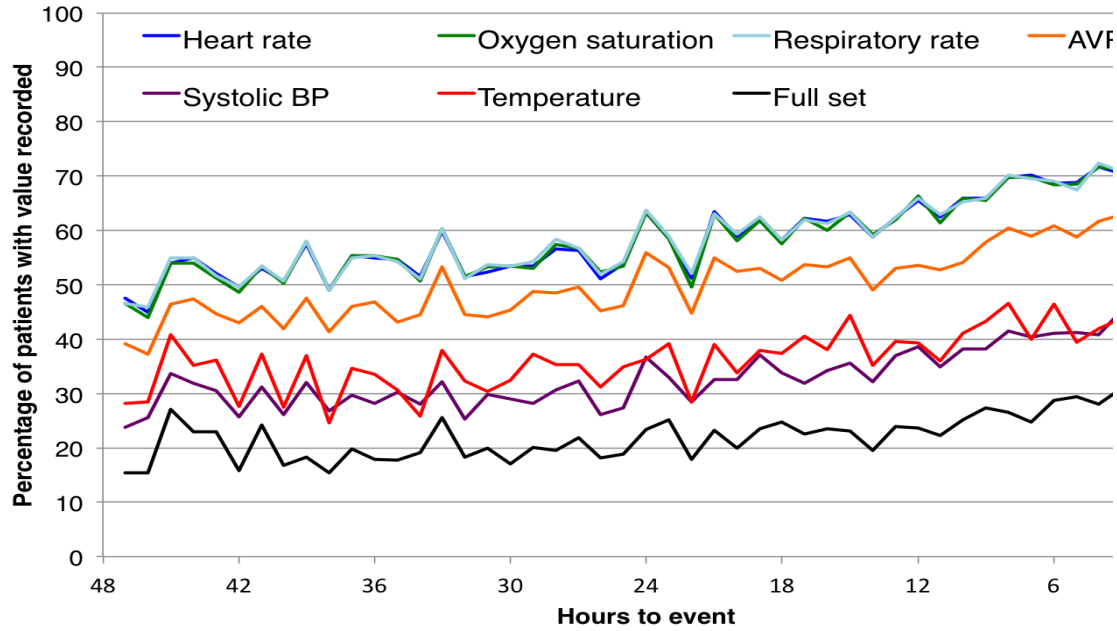


Values are a percentage of the total number of patients who were available for vital sign recording within that hour of the day

4.3.5 Frequency of vital sign parameter recording in the hours before the critical deterioration event

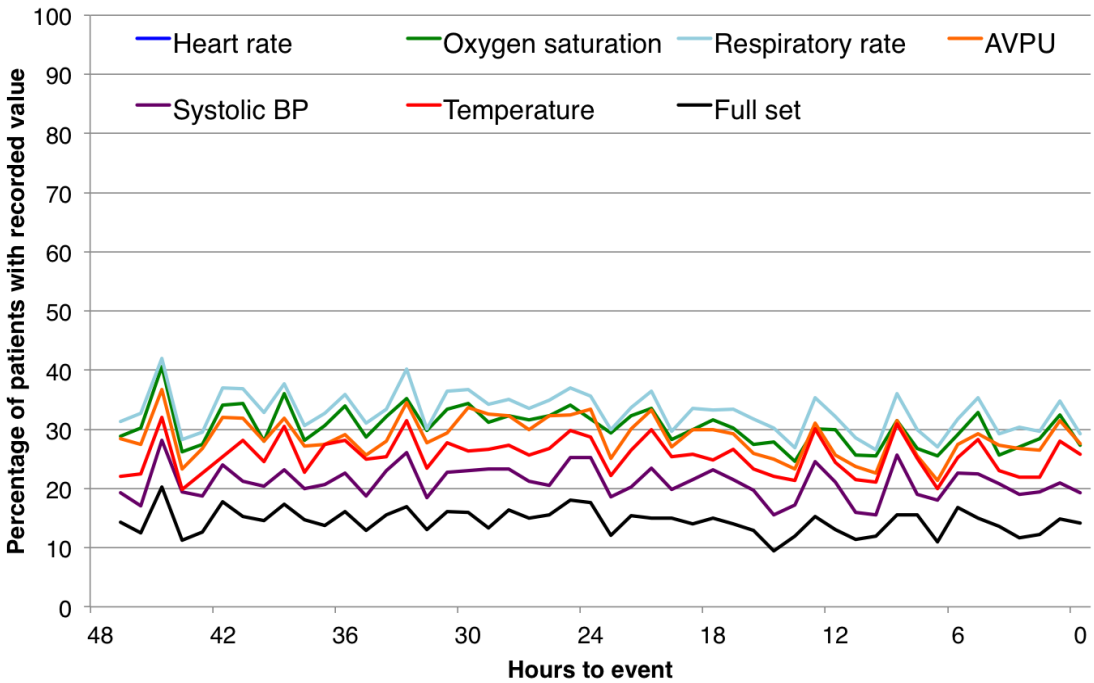
Presence of each of the six vital sign parameters in the 48-hours before the critical deterioration event was plotted against the time to the event for cases (Figure 4.13) and the matching 48-hours for controls (Figure 4.14).

Figure 4.13 Recording of component vital signs in case patients in the hours before the critical deterioration event



Values are a percentage of the total number of case patients who were available for vital sign recording within that hour

Figure 4.14 Recording of component vital sign in control patients in the corresponding hours to time zero (critical deterioration event in cases)

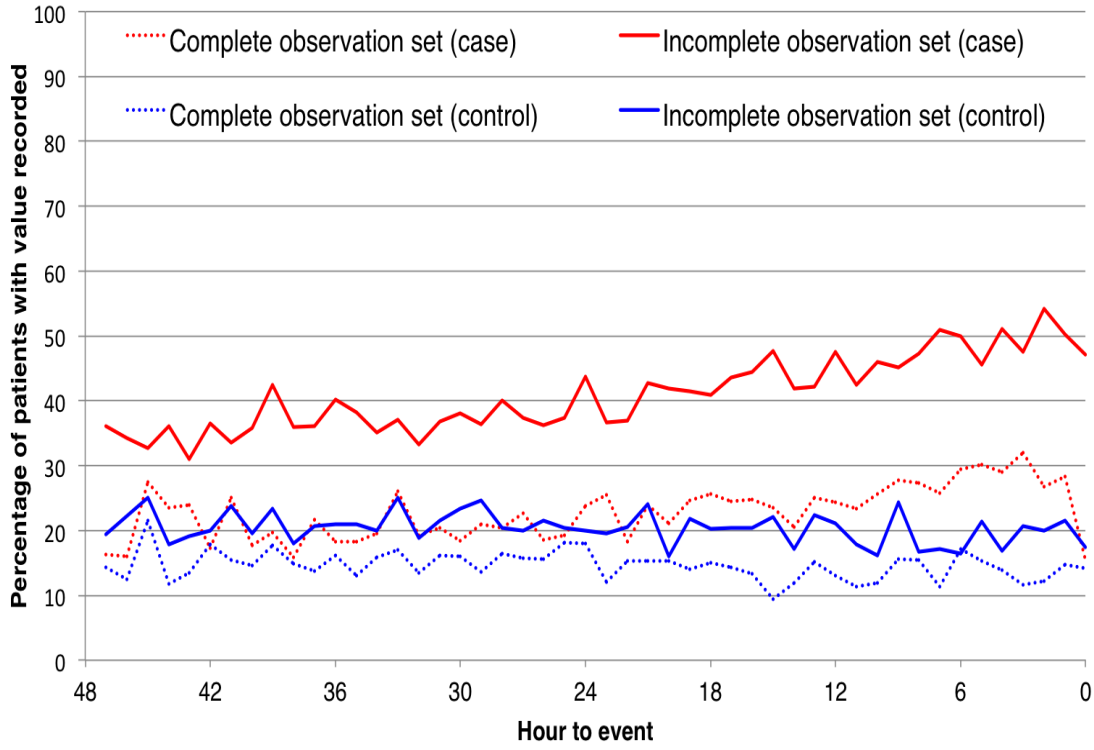


Values are a percentage of the total number of patients who were available for vital sign recording within that hour

Frequency of recording of heart rate, oxygen saturation and respiratory rate were similar in both cases and controls, whilst AVPU, temperature and systolic blood pressure were recorded less frequently. As expected, the frequency of monitoring in control patients stayed fairly constant, with vital sign frequency of between 15-42% for individual parameters. Case patients showed increased levels of monitoring from 48 hours up until three hours before the event. At three hours before the event levels of monitoring dramatically fell, returning to levels close to those at the 48-hour mark. This pattern was seen across all parameters.

The frequency of complete and incomplete observations in the hours before the event demonstrated similar patterns (Figure 4.15), with an escalation in the number of complete and incomplete observation sets in case patients, with controls maintaining a 'steady state' of recording.

Figure 4.15 Complete and incomplete observation sets of cases and controls in the hours before the event



Values are a percentage of the total number of cases and controls who were available for vital sign recording within that hour

4.3.6 Compliance to PTTS monitoring protocol

4.3.6.1 Recording of component vital sign parameters

The protocol required one recording per 12-hour shift of heart and respiratory rate, oxygen saturation, consciousness and temperature, with a single recording of blood pressure once in every 24 hours.

Compliance to the monitoring schedule for each of the component PTTS parameters is shown in Table 4.3. In case patients, compliance was greater than 95% for all vital sign parameters for both the whole study period and the final 12-hours. For controls, aside from systolic blood pressure, compliance for all parameters across the whole study period fell just below 95%, but rose above this threshold in the final 12-hours. All patients achieved greater than 95% compliance for recording of systolic blood pressure throughout the 48-hour study period. There was no statistical difference in compliance between cases and controls in either time period.

Table 4.3 Cases and controls achieving compliance to vital sign parameter monitoring protocol over 48-hour study period and within the last 12 hours before the critical deterioration event

Vital sign parameter	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p value	Cases (n=297)	Controls (n=311)	p value
Heart rate	288 (97.0%)	295 (94.9%)	.190[a]	291 (98.0%)	306 (98.4%)	.699[a]
Oxygen saturation	288 (97.0%)	295 (94.9%)	.190[a]	291 (98.0%)	306 (98.4%)	.699[a]
Respiratory rate	288 (97.0%)	295 (94.9%)	.190[a]	291 (98.0%)	306 (98.4%)	.699[a]
Consciousness (AVPU)	288 (97.0%)	295 (94.9%)	.190[a]	291 (98.0%)	306 (98.4%)	.699[a]
Systolic Blood pressure*	288 (97.0%)	306 (98.4%)	.242[a]	291 (98.0%)	308 (99.0%)	.330[a]

Vital sign parameter	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p value	Cases (n=297)	Controls (n=311)	p value
Temperature	288 (97.0%)	295 (94.9%)	.190[a]	291 (98.0%)	306 (98.4%)	.699[a]

Compliance was regarded as documentation on the PTTS chart of at least one vital sign parameter value in every 12-hour period, with the exception of systolic blood pressure, which was required to be recorded once in every 24-hours.

Patients who were unavailable for PTTS assessment for the entire 12-hour period were considered compliant for that period.

p values represent the difference between compliance for cases and controls for that time frame.

Key: [a]Pearson's Chi squared values

4.3.6.2 Recording of PTTS value

The standards achieved for monitoring of the PTTS score can be seen in Table 4.4. The majority of patients had at least one PTTS score recorded in each 12-hour period, although neither cases nor controls achieved greater than 95% compliance when assessed across the 48-hours. Compliance for the final 12-hour study period achieved high-level compliance. There were no differences between cases and controls in either time period.

Accuracy of PTTS recording was significantly higher in control patients when assessed over the 48-hour study period. No differences were seen in the final 12-hours, although compliance was greater than 90% for both groups.

A greater proportion of case patients had at least one PTTS calculated from a full set of vital sign parameters for each 12-hour period within the study (64.0% vs 52.4%, p =.004). This difference was maintained in the final 12-hours before the critical deterioration event (81.5% vs 72.7%, p =.010).

Table 4.4 Cases and controls achieving compliance to individual elements of the PTTS score protocol for the 48-hour study period and the final 12-hours of data collection

PTTS recording	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p values	Cases (n=297)	Controls (n=311)	p values
PTTS score recorded	288 (97.0)	295 (94.9%)	.417[a]	291 (98.0%)	306 (98.4%)	.699[a]
PTTS score accurately calculated from the available component parameters	215 (72.4%)	262 (84.2%)	<.001	281 (94.6%)	287 (92.3%)	.247
PTTS calculated from a complete observation set	190 (64.0%)	163 (52.4%)	.004	242 (81.5%)	226 (72.7%)	.010
PTTS accurately calculated from a complete observation set	139 (46.8%)	141 (45.3%)	.718	221 (74.4%)	202 (65.0%)	.011

Compliance was regarded as documentation of at least one PTTS value meeting the specified standard in every 12-hour period.

Patients who were unavailable for PTTS assessment for the entire 12-hour period were considered compliant for that period.

p values represent the difference between compliance for cases and controls for that time frame (Pearson's Chi squared values)

The standard considered to be fully adherent to the escalation protocol is highlighted in green

The requirement to have an accurate PTTS score calculated from a full set of vital sign parameters at least once in every 12-hours was met in less than half of patients for the 48-hour study period. Case patients had increased compliance in the 12-hours before the critical deterioration event and this was significantly better than controls (74.4% vs 65.0%, p =.011).

4.3.6.3 Presence of a monitoring plan

Compliance to documenting a plan for monitoring the vital sign parameters on the PTTS chart was significantly better in control patients for both time periods (p <.001). However overall compliance was poor for all patients, as shown in Table 4.5.

Table 4.5 Compliance to documenting the monitoring plan over the 48-hour study period and in the final 12-hours of data collection

Protocol	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p values	Cases (n=297)	Controls (n=311)	p values
Monitoring plan documented	38 (12.8%)	75 (24.1%)	<.001	54 (18.2%)	90 (28.9%)	<.001

Compliance was regarded as documentation on the PTTS chart of a monitoring plan at least once in every 12-hour period.

Patients who were unavailable for PTTS assessment for the entire 12-hour period were considered compliant for that period.

p values represent the difference between compliance for cases and controls for that time frame (Pearson's Chi squared)

4.3.6.4 Overall compliance to PTTS monitoring standards

Overall compliance to the PTTS monitoring standard was poor for both cases and controls (Table 4.6). Less than 5% of case patients achieved the required standard for the 48-hour study period, although compliance increased to 12.5% in the 12-hours before the critical deterioration event. Although better levels of compliance were seen in control patients, the standard was still only met for 10.0% of this group for the 48-hour study period. There was no significant difference in compliance between cases and controls in the final 12-hours.

Table 4.6 Overall compliance to PTTS monitoring standards

	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p value	Cases (n=297)	Controls (n=311)	p value
Compliant	11 (3.7%)	31 (10.0%)	.002	37 (12.5%)	54 (17.4%)	.090
Non-compliant	286 (96.3%)	280 (90.0%)		260 (87.5%)	257 (82.6%)	

To be considered compliant, a PTTS value - accurately calculated from all 6 vital sign parameters - and a monitoring plan had to be recorded at least once in every 12-hour period. Patients who were unavailable for PTTS assessment for the entire 12-hour period were considered compliant for that period.

p values represent the difference between compliance for cases and controls for that time frame (Pearson's Chi squared)

4.3.7 Compliance to the PTTS escalation protocol

Compliance to the escalation protocol was assessed for all patients with a low (PTTS score of two), medium (PTTS score of three and four) and high PTTS (PTTS score of five and above).

4.3.7.1 Compliance for patients considered to be at low risk

A CEWS score of two was considered to represent a low risk of deterioration and the escalation protocol indicated that a full observation set with a PTTS value should be taken within 30 minutes. Compliance to the escalation protocol within one, two and 12 hours is shown in Table 4.7.

There was no statistical difference in compliance between cases and control for repeat recording of the PTTS within one hour when examined across the 48 hour study period or during the final 12-hours of data collection. However significantly more case patients had a PTTS value recorded within two hours when assessed across the complete 48-hour data collection period and during the final 12-hours before the critical deterioration event. Not all patients with a PTTS score of two had

a repeat recording within 12-hours. There was no difference seen between compliance in case patients versus controls.

Table 4.7 Compliance to escalation protocol for the first recorded PTTS value of two in the 48-hour study period and final 12 hours of data collection

Time achieved within	Escalation action	48-hour study period			Final 12-hours		
		Cases (n=221)	Controls (n=134)	p value	Cases (n=154)	Controls (n=45)	p value
1 hour	Repeat PTTS	41 (18.6%)	15 (11.2%)	.065[a]	26 (16.9%)	4 (8.9%)	0.239[b]
2 hours	Repeat PTTS	71 (32.1%)	22 (16.4%)	.001[a]	47 (30.5%)	5 (11.1%)	0.009[a]
12 hours	Repeat PTTS	168 (76.0%)	94 (70.1%)	0.222[a]	104 (67.5%)	22 (48.9%)	0.023[a]

Compliance was assessed for the first documented PTTS value of two within the 48-hour study period and the final 12-hours of data collection.

Repeat PTTS recording had to contain all 6 vital sign parameters and be accurately calculated.

p values represent the difference between cases and controls for compliance to either PTTS recording or clinician review within the target time frame.

The standard considered to be fully adherent to the escalation protocol is highlighted in green.

Key: [a]Pearson's Chi squared values; [b]Fishers exact probability test

4.3.7.2 Compliance for patients considered to be at moderate risk

Scores of three or four were considered to represent a moderate risk of deterioration. Compliance to the escalation protocol was considered to have been achieved if there was a repeat PTTS recording within one hour and documentary evidence of clinical review by a doctor of at least registrar status within two hours. Compliance to the escalation requirements for a PTTS score three can be seen at Table 4.8 and for a score of four at Table 4.9.

When the 48 hour data collection period was examined, repeat recording of PTTS within the required target of one hour was statistically better in case patients than controls (21.6% vs 3.0%, $p<.001$). A significant difference was also seen during the final 12-hours of data collection. However overall compliance was poor for both groups and considerable numbers of cases and controls failed to have a repeat PTTS value recorded within 12 hours.

Compliance was even poorer for repeat recording of the PTTS after an elevated score of four had been documented. There was no difference between cases and controls for repeat PTTS recording within one, two and 12 hours. Levels of compliance were low for both groups. Again, considerable numbers of patients did not have a documented PTTS value recorded within 12-hours of their first documented PTTS score of four.

Table 4.8 Compliance to escalation protocol for the first recorded PTTS value of three in the 48-hour study period and final 12 hours of data collection

Time achieved within	Escalation action	48-hour study period			Final 12-hours		
		Cases (n=208)	Controls (n=66)	p value	Cases (n=157)	Controls (n=21)	p value
1 hour	Repeat PTTS	45 (21.6%)	2 (3.0%)	<.001[b]	38 (24.2%)	0 (0.0%)	.008[b]
	Clinician review	50 (24.0%)	1 (1.5%)	<.001[b]	51 (32.5%)	2 (9.5%)	.040[b]
2 hours	Repeat PTTS	74 (35.6%)	9 (13.6%)	<.001[b]	61 (38.9%)	1 (4.8%)	.001[b]
	Clinician review	88 (42.3%)	6 (9.1%)	<.001[a]	75 (47.8%)	2 (9.5%)	<.001[b]
12 hours	Repeat PTTS	155 (74.5%)	43 (65.2%)	.139[a]	107 (68.2%)	6 (28.6%)	<.001[a]
	Clinician review	159 (76.4%)	38 (57.6%)	.003[a]	131 (83.4%)	10 (47.6%)	<.001[a]

Compliance was assessed for the first documented PTTS value of three within the 48-hour study period and the final 12-hours of data collection.

Repeat PTTS recording had to contain all 6 vital sign parameters and be accurately calculated.

The reviewing clinician had to be a doctor of registrar status or an advanced nurse practitioner.

p values represent the difference between cases and controls for compliance to either PTTS recording or clinician review within the target time frame.

The standard considered to be fully adherent to the escalation protocol is highlighted in green.

Key: [a]Pearson's Chi squared values; [b]Fishers exact probability test

Table 4.9 Compliance to escalation protocol for the first recorded PTTS value of four in the 48-hour study period and final 12 hours of data collection

Time achieved within	Escalation action	48-hour study period			Final 12-hours		
		Cases (n=166)	Controls (n=32)	p value	Cases (n=127)	Controls (n=10)	p value
1 hour	Repeat PTTS	22 (13.3%)	2 (6.3%)	.380[b]	23 (18.1%)	2 (20.0%)	1.000[b]
	Clinician review	44 (26.5%)	1 (3.1%)	.002[b]	43 (3.9%)	0 (0.0%)	.030[b]
2 hours	Repeat PTTS	46 (27.7%)	9 (28.1%)	1.000[a]	51 (40.2%)	3 (30.0%)	.740[b]
	Clinician review	66 (39.8%)	6 (18.8%)	.024[a]	67 (52.8%)	1 (10.0%)	.017[b]
12 hours	Repeat PTTS	119 (71.7%)	21 (65.6%)	.488[a]	83 (65.4%)	5 (50.0%)	.330[b]
	Clinician review	133 (80.1%)	22 (68.8%)	.153[a]	108 (85.0%)	3 (30.0%)	<.001[b]

Compliance was assessed for the first documented PTTS value of four within the 48-hour study period and the final 12-hours of data collection.

Repeat PTTS recording had to contain all 6 vital sign parameters and be accurately calculated.

The reviewing clinician had to be a doctor of registrar status or an advanced nurse practitioner.

p values represent the difference between cases and controls for compliance to either PTTS recording or clinician review within the target time frame.

The standard considered to be fully adherent to the escalation protocol is highlighted in green.

Key: [a]Pearson's Chi squared values; [b]Fishers exact probability test

Escalation to a senior clinician within two hours demonstrated slightly better compliance for case patients. A significantly greater proportion of case patients had documentary evidence of a review across all time periods when compared to controls, but the overall compliance for both groups was poor. Only 37.7% of case patients and less than 15% of controls achieved the required standard of two hours.

4.3.7.3 Compliance for patients considered to be at high risk

Scores of five and above were considered to indicate a patient at high risk of deterioration. The protocol indicated that the nurse should repeat the PTTS recording within one hour. A score of five and above also required escalation to a senior doctor together with activation of the intensive care outreach team. These should be completed within two hours. Compliance to a PTTS score of five and above is summarised in Table 4.10.

Table 4.10 Compliance to escalation protocol for the first recorded PTTS value of five or more in the 48-hour study period and final 12 hours of data collection

Time achieved within	Escalation action	48-hour study period			Final 12-hours		
		Cases (n=154)	Controls (n=19)	p value	Cases (n=123)	Controls (n=7)	p value
1 hour	Repeat PTTS	38 (24.7%)	2 (10.5%)	.250[b]	32 (26.0%)	0 (0.0%)	.193[b]
	Clinician review	64 (41.6%)	3 (15.8%)	.044[b]	50 (40.7%)	2 (28.6%)	.702[b]
	Outreach review	29 (18.8%)	1 (5.3%)	.203[b]	28 (22.8%)	1 (14.3%)	1.0[b]

Time achieved within	Escalation action	48-hour study period			Final 12-hours		
		Cases (n=154)	Controls (n=19)	p value	Cases (n=123)	Controls (n=7)	p value
2 hours	Repeat PTTS	62 (40.3%)	5 (26.3%)	.238[b]	51 (41.5%)	0 (0.0%)	.042[b]
	Clinician review	74 (48.1%)	3 (15.8%)	.007[b]	72 (58.5%)	2 (28.6%)	.140[b]
	Outreach review	39 (25.3%)	1 (5.3%)	.079[b]	50 (40.7%)	1 (14.3%)	.245[b]
12 hours	Repeat PTTS	110 (71.4%)	15 (78.9%)	.488[a]	79 (64.2%)	2 (28.6%)	.103[b]
	Clinician review	125 (81.2%)	13 (68.4%)	.192[a]	105 (85.4%)	2 (28.6%)	.002[b]
	Outreach review	80 (51.9%)	2 (10.5%)	<.001[b]	89 (72.4%)	2 (28.6%)	.002[b]

Compliance was assessed following the first documented PTTS value of five or more within the 48-hour study period and the final 12-hours of data collection.

Repeat PTTS recording had to contain all 6 vital sign parameters and be accurately calculated.

The reviewing clinician had to be a doctor of registrar status or an advanced nurse practitioner.

p values represent the difference between cases and controls for compliance to either PTTS recording or clinician review within the specified time frame.

The standard considered to be fully adherent to the escalation protocol is highlighted in green.

Key: [a]Pearson's Chi squared values; [b]Fishers exact probability test

Repeat recording within the required standard of one hour of a PTTS score at or above five had low levels of compliance. There was no significant change in the rate of compliance for case patients in the final 12-hours before the critical deterioration event (p =.07) and less than half had the PTTS score repeated within two hours.

Although the number of control patients with a PTTS score of five or more was low, there was also poor adherence to the requirement for repeat PTTS recording.

Across the 48-hour study period less than half of case patients had documentary evidence of a review by a senior clinician with 2-hours of the first recorded PTTS of five or more. A significantly lower proportion of control patients achieved this standard (control 15.8% vs case 48.1%, p =.007). Activation of the intensive care outreach team demonstrated similar differences in compliance. Whilst 25.3% of case patients had evidence of an outreach review within two hours, only one of the nineteen controls patients (5.3%) achieved this target. However this difference was not statistically significant.

During the final 12-hours of data collection there was no significant improvement in compliance for case patients for repeat PTTS recording within one hour (24.7% to 26.0%, p =.07) and senior clinician review (48.1% to 58.5%, p =.08) within two hours. However outreach reviews within two hours did show a significant increase in compliance, from 25.3% to 40.7% (p =.007). There was low compliance to the escalation protocol for control patients during the final 12-hour data period. No patients had their PTTS score repeated within the hour. Only two of the seven patients received a senior clinician review and only one had evidence of a critical care outreach review.

4.3.7.4 Overall compliance to the escalation protocol

Overall compliance to the escalation protocol was poor. Compliance was assessed from the first recorded PTTS value of two, three and five or greater. Although 168 control patients were compliant with the required standard, only 164 (of 311) achieved a score which would require escalation. By contrast only 41 (of 297) case patients had a score below two, which would not require escalation.

Table 4.11 Overall compliance to escalation protocol over the 48-hour study period and final 12 hours of data collection

	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p value	Cases (n=297)	Controls (n=311)	p value
Compliant to escalation protocol	44 (14.8%)	168 (54.0%)	<.001[a]	75 (25.3%)	252 (81.0%)	<.001[a]
Non-compliant to escalation protocol	253 (85.2%)	143 (46.0%)		222 (74.7%)	59 (19.0%)	

p values represent comparison of compliance and non-compliance for cases and controls

Key: [a]Pearson's Chi squared values; [b]Fishers exact probability test

4.3.8 Overall compliance to the protocol.

Overall, compliance to the escalation protocol was very poor. When assessed across the 48-hour study period no case patient was compliant with the required standard for monitoring and escalation and only 6.4% of controls patients achieved the standard required. The final 12-hours before the critical deterioration event saw a small improvement in compliance for both cases and controls but levels still fell far below the standard required.

Table 4.12 Overall compliance to monitoring and escalation protocol over the 48-hour study period and final 12 hours of data collection

	48-hour study period			Final 12-hours		
	Cases (n=297)	Controls (n=311)	p value	Cases (n=297)	Controls (n=311)	p value
Compliant to monitoring and escalation protocol	0 (0.0%)	20 (6.4%)	<.001[b]	6 (2.0%)	45 (14.5%)	<.001[a]
Non-compliant to monitoring and escalation protocol	297 (100.0%)	291 (93.6%)		291 (98.0%)	266 (85.5%)	

Overall compliance required adherence to both the monitoring (Table 4.6) and escalation protocol (Table 4.11).

p values represent comparison of compliance ad non-compliance for cases and controls

Key: [a]Pearson's Chi squared values; [b]Fishers exact probability test.

4.4 Discussion

In this chapter the frequency and completeness of the component vital sign parameter recording of an established PTTS have been examined. The accuracy of PTTS scoring and adherence to an established protocol for escalation have also been assessed. These links to the 'recognising deterioration' component of the safe system framework (Figure 1.5 and Table 1.5).[33] Results clearly indicate that PTTS are not used optimally, with frequent errors and omissions in both the monitoring and escalation process.

Heart rate, oxygen saturation and respiratory rate were found to be recorded more frequently than other component vital sign parameters. Systolic blood pressure, temperature and AVPU had fewer recordings. This is similar to findings from other paediatric studies.[59,67,117]

It is unclear what influences the decision to include or omit a vital sign parameter from an observation set. The consistency between this study and other paediatric studies would suggest that inclusion or omission is an active choice rather than a random act of chance. Paediatric nurses may place greater emphasis on recording heart rate, oxygen saturation and respiratory rate as they are aware that the majority

of paediatric cardiorespiratory arrests follow decompensated respiratory or circulatory failure. This is supported by the findings from a small survey of paediatric nursing and medical staff in which respiratory rate was identified as the most important indicator of deterioration, followed by heart rate, conscious level, oxygen saturation and blood pressure.[67]

To function effectively PTTS scores need to be recorded accurately and from complete observation sets. The evidence from this study indicates that PTTS scores are often sub-optimal. A large proportion are based on incomplete observation sets where one or more parameters are missing. Failing to record a full observation set could result in a total PTTS score which is lower than one derived from a complete observation set. This is significant as it will result in a 'missed opportunity' to identify deterioration.[208]

Inaccuracy in total PTTS scoring was also common, with 23.9% of observation sets incorrectly calculated from the available vital sign parameters. Analysis of the reason for scoring errors indicated that an incorrectly allocated sub-score for one or more vital sign parameters was the most frequent cause. This was despite clear guidance that the lower score should always be used if the vital sign reading sat on the border between two differing scores. This should have resulted in a greater risk of over-scoring errors, were the higher and not the lower sub-score erroneously selected. However under-scoring errors dominated, potentially exposing the patient to a missed opportunity to identify and address clinical deterioration. Few studies have systematically examined scoring errors in children, but the preponderance of under-scoring is in keeping with studies of hospitalised adults.[49,54,90] The reasons for this are unclear but researchers have suggested that bedside staff may 'manipulate' the score to support their clinical impression of the patient.[49]

A significant proportion of total PTTS values were not documented. If the PTTS value was not calculated it would be unknown to the nurse and therefore could not be acted upon. This would represent a missed opportunity to act on deterioration. However the nurse may have calculated the value but failed to document it. This would represent a missed opportunity to communicate deterioration to the multi-disciplinary team. These omissions undermine the effectiveness of the system and do not facilitate ongoing monitoring and effective communication of the patient's condition.

Analysis of the time of day that vital sign parameters are recorded suggests that nurses working with children and young people take observations at regular times, namely 10, two and six o'clock. Patients who went on to suffer a critical deterioration event had a greater number of observation sets recorded outside of these times, although the predominance of the four-hourly recording pattern could still be seen (Figure 4.9). This contrasts with the findings of an adult study which identified two large peaks in vital sign recording at 6am and 10pm.[93]

Analysis of the number of vital sign parameter recordings in the hours before the critical deterioration event revealed a steady increase in the number of recordings for case patients (Figure 4.13) whilst controls (who did not suffer a critical deterioration event) maintained a steady rate of recording (Figure 4.14). This indicates that nurses increased the frequency of vital sign recording, possibly because they were prompted to do so by the escalation protocol or because they detected other clinical signs which they interpreted as indicating a deterioration in the patient's condition. The highest recording rate was noted to be three hours before the event. However after this time there was a marked drop in the rate of recording across all vital sign parameters, with levels returning to those seen at baseline (48-hours before the event). The reasons for this are unclear. It may be that nurses have identified that the patient is 'at-risk' and are taking steps to intervene and these interventions prevent the recording of further PTTS values. Or, having identified that the patient was deteriorating, the nurse perceived that further recording of PTTS would not influence the management of the patient, and made an active decision to reduce or discontinue PTTS recording. An alternative view is that the decrease in the rate of PTTS recording fails to identify the patient's critical condition and the lack of appropriate intervention accelerates the physiological pathway towards the critical deterioration event.

Effective track and trigger systems promote adherence to a protocol. Significant and wide-ranging issues with compliance in both the monitoring and escalation of PTTS have been identified in this study. Compliance was assessed using an 'all or nothing' approach[207] which leads to lower reported levels than traditional measures, but provides a more sensitive indicator of the overall stability of the process.

Closer examination of the individual elements reveals the required standard of vital sign parameter recording was not achieved in just 3.0% of cases and 5.1% of controls. Compliance was consistent across all vital sign parameters apart from

systolic blood pressure, where levels were increased for controls. A study of compliance in adults recovering from major surgery identified 3.7% of patients who did not have at least one recording of blood pressure documented during the shift.[95] However compliance varied across differing vital sign parameters. Respiratory rate was the most poorly recorded, with documentation failure identified on 15.4% of occasions. Of greater concern are the findings from a paediatric study reporting adherence to a 12-hourly PTTS monitoring protocol, where only half of the required parameters were recorded, despite the research nurses' consistent requests for adherence to the protocol.[117] Temperature was the most frequently recorded and was present in 88.4% of observation sets whilst blood pressure was the least, at only 25.1%. Whilst oxygen saturation (76.7%), respiratory (79.7%) and heart rate (86.8%) recording were present in the majority of observation sets, levels of compliance fell below that seen in this study (Figure 4.1).

The vast majority of patients achieved the required standard of one documented PTTS value per 12-hour period. However a number of PTTS values were calculated from incomplete observation sets and had inaccuracies in the score calculation (Table 4.3). As a result less than half of patients had at least one recorded PTTS value that met the required standard for each 12-hour period.

Overall compliance to the PTTS monitoring standards was low. Only 6.9% of patients achieved the required standard across all elements for each 12-hour period. The greatest influence on compliance came from the lack of a documented monitoring plan on the PTTS chart: only 18.5% achieved the required standard. Within the 'all or nothing' assessment framework, failure to achieve the standard for any one component in any one 12-hour period results in a failure to achieve compliance overall. In effect, the component with the lowest reported value acts as a 'ceiling' to the overall compliance level. This explains why overall levels of compliance within this study appear at first to be far lower than other studies.

Compliance to the escalation protocol suffered from similar deficiencies. The protocol required elevated PTTS scores to be repeated in 30 minutes. For the purposes of this study compliance was considered to have been achieved if a documented PTTS value was noted within 60 minutes. This was to allow for prioritisation of competing patient-related demands such as toileting or administering analgesia.

Repeat recording of PTTS values rarely achieved the required standard (Table 4.7, Table 4.8 and Table 4.9), although compliance was marginally improved at higher PTTS scores (Table 4.10). Compliance was significantly better in case compared with control patients for scores at or above two and 3. The low number of control patients with a PTTS score of five and above resulted in differences which were not statistically significant.

A number of patients did not have a repeat PTTS value recorded within 12-hours of the initial elevated score. This represents a significant period of time where deterioration (or indeed improvement) in the patient's condition may go undetected. Compliance was only considered to have been achieved if the repeat PTTS value was scored accurately and calculated from a complete observation set. Many patients had repeat PTTS values which did not achieve this standard. The decision to record an incomplete observation set may have been influenced by the nurse's decision to 'check' only those vital sign parameters which were previously assessed as 'abnormal'. This fails to acknowledge that physiological abnormalities are rarely solitary in nature and that PTTS values derived from incomplete observation sets may under-represent the 'true' PTTS score. False reassurance of clinical stability and potentially delayed escalation may result.

Higher PTTS scores of three or more required escalation and review by a senior clinician, with scores of five also requiring input from the critical care outreach team. These elevated score indicate significant physiological derangement. Compliance was achieved if there was documentary evidence of escalation or review within two hours. Overall levels were low. Non-compliance could simply be a failure to document escalation calls or clinical reviews. However this raises concern, as important clinical information may have been lost, particularly around the interventions administered and the patient's subsequent response which might inform future treatment. More seriously, non-compliance may indicate a failure of the nurse to call for assistance or a failure of the relevant clinician to respond. These failures leave the patient vulnerable as delayed intervention in significant physiological derangement increases morbidity and mortality.[31,60,209]

There were significant failures in the escalation of patients who achieved a PTTS of five and above. Less than one third (32.0%) were reviewed by a clinician within the required two hours and a quarter (25.2%) had no evidence of any review within 12-hours. This raises concerns that significantly high PTTS scores were poorly

responded to or worse still ignored. When a PTTS value of five or above occurred in the final 12 hours before the critical deterioration event, no evidence could be found of a senior clinical review in 14.6% of cases and 73.4% of controls.

Overall compliance to the escalation protocol was poor. Only 15.8% of cases were compliant to the protocol for the 48-hour study period. Results appeared better for controls, where over half (54.0%) achieved compliance. However closer examination reveals that only 147 controls achieved a score which would require escalation. Of these, only four met the necessary standard. Of the 297 cases patients, 256 had PTTS scores of two or more. Just six met the required standard.

When compliance to both the monitoring and escalation protocol were combined, the results were disappointing. Across the 48-hour study period only 20 control patients met the required standard and no case patients were considered compliant. These standards were considered the minimum requirement for monitoring and escalation based on clear guidance that was shared with all nursing and medical staff on induction and through yearly updates.

The reasons for non-compliance are unclear. The failure to escalate has previously been perceived as an inadequacy in education around the signs of clinical deterioration and insufficient knowledge of the role of the intensive care outreach team.[210] However it is becoming apparent that the situation is far more complex, with multiple factors influencing whether a PTTS protocol is followed or not. Studies conducted with nurses caring for acutely ill adult patients have identified issues around the inexperience of both nurses[83,111,114] and doctors,[83,102,111] nursing workload,[111] issues of staff shortage (both medical and nursing),[113] interprofessional relationships and teamworking,[81,83,111] institutional hierarchy,[81,83,112,113] and staff inexperience.[111]

A qualitative paediatric study of the perceived benefits of a PTTS highlighted that staff perceive the PTTS as unhelpful in patients who were stable, those with abnormal baselines physiology and children with neurological deterioration.[79] This may offer an explanation of non-compliance in some, but not all, patients.

Clinicians may also regard protocol-based care as too rigid and unresponsive to the individual needs and desires of children and young people and their families. Others have reported that staff may ‘re-prioritise’ the escalation of an elevated track and trigger score dependent on multiple factors, such as the environment, the perceived

competence of the attending medical staff and the status of pending investigations.[210] The evidence to quantify and explain failures in the monitoring and escalation of PTTS compliance is currently very limited.

4.4.1 Limitations of the study

This was a case-controlled study conducted in a tertiary specialist children's hospital. As such, the population may not be representative of patients within specialist children's hospitals or paediatric services in other centres.

The findings are based on retrospective data collected through healthcare record review. There was no way to verify if failures in compliance were due to failures in care or failures in documentation. There was no attempt to explore whether the errors or admissions caused patient harm, nor to explain or justify why these events had occurred. This initial exploratory study merely sought to quantify and describe their occurrence in a population of 'sick' and 'stable' patients within a specialist children's hospital.

Compliance was based on 'all or nothing' measurement of the standard of care. The methodology is such that the selected standards should be clearly linked to an improvement in clinical outcomes, however current evidence is limited. The measures used in this study were chosen on the basis of national recommendations and professional consensus,[3,5,6,51] but there is a possibility that other measures may have been more appropriate. Greater standardisation of pragmatic measures to evaluate PTTS and other similar interventions would facilitate meaningful comparison and collaborative research.[168]

To facilitate analysis, escalation compliance was only assessed on the first recorded PTTS value at or above a score of two, three and five for each 12-hour time period. Analysis of repeated high PTTS values may have yielded different results.

4.5 Conclusion

This chapter has assessed the compliance to a monitoring and escalation protocol for an established PTTS in a specialist children's hospital. The findings have highlighted deficiencies in the documented recording and escalation of PTTS scores when assessed against an 'all or nothing' standard. As such, the use of PTTS is sub-optimal. This jeopardises the 'recognising deterioration' component of the 'safe

system' approach to managing deteriorating children in hospital[33] with a potentially negative effect on clinical outcomes.

The next chapter will explore how children and young people, their families and nursing staff perceive and use vital sign parameter and PTTS monitoring.

Chapter 5 Utility: the experiences of children and young people, their families and nursing staff of vital sign observation recording and use of a paediatric track and trigger system

5.1 Introduction

Vital sign observations and paediatric track and trigger system (PTTS) values are traditionally recorded and acted upon by the bedside nurse. As such, the interaction between nurses, children/young people and their families is pivotal to the early identification and prompt response to critical deterioration.[211-213] The safe system framework[33] has highlighted that greater involvement of children/young people and families is needed if these systems are to be effective.

The previous chapter presented the variability in recording of vital sign parameters and PTTS values. This chapter focuses on understanding the experiences of children, families and nurses of vital sign recording and use of a PTTS (Utility). This may offer insight into the reasons for variability in vital sign and PTTS recording, potentially highlighting factors that may be amenable to change. This could improve the reliability of PTTS and have a potentially positive impact on childhood morbidity and mortality.

5.1.1 Background

Paediatric nurses are expected to work in partnership with children and parents[214] but little is known about children's and families' perceptions and understanding of vital sign monitoring and PTTS. Effective use of PTTS systems requires regular and complete recording of component parameters and prompt escalation of elevated scores. It is unclear what role, if any, parents and children play in this process.

The systematic review reported in chapter two identified nine PTTS systems incorporating parental concern as a parameter. Despite this, no studies were identified which specifically explored the views of parents on PTTS that are used and activated exclusively by healthcare professionals. The recently published safe system framework seen at Figure 1.5 for children at risk of deterioration[33] places children and young people at the centre, surrounded by their parents and carers and then clinicians. The framework makes specific reference to the partnership between patients, families and clinicians, emphasising that this is an area which requires growth.

Some institutions have facilitated parents and family members to be able to activate specialist teams such as a rapid response team if they perceive their child is deteriorating. Condition H[123] (for help), for example, evolved following the death of a child in hospital whose deterioration was missed despite her mother expressing concerns to healthcare professionals.[215] Despite staff concerns that this service would be overburdened with calls from parents, the evidence indicates that numbers are small.[216,217] Breakdown in relationships between parents and professionals were cited as a frequent underlying reason for the call.[217] Further evidence of the role that parents can play comes from a recent paper on detection of deterioration in infants discharged home after congenital heart surgery. The behavioural changes noted by parents were reported as a potential indicator of deterioration.[218]

There is a small but growing body of research exploring the views of staff on vital sign monitoring and use of PTTS. A systematic review of vital signs in hospitalised adult patients noted a lack of evidence on optimal practice and suggested that vital sign measurement is based more on tradition and expert opinion than research.[219] Evidence on track and trigger system use is largely adult based, although studies on paediatric specific tools are now emerging.[79,83] Findings from qualitative studies suggest that clinicians identify benefits of a PTTS, such as providing junior staff with guidance on the expected vital sign values for children and facilitating an objective assessment of the child's condition, using criteria unrelated to their validity and reliability.[79,83,217] However no studies have been identified that specifically canvas the views of children and young people on vital sign monitoring or PTTS use.

5.2 Aim

The overarching aim of this study was to describe the experiences of hospitalised children/young people, their families and nurses of vital sign monitoring and use of a PTTS in a medical, surgical and short stay paediatric ward.

5.2.1 Principle research questions to be addressed

Three principle research questions were identified:

1. What are the experiences of hospitalised children/young people undergoing vital sign monitoring and their perceptions and understanding of PTTS in detecting critical deterioration?
2. What are the experiences of families of hospitalised children/young people undergoing vital sign monitoring and their perceptions and understanding of

PTTS in detecting critical deterioration?

3. What are the experiences of nurses undertaking vital sign monitoring of hospitalised children and young people and their perceptions and understanding of PTTS in detecting critical deterioration in these patients?

5.3 Methods

5.3.1 Study design and rationale

This was an exploratory study examining the experiences, perceptions and understandings of children/young people, families and nurses on PTTS. A qualitative approach was selected as being most appropriate for facilitating the production of rich data and allowing issues of importance to participants to emerge.[220]

It was recognised that differing data collection techniques would be needed for children, young people, parents and nursing staff. Research with younger children presents specific challenges, particularly with those who are hospitalised or have learning disabilities.[221,222] It is well documented that eliciting their thoughts and views may not be amenable to traditional qualitative techniques such as interviews.[221,223,224] The draw and write technique was selected because it has been used successfully in research with hospitalised children under 12-years of age.[225,226] It is an approach which allows children to contribute their perspective in a way that is most suited to their needs and preferences.[227] The technique facilitates children, particularly younger children, to become active participants in research by revealing their unique perspective on illness and healthcare as they see it.[228,229] Drawing is a familiar activity and is seen as pleasurable and non-threatening by children. It is often used by younger children to communicate their perception about the world.[221] Because children may know more than they are able to say, the drawings are used by the researcher as a springboard to facilitate discussion and engage children in verbal descriptions or writings describing the area in question.[221,228] As such, it has been seen as a useful research tool for eliciting the views of children of differing developmental ages who are suffering from acute and chronic diseases.[221,225,226,228,230]

Older children have more developed cognitive and verbal functioning and there are many examples of them having successfully participated in interviews in a hospital

setting.[221,223,231,232] An informal, conversational approach using semi-structured questions has been recognised as encouraging the young person to talk freely about their views, allowing them to raise issues which they feel are important.[221,233-235] In this study, it was important that young people felt their views were heard and respected, so they were encouraged to discuss both positive and negative aspects of vital sign monitoring. Facilitating this was key as they were being interviewed by a nurse whilst they were on the ward receiving treatment and could have felt unable to be honest.

Semi-structured interviews were also used to elicit the views of parents. This method was selected as the most appropriate way of collecting data in a single session, allowing the conversation to be structured around PTTS and vital signs but with the flexibility to explore factors that participants felt were important. Furthermore, individual interviews could be more easily scheduled to accommodate the needs of the child and family than other qualitative approaches such as focus groups.

Focus groups were selected to capture the views of nurses. Focus groups are particularly useful when participants have a shared goal or characteristic, in this case their role as a paediatric nurse.[236] This methodology was selected as it was considered that the interaction between participants was likely to enhance the richness of the data. Focus groups may also highlight similarities and differences between the participants in a way that individual interviews cannot. Participants may not only question each other, but offer explanations to the group,[237] which may be relevant when seeking to explore the inconsistencies in practice highlighted in chapter four. The methodology has been highlighted as particularly useful when little is known about the topic under investigation,[236] such as nurses perceptions of PTTS and vital sign monitoring and how they make decisions in clinical practice.[54,111,219] Focus groups also offered a pragmatic way of collecting data from groups of participants in a relatively short time frame. To minimise the burden on participants, data collection took place during working hours. Releasing staff from their clinical duties can sometimes be problematic and participants' attention may not be focused on the research if clinical workload is high. Focus groups were therefore conducted on existing training days when staff were rostered for non-clinical duties. This allowed data to be collected from a larger number of participants than could have been achieved with individual interviews.

Framework was chosen for analysis of the qualitative data.[238] Although framework analysis has been used to generate theories, it is more suitable for describing and interpreting what is happening in a particular setting.[239,240] Framework analysis allows for case-based and theme-based analysis, or a combination of the two.[240] This was felt to be useful as data was collected from 3 separate groups of individuals (children, parents and nurses) in three different environments (medical, surgical and short-stay ward). As such, theme and case-based analysis may yield differing benefits and enrich the interpretation of the data. Framework analysis has also been used to combine mixed methods data.[240] Framework analysis is reported as being more explicit in its approach, providing transparent results and conclusions that can be clearly linked back to the original data.[240] All of these factors makes it particularly suitable for use within this study.

5.3.2 Sampling strategy

Small sample sizes are acceptable in qualitative research. The richness of the data is considered to be more important than the absolute number of participants.[220,241] Small sample sizes also allow the data to be effectively managed.[220,241] In qualitative research large sample sizes can be considered to waste resources and subject participants to unnecessary involvement when they are unlikely to add any new data. [242]

A purposeful sampling approach was used for children and families with the aim of recruiting three to five parents and three to five children from each of three types of wards: medical, surgical and short stay. These wards were felt to have a mixed caseload with patients of differing ages, with acute and long-term conditions and differing levels of acuity. The sample was anticipated to be reasonably homogenous, so a large sample was not considered to be necessary.[242,243] However variation with regards to factors such as age of the child, gender, previous admission to intensive care and number of previous hospitalisation was desirable. To address this, a sampling matrix[242,243] was constructed, comprising these variables. Participants were purposely selected to fulfill those criteria across all three wards.

Nurse participants were also purposefully selected from a convenience sample of nurses attending staff training days. Focus groups were scheduled to take place on those days. Using a sampling matrix, the ward manager identified nurses of differing

gender, banding, age and years of nursing experience to maximise the diversity of the sample.

5.3.3 Inclusion and exclusion criteria

5.3.3.1 Children

Children/young people from four years up to 18 years of age were eligible to participate. Children younger than four years were excluded as they may have lacked the developmental capacity to participate fully in the study. Young people of 18 years and over were considered adults and therefore fell outside the scope of this study. Children/young people with an active 'Do Not Attempt Resuscitation' (DNAR) or End of Life care pathway were excluded, as PTTS or vital signs may not be actively monitored or escalated as a result.

5.3.3.2 Parents

Parents who were resident for at least one night during their child's stay were eligible to participate. Overnight stay was considered important so families could discuss the impact of vital sign monitoring and PTTS at night. Parents were excluded if their child had an active DNAR or End of Life care pathway for the reasons outlined above.

5.3.3.3 Nurses

Nurses of band 6 or below who worked on the three identified wards were included in the study. Nurses of band seven and above were excluded as these staff may not record vital sign observations and use the PTTS on a daily basis. No other exclusion criteria were applied.

5.3.4 Ethical issues

Approval was granted by the NHS research ethics committee and can be seen at Appendix 6

5.3.4.1 Recruitment

Child/young people and parent participants were identified and screened by a member of the direct care team. The direct care team were aware of the aims and demands of the research and provided information leaflets to those who expressed an interest in participating. These leaflets can be seen at Appendix 7. The team

were asked to make it clear to potential participants that their care would not be affected if they declined either to speak to the candidate or participate in the study.

Staff were allocated to the focus group by the ward manager. A brief overview of the study was provided at the beginning of the training day together with a request to participate. Staff were advised to speak to the ward manager if they did not wish to be approached by the candidate and given reassurance that they would be removed from the focus group with no further clarification required.

5.3.4.2 Informed consent

Children/young people and parents who expressed an interest in the research to the direct care team were approached by the candidate. The aims and requirements of the study were explained and they were provided with further copies of the information leaflet if required. If the child/young person and parent required time to consider the study, a further meeting was scheduled at a mutually convenient time. If the child/young person wished to participate, written informed consent was obtained from their parent (Appendix 8.1). Children and young people were also asked to give their assent and could sign a form if they chose to (Appendix 8.2). Written consent was also obtained from parents for their own participation. Parents and children/young people were provided with a copy of the assent/consent form to keep. Consent was seen as a continual process rather than a 'one-off' event and hence it was reviewed prior to and during the interviews and draw and write sessions.

At the beginning of the focus group, staff were asked if they wished to participate in the study. The candidate answered any questions that the participants raised. Those who agreed to participate were asked to sign a consent form (Appendix 8.4).

5.3.4.3 Anonymity and confidentiality

Each parent, child and young person and nurse was assigned a unique identification code. The names of the participants and all personal identifiable details were kept separately from the research data. All electronic data were maintained on a password protected Trust computer or Trust-supplied encrypted USB device in line with local hospital policy. Consent forms and drawings were stored in a locked cabinet. Files transferred via e-mail for transcription were encrypted.

Direct quotations from participants were pseudo-anonymised to protect participants from identification. Particular care was taken to ensure that children with rare conditions and/or their parents were not identifiable.

Participants were made aware that information disclosed during the interview or focus group would not be shared with members of the patient's direct care team or their managers. Participants were told that anonymised data would, however, be shared with the candidate's supervisory team as part of the research supervision process.

5.3.4.4 Maintaining privacy

Respect for the participants' privacy was maintained at all times. Children/young people and families were offered flexibility as to the location and scheduling of the interview and draw and write sessions. Two child participants and one parent chose for the interview to take place away from their bedside in the communal playroom area. All other participants chose their child's bedside.

Focus groups were held in a seminar room identified by the ward manager. A member of the candidate's supervisory team attended one session. All other sessions were restricted to the candidate and the participants.

5.3.5 Data collection procedures

An interview schedule for each group of participants was built around the research questions. For older children, parents and nurses the interview questions were designed to elicit participants' views of their understanding and experiences of PTTS use and vital sign monitoring. Questions for younger children focused only on vital sign monitoring as it was felt that the PTTS would be a complex concept for them to understand. Where appropriate, prompts were used to guide the interview. The interview schedules can be seen at Appendix 9

All interviews, focus groups and draw and write sessions were tape-recorded after the participants had provided consent/assent. Field noted were made after each interview and focus group. Tape recordings were transcribed verbatim by a professional transcription service used by the candidate's supervisory team.

5.3.5.1 Children and young people

The following equipment was taken to interviews with children and young people: paper, a selection of pens, pencils and crayons, tempadots, a small and large sized blood pressure cuff, an oxygen saturation probe and a PTTS chart. An example of the monitoring equipment taken to each interview can be seen at Figure 5.1.

Children up to eight years of age were given the choice of talking about their experiences or drawing a picture. Children who opted to draw a picture were provided with paper and a selection of pens, pencils and other colouring tools. They were asked to draw a picture and/or write their thoughts on what it felt like when they had their vital sign observations taken (Appendix 9.1). The vital sign monitoring equipment was placed on the table and the child was encouraged to 'play' with the equipment if they wished. Whilst the child was drawing, the candidate asked the child questions about the content for the picture or why they had chosen a certain type of pen or colour. The dialogue was conversational in nature and the candidate allowed the child to discuss anything that they brought up during the session. The vital sign monitoring equipment was used as a prompt if the child no longer wanted to draw or was not sure what the candidate was asking. At the end of the session, pictures were scanned and then returned to the child.

Figure 5.1 An example of the vital sign monitoring equipment provided during interviews

Interviews with younger children who chose not to draw pictures were adapted to meet the child's preferences. Children were shown monitoring equipment, generally one piece at a time. They were asked questions about what each piece of equipment did and how it felt when it was used. If they wanted to 'act out' taking the candidate's vital sign observations, this was encouraged. Questions and prompts were used to clarify the child's meaning.

Older children and young people were asked questions in a more structured manner. Interviews were conducted in an informal, conversational style using the interview schedule as a guide (Appendix 9.2). Children/young people were encouraged to discuss any aspect of vital sign and PTTS monitoring they felt to be important. Conversations often 'strayed' into other areas such as school, what they

liked to do outside of hospital, where they lived, pets and siblings. This was considered important as it helped develop a rapport[223] with the participant and demonstrated that the candidate was interested in them as a person not just as a research participant.

5.3.5.2 Parents

Semi-structured interviews with parents followed an interview schedule (Appendix 9.3). If a parent wished to discuss a relevant topic 'out of sequence', the ordering of the questions was adjusted. Parents were encouraged to discuss both positive and negative aspect of vital sign and PTTS monitoring. If parents wished to introduce a new topic area that they felt was relevant to PTTS and vital sign recording, this was encouraged. For example, some parents wished to discuss other measurements such as height, which they associated with the recording of vital sign observations. Interviews were informal and conversational in style. Participants chose the location of the interview and whether this was conducted in the presence of their child and other family members.

Demographic data were collected on the following: age of child, relationship of participant to the child, gender of child, number of times the child had been hospitalised previously, whether the child had been admitted to intensive care in the past and length of stay before the interview.

5.3.5.3 Nursing staff

Focus groups were separated into junior (nursing staff of band 5 and below) and senior (band six) staff. Four to eight participants were allocated to each group and sessions were scheduled to last up to an hour. The first 15 minutes were planned to respond to participants' questions about the study and to gain their written consent. The remaining 45-minutes were allocated to data collection. An interview schedule was followed to ensure consistency between the groups (Appendix 9.4).

5.3.6 Data analysis

The five-stage approach for framework analysis described by Ward[240] was followed. This has five distinct but inter-linked stages which, rather than being a linear process, overlap backwards and forwards in an iterative fashion.[244,245] This

interpretive process allowed data to be systematically searched for patterns in order to provide insight and description of the phenomenon in question.[240]

The five stages are:

1. familiarisation through immersion in the data
2. development of a theoretical framework through identification of important and recurrent themes
3. indexing and charting
4. summarising data in an analytical framework
5. mapping and interpretation.

5.3.6.1 Stage one: familiarisation

The interview tape recordings were listened to in order to get a sense of the data as a whole. Transcripts were read several times, and field notes and comments were examined. Recordings were then listened to with the transcripts.

5.3.6.2 Stage two: identification of the framework

The purpose of the framework is to facilitate the management of the complete data set in an organised 'matrix' fashion. This allows data to be viewed across categories or participants and helps with subsequent retrieval, exploration and examination of the data.[246]

The approach recommended by Parkinson and colleagues was adopted.[246] An initial framework based around the areas explored in the interviews and focus groups was developed. Charting was piloted with one focus group and two interviews. Areas of overlap that could be condensed, and areas that were missing from the framework were identified through discussion within the supervisory team. The framework was modified. Categories were added, developing and building the framework through a number of iterative revisions. The final framework can be seen at Appendix 10.

5.3.6.3 Stage three: Indexing

During this stage the data were prepared for entry into the framework (Appendix 10). Data in the transcripts were coded using the number identified for each sub-category. Where relevant, data were coded to a single category. However when data could fit across two or more categories, multiple coding was used. For

example, data about vital sign monitoring at night was coded to pain and discomfort, keeping watch, needing to conform and anxiety and fear.

5.3.6.4 Stage four: Charting

Charting aims to organise the data in a manageable format to prepare for the final stage of mapping and interpretation.[246] Microsoft Excel was used to display and manage the data. Each of the four categories was assigned a separate spreadsheet with columns allocated for each sub-category.[247] Participants or focus groups were each allocated a row.

Data were summarised and inserted into the spreadsheet under the corresponding column and row in a matrix fashion. Words or phrases used by the participant were indicated by quotation marks. Summarised data contained the transcript line to facilitate easy referral back to the original data.

5.3.6.5 Stage five: Mapping and interpreting the data

Data were synthesised by mapping and interpreting the data. To facilitate the initial identification of themes and sub-themes the matrix was printed, so each spreadsheet could be displayed side by side.

Initially the data were examined for themes that were present across multiple cells in the framework. Sub-themes sometimes emerged from a phrase or word used by a participant which captured a sub-set of the data. A total of 55 sub-themes were initially identified. Each was written on a post-it note as shown at Figure 5.2.

Figure 5.2 Initial sub-themes identified from the data

These sub-themes were then examined for connections and associations. The post-it notes with the sub-theme headings were ‘moved around’ and clustered together until the list was reduced to 10 sub-themes. These revised sub-themes were captured on a single post-it note and the process repeated to identify and organise the main themes. Themes and sub-themes were critically appraised for overlap and duplication. Sub-headings were merged where there was felt to be significant overlap. For example, the boundaries between the sub-themes of ‘providing reassurance’, ‘tracking progress’ and ‘alerting to deterioration’ were examined and were felt to be closely related. These were captured under the sub-theme ‘providing reassurance and alerting’.

5.4 Results

The final sample comprised 13 parents, 10 children and young people and 36 nurses. Fourteen interviews were conducted in total. Five interviews had a single participant: one child, four parents. Nine interviews had two participants: eight parent and child/young person dyads, one mother and father dyad.

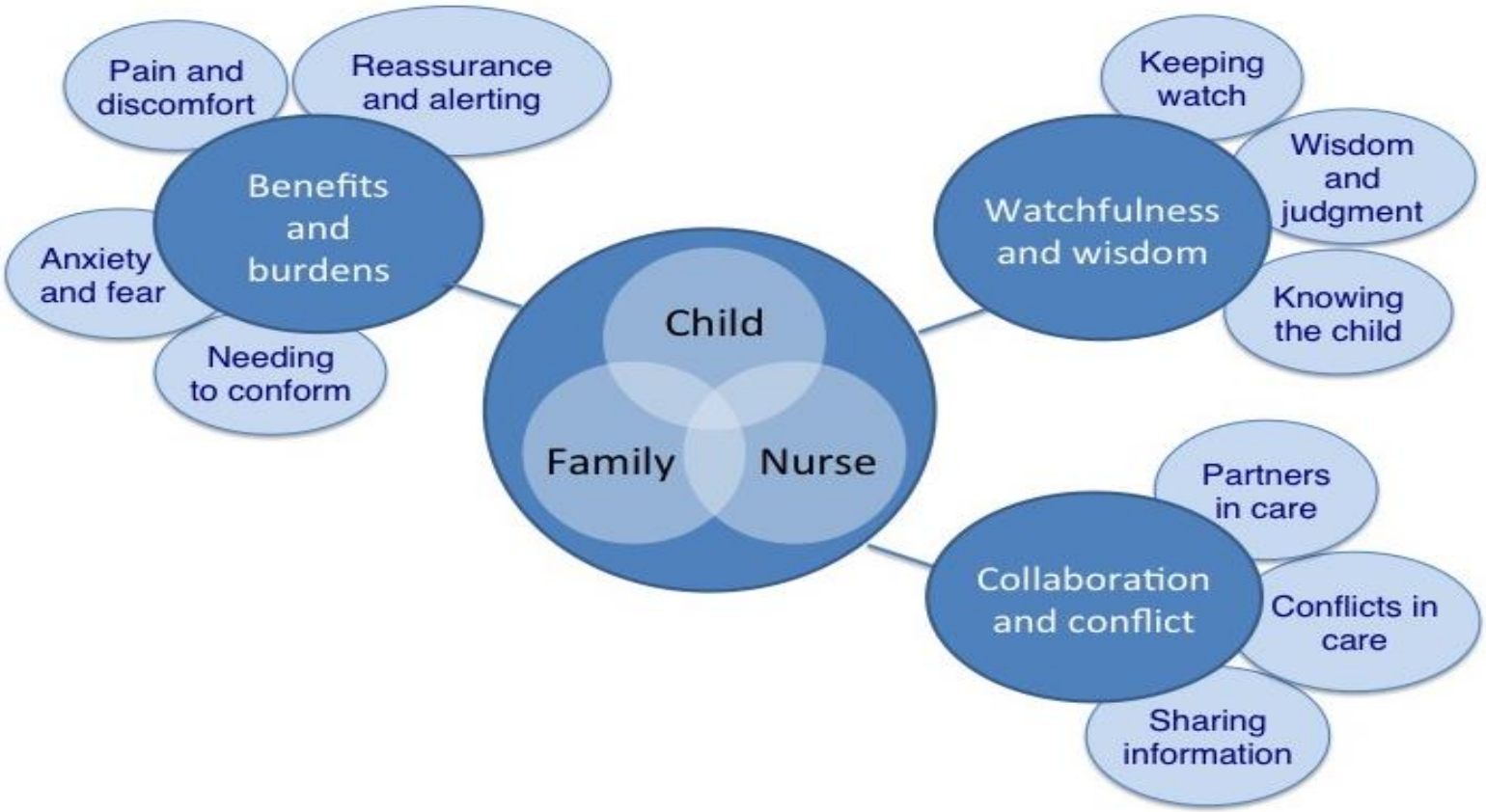
All but one of the parents was interviewed in the presence of their child. Most interviews took place at the child's bedside with just one interview taking place in the playroom of the ward. Eight interviews took place in single rooms and seven were in open bay areas. Parents were present for all child/young person interviews, although one parent left part-way through the interview at her own request and with the child's consent. Interviews lasted between six and 85 minutes (median 20.5 minutes). Only one child chose to participate in a draw and write session. All other child/young person participants chose to describe their experiences in a semi-structured interview.

Six focus groups were conducted: three on a surgical ward, two on a medical ward and one on a short stay ward. Three focus groups were conducted with junior nurses and three with senior nurses. Four focus groups were facilitated by the PhD candidate. Two were facilitated by an experienced senior nurse who was instructed by the candidate and followed the interview schedule seen at Appendix 9.4. Focus group sessions lasted between 24 and 56 minutes (median 40 minutes). Groups had four to eight participants (total 36 participants).

5.5 Findings

The aim of this section is to present an overview of the key findings to emerge from the data. Three major themes and 10 sub-themes were identified that reflect participants' understanding and experiences of vital sign monitoring and use of a PTTS in the paediatric ward. A diagrammatic representation of the themes and sub-themes is shown at Figure 5.3

Figure 5.3 Diagrammatic representation of main themes and sub-themes



The three main themes are represented in dark blue. Sub-themes are in light blue

5.5.1 Benefits and burdens

Participants identified the benefits that using a PTTS score and monitoring vital sign observations could bring. Providing reassurance about the child's condition, tracking their progress over time and alerting them to problems were highlighted as beneficial. However there were also associated burdens. Pain and discomfort, particularly around the taking and recording of vital sign observations, and anxiety and fear were identified by participants.

Benefits and burdens were interlinked. For example, parents described in positive terms the reassurance gained by continuously monitoring their child's oxygen saturation levels but simultaneously reported the burden of constant negotiation and vigilance to prevent their child from removing the monitoring probe. Because of the close relationship between benefits and burdens, these are reported together. Four sub-themes were identified and will be discussed in turn: reassuring and alerting, pain and discomfort, anxiety and fear and needing to conform.

5.5.1.1 Reassuring and alerting

None of the participating parents or children/young people were familiar with the local PTTS system, the Children's Early Warning Score (CEWS). This was despite the fact that all but one young person and one mother and father dyad reported that this was not their first stay in the hospital. Many participants had experienced three or more admissions to the hospital and their lack of familiarity with the CEWS was somewhat surprising, especially as it had been in place for around eight years.

Despite their unfamiliarity with the CEWS parents and young people appeared to understand its function and purpose after they had received a brief explanation. Young people were generally positive about its use and made comments about the potential benefits of using such a system:

> *That makes me feel good, because they're keeping track of how you're doing, and if you're well overall, I think that's good, that's very good system, because that sounds also quite-, a good way of keeping track. I think that's good, I'm happy about that, because I didn't know that before.*
>
> Female young person, 14-years, surgical ward

Parents and young people felt reassured by the PTTS and cited the benefits of being able to track progress, particularly if the young person was unwilling or unable to self-report. One parent likened the PTTS to a traffic light system, drawing parallels to a red-amber-green system of alerting. This was particularly interesting as the CEWS escalation protocol also used this methodology to indicate patients at low, medium and high risk of deterioration (Appendix 3).

> *Helps you know what's going on, doesn't it? Whether everything's alright or whether there's a problem*
>
> Mother, daughter 11-years, surgical ward

> *I think that's reassuring. It's like a traffic light* [system] *… and you know that, in the night, your child's just as safe as they are in the day. Because, in the day, they can express that they're not feeling very well. At night is normally when these things spike…or if you're asleep, you don't know that, that your temperature has risen to the extent that … you've got to be observed, observed a bit more than you perhaps were earlier on in the night. No, I think that's a brilliant idea.*
>
> Mother, daughter 9-years, medical ward

Children and families saw vital signs as an objective measure of their progress. Children and young people talked about vital signs being able to '*track your progress'* to see whether you are '*getting better'*. One young person said this made her feel '*good'* because staff could then see '*how she was doing*' and if they were '*well overall'*. Another young person talked about 'checking' for signs such as a fever, which would then allow staff to *'do something about it'.*

> *You'd rather have your mind be put at rest and know that if the nurses think that there's something not right, that they're going to get somebody who's knows what they're doing more, like a higher-up, the doctor, to come and double check, you know?*
>
> Mother, daughter 11-years, surgical ward

Nurses also identified benefits associated with the PTTS. They highlighted that it may be most beneficial to junior staff who were less able to draw on previous experience and apply clinical judgment. The PTTS could help them 'make sense' of the observations by providing guidance on the expected vital sign values and indicating when they may need to alert someone with more experience. Detecting

and alerting staff to children who were deteriorating was reported as a key benefit of the CEWS by participants in all focus groups:

> *It's about alerting us when a patient is deteriorating … so we can seek help appropriately.*
>
> Senior nurse, medical ward

> *I think* [for] *the less experienced nurses it gives them some, not so much taking it from observation. If you've got this score, contact this person and they have to come. That's very useful*
>
> Senior nurse, medical ward

> *It is helpful, especially if we're working with a student. It helps alert them to if the child's deteriorating.*
>
> Junior nurse, medical ward

The PTTS was reported as particularly useful when staff were working in unfamiliar areas or with children from specialities they were less familiar with:

> *Because every ward is so specialised, they all have different criteria for each of their patients, and people don't always realise that. You can go and work on another ward and it's like going to France! You've got no idea what they're talking about!*
>
> *So you might not know anything else about their conditions at all, and you might not know how to look after that patient but you can look at their* [PTTS] *scores and go 'this patient is okay'.*
>
> Junior nurse, surgical ward

The benefits of a universal risk assessment were clearly highlighted by this junior surgical nurse. The PTTS was felt to offer a means of recognising whether a patient was 'sick' or 'stable'. Low scores provided reassurance that a patient was 'okay' and this reduced anxiety. Whilst this universal language was particularly helpful when nurses were faced with unfamiliar diseases or challenging situations, it could also be seen as unnecessary in some settings:

> *For the patients coming back from theatre … it's fine because you can assess them and you'd be able to tell if they are deteriorating or if they're the same level as they were before. For patients that come in for infusions and things like that, it's not really helpful. It doesn't really do anything for us.*
>
> Junior nurse, short stay ward

Most children on the short stay ward were admitted electively for tests and treatments. As such, the nurses felt that they were considered to be stable and 'well'. The PTTS was seen as adding an unnecessary addition to their workload and was reported by nurses to raise parental anxiety.

5.5.1.2 Pain and discomfort

When discussing vital sign observation recording with children/young people, they frequently recalled the pain and discomfort that the procedure brings. Children/young people repeatedly cited blood pressure as inducing pain and they and their parents often used the word *'hate'* when this vital sign was discussed. No child discussed blood pressure recording in a positive manner. During one interview a five year old boy became visibly distressed when he saw the blood pressure cuff, despite reassurances that no recordings were going to be taken. He tried to hide away under the bed covers. When asked why he was upset he pointed at the blood pressure cuff and said it was *"Very hurty … and it goes, and it squeezes really tight*"

For others, the repetitive nature of the procedure, especially during prolonged hospital stays, was identified as a burden. As one child explained:

> *… especially for the three months* [in] *hospital. There I had this for about three months. Days and days and days and days…and then pain and pain and pain*
>
> Female child, 7-years, medical ward

When this young girl was recounting her experience, it appeared that she wanted to emphasise that three months was a long time. Each time she said the word '*days*' the delivery of the word became longer and more drawn out. She gave similar emphasis to the word '*pain*'. Her words and the way that she said them appeared to underline how difficult this was for her.

Temperature recording was also a source of discomfort for some children/young people. Although it was not universally disliked to the same degree as blood pressure, many still reported it as restrictive or uncomfortable. The taking of oral temperature recording was reported to restrict speech, create difficultly when children/young people need to cough and made one child feel *'sick'*. Keeping it under the tongue *was 'a big problem'*. One child reported that '*it digs into the top*

and the bottom' of your mouth although another younger child described the temperature probe as *'soft'*. One child perceived that the nurses took his temperature *'every hour',* although his mother indicated that this was not the case. The route of temperature recording appeared to be important to children and young people:

> *The only thing I don't like is when they put it under the tongue*
>
> Male young person, 10 years, short stay ward

The taking of oxygen saturation levels evoked mixed responses, with some children/young people reporting it as *'okay'* and others saying they disliked the *'sticky'* feel of the recording probe. One child highlighted that whilst she *'didn't really notice it',* she couldn't *'wave her arm around'* when monitoring was in progress. As a consequence, she felt she had to sit still whilst the probe was on her finger.

No child or parent discussed the monitoring of the remaining component vital sign parameters for the local PTTS: heart rate, respiratory rate or consciousness.

It was apparent that the impact of monitoring could be exacerbated if the child was more vulnerable either because they had special needs or if they had just undergone surgery. One mother explained that postoperative oxygen saturation monitoring could be irritating for her son and this could be more distressing than the surgery itself. Tiredness was identified by a number of participants as affecting the child's tolerance to vital sign observation recording. This was particularly true if monitoring was required overnight and sleep was disturbed as a result. It emerged that the reaction to vital sign recording could be influenced by factors such as medication, as this parent reported:

> [he does] *put more of a fight, when he's had his Melatonin … he's more harder to wake up, and he does wake up very moody … he doesn't wanna, sort of like, turn over, or he doesn't want 'em touching his fingers, and he gets really sort of rude, and starts shouting at them. Whereas before when he wasn't on his medication, he was still a bit miserable, but it makes him a bit grouchy*
>
> Mother, son 7-years, surgical ward

Although nursing staff recognised the discomfort that children/young people experienced when having vital signs recorded, none characterised this as painful.

They mainly discussed the response to recording vital sign observations using words like '*distress'* and *'anxiety'*. Discussion tended to centre around the challenges of obtaining 'reliable' recording of vital sign observations when a child was distressed and the impact this had on PTTS values.

Nurses on the short stay ward emphasised that taking observations could invoke abnormal vital sign readings, such as a high heart rate or elevated blood pressure. This was seen as potentially interfering with tests results and causing the child and family more distress.

5.5.1.3 Anxiety and fear

Although nurses reported PTTS as providing reassurance about the child's condition, they also cited episodes where use of a PTTS could raise anxiety. Junior staff in particular recalled past experiences where they had calculated a high PTTS and how they felt '*panic*' and *'nervous'* and '*frightened'* in the moments afterwards. One nurse described how she felt when faced with an elevated PTTS score:

> *It is still nerve-wracking though, especially when you're newer and obviously it comes with experience and stuff. It is quite daunting.*
>
> Junior nurse, surgical ward

Junior staff also reported *'fear'* when they calculated a PTTS score and realised it was high. This fear was evoked by past experiences of finding elevated PTTS and the potential consequences for the child and family.

Recording the PTTS was a task that was often delegated to junior staff, health care assistants and student nurses. Senior nurses reported that this required supervision and support, which could place an additional burden on their workload. When workload was high, this caused anxiety about whether tasks were completed properly as senior nurses felt they could not be *'in all places at once'.*

Making decisions on recording or omitting vital sign observations could also lead to anxiety. Assessment of consciousness using the 'alert-responds to pain-responds to voice-unresponsive' (AVPU) scale was discussed in a number of focus groups as participants were unsure what they should do at night when a child was sleeping. Views differed but people were anxious about balancing the need for the child to sleep with the need to record the observation. In one focus group a nurse recalled a

child admitted with a relatively minor problem who deteriorated overnight and '*didn't wake up'* the following morning. An AVPU value had not been recorded but continuous oxygen saturation monitoring was in place and had been '*stable'.* The child deteriorated and required admission to PICU and '*almost died'*. The nurse described being '*scared'* because she didn't know '*how long that child had been unconscious for'.* The incident had clearly left its mark as the nurse continued to return to the event throughout the remainder of the focus group. Others spoke of their fear of litigation if anything was to '*go wrong'*, particularly where there was a dispute between the parent and nurse about taking recordings at night.

The constant nature of vital sign observation recording led it to be described as the '*last straw'* by children, young people and families. Parents reported how vital sign recording assumed a greater importance to the child after repeated admissions. Nurses also reported that some children became distressed when '*anybody in a uniform'* came near them. During the interviews, two younger children became visibly distressed when they saw a blood pressure cuff. This was despite the candidate and the parent reassuring them that no measurements would be taken. One child tried to hide under the bed covers. Another child repeatedly said '*take it off'* and '*all finished'* when he saw the blood pressure cuff. This was despite the cuff not being applied to his arm. His parent explained that this was a sign that he was distressed, feelings that were felt to be exacerbated by his autism. She reported that blood pressure recordings made him *'sad' and 'cry'*.

Another mother, whose daughter was currently an in-patient, relayed how, during a previous admission to the same ward with her son, he became *'stressed'* whenever a nurse entered the room. She described how he became '*annoyed*' when the nurses placed their equipment amongst his toys and this was increased when they did not remove them after the procedure was finished. Vital sign monitoring became a focus for his frustration and he began to refuse to have these taken. The situation continued to escalate as he struggled to exert some control over his situation. She described how this created additional pressure for her:

> *It's embarrassing for the parents because you're trying to persuade* [him] *to do some of the most basic things when actually you haven't got the energy to, and you think 'Do you know what? Does it really matter today?'*

Mother, daughter 14-years, medical ward

Many parents described feelings of '*embarrassment'* when their children refused to have their vital sign observations taken. They characterised their child's behaviour as '*playing up'.* Parents themselves came to '*dread*' the procedures and became stressed when they knew observations were due to be taken. Other parents described how their child's responses varied, but appeared to be related to repeated episodes of hospitalisation. Two mothers described their experiences:

> *Last year, that was his way of, sort of, gaining a bit of control. Sort of saying no to sats or running away from them and, you know, all the ops and things. The nurse would come in and say, 'Can we put the probe on your finger?'' "No, you can't"' and we'd say, 'come on* [child's name], *I need to know.' So I was dreading this admission, thinking he's going to be so awkward and he's been brilliant this time around.*
>
> Mother, son 5-years, medical ward

> *'cause he knows as soon as that goes up he knows it's obs time and he, I think he knows what time the obs are! He just knows. But if he don't want it done, you can't force him. Yeah, head-butts the cot and everything if he don't want it done.*
>
> *I've been lucky for the last ten days he has wanted it done.*
>
> Mother, son 5-years, medical ward

The effect of non-compliance on the parents was palpable. There was a sense of relief expressed by both these mothers when their child consented to have their vital sign observations taken.

Staff discussion included the impact of repeated vital sign recording on parents and children/young people, which was perceived by nurses as increasing parental stress and anxiety. This was felt to be particularly true when the child was assessed as well and stable:

> *The more anxious the parents get, the last thing you want is for parents to get really anxious.*
>
> *What's the normal range? Why are you doing it again? Things like that. So we want to keep the children as normal as we can in order for our tests to be normal.*

> *Yes, you don't want to be stressing a child out and then their cortisol response going through the roof and that's actually what they're in there to look at that and stressing a child out by doing blood pressure is less helpful for their test.*
>
> Junior nurses, short stay ward

Parents reported anxiety and fear when they perceived their child to be at risk of deterioration. Feelings were particularly acute if they felt that staff may not recognise or be able to respond adequately to the signs of deterioration. This led them to 'keep watch' over their child, a theme that is explored in later section below.

5.5.1.4 Needing to conform

Children/young people, families and nurses all described how vital sign recording and PTTS imposed restrictions on their behaviour and decision-making. Although restrictions differed for differing groups of participants, all explained a need to conform to the demands imposed by the PTTS and the associated protocol.

For children and young people restrictions revolved around vital sign recording and continuous monitoring. This often require the child to '*sit still'* or *'not to talk'* during procedures such as oral temperature recording. One child described how he disliked being still for observations as they '*weren't very good at it'.* Continuous monitoring imposed more sustained restrictions, as children/young people described feeling like they were *'all tied up'* particularly when they became *'tangled up'* in the leads overnight.

Nurses spoke of having to conform to monitoring protocols even when this conflicted with their own judgment. On some wards there were also informal protocols to regulate the frequency of vital sign monitoring. Nurses were advised '*to stick to four-hourly'* recording of observations, with the caveat that nurses who stepped outside of this guidance would need to *'justify'* their actions. The fear of litigation was also cited as a driver to conform.

Nurses also reported the impact of conforming to the PTTS escalation protocol. For many children, a high PTTS value accorded with the nurses' clinical impression of the patients. However others had an elevated PTTS, which conflicted with their judgment. In these cases, they described the conflict they felt when escalating an elevated PTTS value in a child they assessed to be well. This was seen as being

particularly frustrating when a senior clinician subsequently appeared to belittle their decision. Nurses in one focus group described their experience of escalating a patient to the intensive care outreach team whose PTTS score was repeatedly high:

> *You say to somebody, this patient has a score of eight and frequently has a score of eight and they're like "oh, it's just him".*
>
> *Like that we can't use our own judgment! We are trying to bring it to the attention of somebody more senior and they just don't seem to take any notice. It's just rude!*
>
> Senior nurse, surgical ward

The perceived reluctance to attend to this patient appeared to have a detrimental effect on inter-professional relationships and led staff to remark that the intensive care outreach team, '*don't really care'.* This was despite the protocol indicating that a score of eight signified a child at high risk of deterioration where attendance by the intensive care outreach team was required within 15 minutes (Appendix 3).

When faced with an elevated PTTS score, junior staff would often 'seek out' more experienced nurses. These senior nurses would make an assessment and sometimes judge that escalation was not needed. However junior staff sometimes ignored this advice and escalated the child to a doctor or the intensive care outreach team despite the senior nurse's recommendation, as they feared the criticism and consequences of failing to conform to the escalation protocol.

Nurses appeared to recognise that complying to the protocol and obtaining a full set of vital sign observations on which to calculate the PTTS was required, however achieving this in practice was more challenging. They also appeared to want the PTTS chart to appear regular, structured and complete. Additional information, which may be useful in tracking the child's progress, was seen as disrupting the quality of the chart:

> *You have a perfect chart and then just because you tried to do better and put these extra obs in it looks crap because you can't see little bits, maybe the few you literally can't do.*

> *And it doesn't always look straight. If you do the sats and resp rate four times every hour so every 15 minutes for a patient, and then on the next hour you do them but then you're doing the BP and the full set of obs, your obs then have got four gaps in between*
>
> Junior nurse, surgical ward

Others described challenges in recording the PTTS score during transient episodes of physiological instability. Frequent but fleeting changes in the child's condition, such as desaturation or bradycardic episodes, created difficulties as the problem had sometimes resolved before a full set of vital sign observations could be captured.

> *And it doesn't look like a full set and they'll say well what were the resps? And you're like, well, you try getting the resps!*
>
> Junior nurse, surgical ward

Nurses appeared to put 'pressure' upon themselves to achieve the 'perfect' chart, despite being unable to explain what this constituted. However partial vital sign observation sets, with missing parameters, appeared to be regarded as 'sub-standard' and failed to conform to the expected standard. Sometimes staff developed additional charts to 'work-around' the problem. These 'desaturation' and 'apnoea' charts allowed documentation of selected vital sign observations, together with relevant information such as interventions to resolve the apnoea. This resulted in documentation that worked outside of existing protocols.

Conforming to the PTTS protocol was, in a few instances, also perceived to bring benefits. Whilst a high PTTS score was seen as an indicator that the child might be deteriorating, it was also perceived as a mechanism to secure help from senior clinical staff, as they were also required to conform to the protocol. As such a high PTTS value was seen as an indicator that was difficult to ignore.

> *It helps you as well because they have to listen, so if the CEWS are high enough they have to do something about it, so it helps nurses.*
>
> Junior nurse, surgical ward

5.5.2 Watchfulness and wisdom

The second theme of watchfulness and wisdom encompassed the need by families and nurses to watch over the child/young person, make sense of their own visual observations and recognise what this meant for that particular child. Watchfulness and wisdom was grouped into three sub-themes: keeping watch, wisdom and judgment and knowing the child

5.5.2.1 Keeping watch

Parental confidence in the skills and ability of the staff appeared to influence their actions and behaviours in keeping watch over their child. This appeared to be closely linked to the degree of trust and the strength of the partnership between the parent, staff and child. Parents reported feeling uncomfortable about leaving the ward if they were '*not happy'* with their child's condition and this was exacerbated if they perceived that the ward was busy or short staffed:

> *I was about to leave* [my child] *for the night and I just wasn't happy.* [He] *was on constant monitoring and they were really short staffed and I just stayed and watched because I knew what was going on.*
>
> Mother, daughter 14-years, medical ward

This mother's quote highlights particularly clearly how parents' response to vital sign monitoring can be affected by their previous experiences of care, in this case a previous admission to the same ward with her son. She went on to describe how this increased her anxiety and how she feared the consequences if he were to deteriorate and this was not detected. Another parent described how she felt '*like the responsibility's again on your shoulders'* when her child's nurse did not take regular vital sign observations. Parents described how they assumed responsibility for monitoring their child's condition when they perceived that healthcare professionals may not do so.

Continuous monitoring was also important to parents, as they could see how their child was and make their own independent judgments. This was particularly significant during prolonged admissions. When parents could see the monitor they reported feeling reassured about their child's progress. However prolonged use could make the transition at discharge more challenging:

> *… when you're in for a long admission you become a bit reliant on those monitors when they're on all the time because they do put your mind at rest or they alert you if there's any problems. Once you go home and you don't have that equipment, sometimes you feel a little bit like your sleeping bag's been taken off*
>
> Mother, 5-year son, medical ward

This mother's feeling of having her sleeping bag removed could reflect the exposure she felt at being responsible for monitoring her son's health status at home in contrast to the security of being in hospital. However nurses sometimes appeared critical of parents who watched their child's monitor:

> *Some of them get a bit obsessed about watching the monitors. Particularly post procedure, when they're on the monitor, they'll get very, very obsessed with watching it.*
>
> Junior nurse, short-stay ward

Characterising parents as becoming *'hypnotised'* or '*obsessed*' by the monitor appeared to imply that parents paid more attention to the monitor than to the child themselves.

A lack of suitable equipment appeared to hamper nurses' efforts to record vital sign observations. This was particularly problematic at times when nurses were trying to record vital sign observations at scheduled (four-hourly) times and was noted by parents who observed that the shortfall led to nurses *"fighting'* over monitors. This could, in part, account for parents feeling the need to keep watch over their child.

Parents kept watch not only to detect signs of deterioration, but also to protect their child from other dangers. One child would chew the wires of the monitoring equipment and required constant vigilance to prevent this from happening.

Keeping watch at night was cited as particularly problematic. Parent participants frequently discussed the disruptive effect that overnight vital sign monitoring had on both their own and their child's sleep. Monitor alarms were a particular source of frustration. Parents recognised that alarms were activated by a change in the child's condition. However these were sometimes not responded to promptly and parents reported having to get out of bed, check their child and seek out a nurse to address the alarm. Initially this created fear and anxiety in parents, a theme already described. However parents of children hospitalised for extended periods reported

'*irritation',* driven by their *'exhaustion'* after continued nights of broken sleep. The situation was aggravated if the alarms were frequent or the nurse appeared dismissive or unresponsive to the underlying cause.

Children also appeared to become involved in keeping watch over their condition, with some reporting using their own judgment to alert staff to a potential change in their condition. This five-year old boy described what he did when he felt he had a temperature:

> *I can tell by it because I'm hot because you get all sweaty. And my hair gets all wet…when Mum's not here I just have to press a buzzer.*
>
> Male child, 5-years, medical ward

5.5.2.2 Wisdom and judgment

Making decisions on how and when to record vital sign observations and PTTS scores was seen as important by nurses. They described how the taking of vital sign recording and PTTS scores could require considerable skill and dexterity, particularly around those observations that were seen as more technically challenging, such as blood pressure. Whilst the expertise needed to record vital sign observations was also recognised by parents, they valued the ability of the nurse to successfully engage with their child, negotiate and offer choice and 'persuade' children and young people to have their observations taken.

More experienced nurses and some parents considered junior staff sometimes to be lacking in basic skills of organisation or '*common-sense'*. They cited issues around coordinating the recording of vital sign observations with other aspects of nursing care such as medication or hygiene needs. Parents also spoke of more inexperienced staff being 'inflexible' over the recording of vital signs.

Children and young people also developed practical knowledge and skills around vital sign monitoring. When presented with vital sign observation equipment even young children under the age of eight years could demonstrate how to apply a blood pressure cuff, or take a temperature or use an oxygen saturation probe. They would often accompany their actions with words and phrases such as '*you're okay'* and *'take it out now',* which appeared to mimic words they had heard their nurse say. As

with parents, children and young people also indicated that they valued nurses who offered them choice and flexibility when recording vital sign observations. It is possible that this could reduce their anxiety, increase compliance and strengthen partnership working.

Making decisions on how frequently to record the PTTS was seen by nurses as complex. When faced with an unwell or deteriorating child, some vital sign observations were seen as more important than others:

> *Pulse, resps, sats are your kind of key, more hourly ones…temperature and blood pressure are still four-hourly unless there's something that requires you to check it more*
>
> Senior nurse, surgical ward

Families, particularly those with children who required long-term or frequent admissions, displayed considerable knowledge and skills around vital sign observations. Some relayed quite sophisticated knowledge of the purpose and function of the vital signs, such as monitoring oxygen saturation levels to detect respiratory issues and guide oxygen therapy. They also adopted language frequently used by healthcare professions such as their child having *'spiking temperatures'.* The need to monitor their child's progress and ability to make their own judgments appeared to be both a protective mechanism and a source of reassurance. Skills and knowledge appeared largely self-taught, with parents reporting that they *'pieced this together'* whilst looking at bedside monitors or vital sign observation charts. Knowledge increased either through repeated hospital admissions or exposure to periods of intensive monitoring such as critical care. The father of a 2-month old girl who had spent considerable time in intensive care characterised his wife's knowledge as '*like a trainee nurse now'*.

Some reflected back on the time before they developed these skills and '*regretted'* that they didn't know then what they knew now. Whilst some parents said they felt they had sufficient information on the meaning and significance of vital sign observations, others felt very strongly that additional knowledge and skills would enable them to be better partners in their child's care. One mother spoke of a time after two of her children had been admitted to hospital, both acutely unwell:

> *But I was watching them and I thought, I wished I understood better what was going on … I wished I had understood better when to call for help*
>
> Mother, daughter 14-years, medical ward

In all six focus groups it was reported by staff that PTTS should be used with clinical judgment, never in isolation. Although it was seen to be of particular value to junior staff and student nurses, there were concerns that they may not have the experience to recognise its limitations:

> *Because a junior staff member might not see that a child is fine … They could normally have a respiratory rate of 60, but actually you go and look at that child, they've dropped their respiratory rate and a junior member of staff might say 'That's fine, great, they're back in their normal CEWs,' but actually you could go and look at them and say, 'But that child doesn't look right for whatever reason.'*
>
> Senior nurse, surgical ward

They explained that this was due, in part, to the inherent limitations of PTTS. In particular they reported the tendency to over-trigger in certain patient groups - particularly neonates and adolescents - and their concern that PTTS would fail to detect deterioration in some children. Inappropriate thresholds for vital sign parameter sub-scores were felt to be a frequent cause of over-triggering:

> *I think it is useful in a normal child that's had an appendectomy but outside of that, especially not for neonates … that generally have a lot of other problems, I don't find it* [useful], *because I don't look at the CEW scores. I always think of everything else and then look at the child and then kind of ignore the CEWS. I probably shouldn't say that, but I do.*
>
> Senior nurse, surgical ward

This senior nurse described how the PTTS was used to confirm, rather than detect the signs of deterioration. She used her judgment to assess the individual clinical indicators and make her own assessment regardless of the PTTS. She emphasised how looking at the child was seen as more important than the score.

When vital sign values fell on the border between two differing PTTS sub-scores, staff in one focus group told how they selected the score which supported their clinical impression of the patient's condition: a higher score if they felt the vital sign value was '*wrong*' for the patient and the lower score if it was felt to be '*normal'*.

Some children and young people had long-term health problems that led to persistently high PTTS scores. Nurses recognised that the PTTS score was a poor indicator in these patients and used their judgment to determine whether to escalate the situation or not. These limitations resulted in staff, particularly those who were more senior, making active decisions to over-ride the PTTS escalation protocol. As such they used the PTTS as a mechanism to support rather than direct their decision-making.

5.5.2.3 Knowing the child

In relation to the sub-theme of watchfulness and wisdom, nurses discussed the value of '*knowing the child'*, and the benefits this brought when assessing their condition and interpreting PTTS scores. Caring for a child and family on consecutive shifts helped to build this knowledge. Staff became familiar with the child's preferences and this helped with the recording of vital sign observations. Families also appreciated seeing a 'familiar face' and this helped to reduce their anxiety. As previously mentioned, they appreciated when nurses knew and understood the child's preferences, as this improved the child's compliance to vital sign monitoring, easing their own workload and burden.

Familiarity with the child was also reported to improve decision-making, as nurses were better able to judge the significance of changes in vital signs and PTTS values. Acute changes in the child's condition were more readily interpreted as the nurse was familiar with the risk factors and changes to therapy that may have precipitated the event.

Non-specific concerns were often raised by families, who reported their child was *'just not right'*. Nurses placed a high value on these reports, recognising that parents know their own child best. This was particularly valuable when the child had a long-term health condition, limited vocabulary or special needs.

Nurses, parents and children/young people placed value on care that was individualised and tailored to their own particular circumstances. Nurses recognised that PTTS could detract from this, as a 'one size fits all' methodology was not necessarily appropriate for all children. This was particularly true of children they perceived as physiologically *'different'* to other children of the same age. The local

PTTS had four charts with different age-dependent vital sign scoring (Appendix 2.1). Some nurses questioned whether this approach was appropriate, as some children were physically or developmentally different from their age-related peers. Participants in two focus groups felt that the local PTTS should have individual scoring frameworks and thresholds that personalised the PTTS to each child.

Children with long-standing illnesses were also identified as a particularly challenging group. Many nurses identified children whose vital sign observation values always sat outside the 'normal' range, even when they were experiencing a period of well-being. This led to persistent false triggers despite staff recognising that this was *'normal for them'*. Although mechanisms were in place to deal with this, through the adjustment of the vital sign scoring thresholds, nurses reported these were poorly used in practice. Nurses perceived that responsibility for adjusting these parameters lay with the doctor or intensive care outreach team. However they reported a reluctance from doctors to formally document these adjustments, which led to ongoing recording of falsely high PTTS scores. Initially this resulted in repeated escalations, but as time went on, nurses began to 'ignore' these high PTTS score. They expressed concern that they were effectively going against the protocol and how this might be perceived, particularly by junior staff:

> *I think that's the bad thing about the CEWS. If a patient does consistently score, you just become complacent, like 'Oh, it's normal for them'. So it's not…like you say, if someone was to come in that's never had the child before you can't notice that they're deteriorating, because it's still the same respiratory* [rate]. *Especially if the doctors aren't saying 'this is what we'd accept for this child'.*
>
> Junior nurse, medical ward

Nurses also talked about falsely low PTTS scores. In two focus groups staff talked of having a '*gut instinct'* that some children were deteriorating, despite the PTTS score being low. However attempts to escalate these children to a senior clinician could be problematic:

> *I've had experience where, like you said, the child is really poorly and they don't score a CEWS And it seems like all the person on the phone wants to know is the CEWS score and actually that's when I don't find it very useful. Because when you are worried about a child, you need somebody to come. It's great in other*

senses and I think it is good for less experienced nurses as a helpful guide, but I don't think it's a fool-proof tool.

Senior nurse, medical ward

In these scenarios the PTTS was perceived as not only unhelpful, but also potentially obstructive to their escalation attempts. Inappropriately low PTTS scores appeared to undermine confidence in the validity of local PTTS. The reluctance of senior staff to attend these patients had a consequential effect on intra-professional relationships.

The theme of watchfulness and wisdom highlights the vigilance displayed by nurses, families and, to a lesser degree, children and young people. Keeping watch was a way of managing the child's condition and protecting them from harm. This required considerable skills and knowledge. Although the PTTS was reported as assisting nurses to monitor the child's progress, it also needed to be used with judgment. Knowing the child was seen as important to nurses and families as it helped to make sense of the vital sign observations and PTTS score. This could strengthen the partnership between parents and nurses, as highlighted in the next theme, collaboration and conflict.

5.5.3 Collaboration and conflict

The care of children in hospital is underpinned by the partnership between children/young people, their families and healthcare professionals.[214] Collaboration is seen as important but views and opinions may differ and this can lead to conflict. Effective communication and sharing of information may mitigate against this conflict whilst poor communication may or may not exacerbate it.

Three sub-themes were identified: partners in care, conflicts in care and sharing information.

5.5.3.1 Partners in care

Children and young people recognised that it was important for nurses to be able to take their observations. Although younger children could find the procedure distressing, older children and young people understood that the nurse 'needed to know' what their vital sign values were so they could 'track their progress'. Some

would hold out their arm in readiness for observations to be taken. As previously described, they and their families appreciated nurses offering them choice and flexibility when recording vital sign observations. Negotiating the timing of recordings and allowing the child to choose how these were taken - such as offering a choice between oral or axillary recording of temperature or blood pressure measurement on the arm or the leg – was seen as particularly valuable. Parents felt this allowed the child/young person to regain a sense of control, which minimised subsequent issues with compliance.

Some children and families reported that nurses allowed them to enter their own vital sign observation values into the iPad system that had recently come into operation. This was seen as enjoyable by children and was reported by to facilitate discussion between the nurse, child and family about the vital sign values and their significance.

At night, using small torches and talking quietly were highlighted as making a difference and reportedly improved the quality of sleep experienced by children/young people and their families. Small things, like leaving a blood pressure cuff in place overnight rather than removing and reapplying it for each reading, were appreciated by parents as they reduced the child's distress and improved their compliance. This was particularly important if they experienced a long period of hospitalisation. Actions like these were perceived by families as indicating a high level of nursing skill and expertise, illustrating the link between the theme of watchfulness and wisdom and collaboration and conflict.

Parents also reported working with nurses to take their child's observation recordings. This collaboration was seen as particularly important if their child had special needs. One mother, whose son has autism, explained how she assisted with the recording of her son's observations at night:

> *I wake up because he's awake and he gets quite aggressive, you know, refuses it, and turns over, and he'll turn the other way and won't let 'em, sort of, get hold of him, so I have to get up in the night and sort of help them to do what they've gotta do.* [Its] *helping him, helping them persuade him to let 'em do what they've got to do.*
>
> Mother, son 11-years, surgical ward

This mother described how she had to ‘persuade’ her son to allow his vital sign observations to be taken, resulting in her experiencing broken and disturbed sleep. This was echoed by other parents, who spoke of the need to ‘persuade and cajole’ their child into having their observations taken. Whilst most accepted the need for such collaboration, some observed that they themselves could not see the value of the observations.

One nurse described how parents would alert them to potential changes in their child’s condition and how this might instigate the recording of a PTTS value:

> *So they'll come out and go, 'Ooh, I think they're quite warm,' or, 'Ooh, I think he's very sleepy,' and then you'll go and, 'Mmm, he looks okay, but I'll do a set of obs,' and then that will give you your CEWS. So…they're either your instigation for doing the obs or, you know, they're your calm me down factor when you think, 'Oh dear, their CEWS are high,' and they'll say, 'That's normal." So they do have an impact on where you would go from either starting your CEWS or answering your CEWS, kind of thing.*
>
> Senior nurse, surgical ward

This nurse valued parents’ input for alerting them to problems, but also sought their advice on interpreting the findings. This sharing of expertise combined parents’ unique knowledge of the child, as previously described, with the nurses’ clinical and professional expertise. This collaborative effort relied on the nurse actively listening and valuing their input.

5.5.3.2 Conflicts in care

Whilst the benefits and burdens of vital sign monitoring have already been described, a separate but related theme was the resulting conflict that can arise particularly when vital sign monitoring occurs at night. Both parents and staff reported this as an area of challenge.

Parents shared their frustration when nurses came to record observations at night when they had just settled their child to sleep. Although they recognised the importance, they sometimes felt their views as parents were not always listened to:

> *… on other occasions [my child] looks hot … but sometimes they’re, sort of, rigidly to their times ... so I shove a Temper-DOT [in] … and then I’ll go tell them!*

Mother, daughter 14-years, medical ward

Parents also described feeling a loss of control, particularly over monitoring at night.

> *there are some times when you might be coming towards the end …of an eight month admission and actually he's alright in himself, and the nurses are coming to him in the morning and depending what nurse you get there are a couple that put all the lights on,* [and] *come in. It's a broken night's sleep and you wonder why*
>
> Mother, son 5-years, medical ward

This mother questioned the need to perform her son's vital sign observations overnight after such a prolonged admission, particularly when staff were making plans to discharge him soon. Overnight vital sign observations was perceived by the parent as adding little to his clinical management, but resulted in broken sleep for both the child and herself.

The following example highlights particularly clearly how the requirements of nighttime monitoring appeared to undermine partnership working between nurses and parents and disturbed the parent's sleep. In a senior nurse focus group two participants highlight the challenges of taking vital sign observations at night:

> *You're walking in…and you've got your stethoscope and they're like "no, I've just put them to sleep, can you come back?"...Yeah, it's frustrating, and you do kind of think you're here and you're trying to do a certain thing for a certain reason, and how long is it acceptable to leave it?*
>
> *… if there was a, God forbid a court case or anything, there's nothing you could say to justify "oh no I didn't do it, oh no the Mum didn't want me to do it". I mean, you haven't got a leg to stand on…*
>
> *If they're here, resident, they play such a big role in what we do and when we do it, and sometimes how we do it, then they do dictate to a certain degree. Whether or not they do actually understand what we're doing what we do and why and how.*
>
> Senior nurses, surgical ward

The nurses characterised parents' requests as '*dictating'* their child's care. They reported frustration as tasks were delayed and took longer to complete. If parents resisted this, staff labeled them as '*awkward'*. Persistent resistance caused nurses

to '*dread'* taking the observations, as this discussion between two junior nurses about taking observations at night illustrates:

> *I think they can hinder, because on a night-time sometimes they don't want you coming in doing obs.*
>
> *Yeah, its' a nightmare. Especially if they've got the baby in the bed with them. You feel like you're invading their space as well.*
>
> *I think sometimes they have to be reminded that they are in hospital…*
>
> *Yeah, 'cause you accidently wake the parent up and they tut and they go 'Oh, for God's sake!'*
>
> *But they choose to sleep there… we shouldn't feel responsible for waking them up, should we? But it is awful.*
>
> Junior nurses, medical ward

On occasions when the partnership between children and families functioned less well nurses sometimes perceived that parents had overstepped their boundaries. Consequently they sensed there was a need to reassert their role and 'authority'.

Some parents reported particular challenges related to their child's individual needs. One mother explained how her son's autism meant he responded poorly to noise, especially at night. To try to overcome some of these difficulties, they always had a single room when he was admitted to hospital. She explained how she responded if the nurses wanted to record her son's vital sign observations at night:

> *No I'll refuse that. 'Cause he has melatonin at night, so that's the only way to get him to sleep and if they 'sturb him he's awake. That's why we're in here* [in this single room].
>
> Mother, son 5-years, medical ward

However sometimes the PTTS could mitigate conflict between staff and parents by providing a score that symbolised a change in the child's condition and an objective measure of the need for intervention:

> *I had a child who, I think she was scoring a six, which was quite unusual for her, and the doctors, at two in the morning, she had a low blood pressure, and he wanted us to wake her up and weigh her and do a blood sugar. But because I explained to mum that she was scoring a six and what it meant, she was all right-ish about us weighing her at two o'clock in the morning. So it did help.*
>
> Junior nurse, medical ward

Other nurses reported challenges around managing a child's temperature. Nurses described how they would attempt to reduce a child's fever by removing excess clothing and blankets only for the parent to '*swaddle'* them again. The situation was seen as particularly challenging as swaddling was perceived by parents as offering the infant comfort and protection. Nurses recited the potential for conflict if parents perceived that the nurse was straying into their role as a parent. Staff reported that this may be due to their relative inexperience with a young baby and that education on caring for a newborn baby, particularly with regards to temperature management, may be required.

Nurses also reported disagreements with senior staff over the management of children/young people who were deteriorating. The PTTS could be seen as a hindrance, particularly if senior staff had previously been called to review the child for an elevated PTTS. A low PTTS value in this scenario appeared to sometimes over-ride the nurse's judgment, despite the bedside nurses having clear concerns about the child. This led nurses to vent their frustration by labeling other staff as '*uncaring'*.

5.5.3.3 Sharing information

Nurses saw the PTTS chart as central to communicating the child's condition to other healthcare professionals and it was apparent that it was a key source of collaboration and conflict. Documenting the child's vital signs and PTTS score provided an ongoing record and was felt to create a shared language to summarise the child's progress, potentially reducing miscommunication. It gave *'structure'* to junior staff's communication with senior staff, eliminating the need to remember and recite individual observation values. Junior staff in emergency situations particularly valued this:

If you want a doctor to come and review them, instead of just … going through it all, you can just say 'their CEWS is a six, so you need to come and see them now 'cause I'm worried'. And it's a way of saying you're really concerned without … you know, going through it all.

Junior nurse, medical ward

It gives you a quick handover to a doctor or to a CSP, rather than having to go through every vital sign, you can give them a CEW score, which then alerts them to the need to be looked at and flagged

Senior nurse, medical ward

This shared language also allowed staff who were less familiar with the child to make the escalation call to the doctor or intensive care outreach team, allowing the nurse caring for the child to remain with them and their family.

Or you have to send someone else off to make the phone call because you're looking after your patient who are deteriorating, you'd need something there and the CEW score helps.

Junior nurse, surgical ward

In emergency situations, documenting the vital sign observations and the PTTS appeared to be more challenging. The need to intervene and respond to the situation was, by necessity, prioritised above the documentation of vital signs.

I think when you do have an emergency situation you can go back and look at the chart … and for two hours probably nothing was recorded because you were doing so much other stuff. So … for people that do rely on looking at charts … you're not actually recording anything. So CEWS would probably have been awful - there's nothing to say what happened at the time. So, I think in like emergency situations they're not there to be relied on because you're just not interested in writing things down on what the CEWS are, because you're just treating the patient as you see fit.

Senior nurse, surgical ward

Nurses appeared to recognise the importance of creating a record of the child,'s progress especially during a clinical emergency. However they identified that significant time could pass with no opportunity to document key vital sign observations. This was recognised as creating difficulties for people who may view the chart at a later time.

All parents expressed an interest in knowing about their child's vital sign observations. Views were mixed on whether they felt they received sufficient information. Some relied on the nursing staff keeping them informed. Others felt strongly that it would be valuable to view their child's charts, as they would be better informed and be able to assist with their child's care from the nursing staff. Children and young people expressed less interest in knowing about their own vital sign observations. These young people expressed indifference regarding their vital sign observations and PTTS scores.

> *Yeah, I understand about it all. I would've liked to know but I wouldn't-, wouldn't be that bothered about it …*
>
> Male young person, 12-years, short stay ward

> *I would like to know about the other ones* [PTTS and vital sign observations] *but the height is the most important one.*
>
> Male child, 10-years, short-stay ward

One parent felt that all parents and children should be informed about vital sign observations on admission and suggested that a leaflet explaining what they were might be helpful. Some also felt that the child should be involved more:

> *I know they're* [nurses] *very busy, but to take your observations, have them all put down, and then show the child, 'This is what you was yesterday, this is what you are today,' and help them, probably, understand more of why they have that…*
>
> Mother, daughter 9-years, medical ward

Some parents particularly valued viewing their child's observation charts independently without the need to ask a nurse. Those parents who viewed their child's PTTS chart appreciated being able to see their progress for themselves. Sometimes this resulted in questions about specific issues they noted on the chart. This type of interaction appeared to make them feel more of a partner in their child's care. However a number of parents expressed reticence about asking about the vital sign observations because they perceived this as placing an additional burden on the nurses:

It's just easy as a parent coming in and you don't have to ask anyone, they just see. I walked in and … you just see straight away and if there are any questions you just ask the nurse and they explain.

Mother, daughter 2-months, surgical ward

I think they should be at the end of the children's bed … because it's your child, and you should be able to read the child's notes … You can see what is the plan without bothering the nurses.

Mother, daughter 11-years, medical ward

I just don't want to ask, 'Oh, would you mind showing me…all the obs', you know.

Father, daughter 2-months, surgical ward

Participants in one focus group discussed the impact of parents having ready access to the PTTS charts at their child's bedside.

…they're like 'Oh what's this up here?' and you'd be like 'they were crying, they were unsettled before feeding', but the parents are like 'well he hasn't been like that before', and the parents because they start being quite "nursey", it then makes them anxious, which make you more anxious, and then the baby gets more anxious and it's a bit of a Catch 22 really.

…you like to think 'Trust me, it's cool, I've trained'. But I understand why they do it and that's fine, I'd do the same, but that can be a problem sometimes.

Junior nurse, surgical ward

The use of the word 'nursey' appeared to indicate a perception by nurses that parents were encroaching into their professional role. Although staff reported that they 'understood' why parents asked questions about their child's vital sign observations, there was a sense that these questions indicated a lack of trust in their skills and abilities.

Families also reported their frustration at the introduction of an electronic method of recording vital sign observations and it can be seen how this could become a source of conflict between parents and nurses. Some saw this as a deliberate attempt to hide the observations away so they, as parents, could not see them. Others felt this extended into nurses turning monitors towards them so that values could not be seen. This lack of transparency prevented the parent from '*keeping watch'* over their

child and stopped them making their own individual judgment and assessment of their child's condition:

> *The iPad, it feels like it's more like a secret thing. I don't want to ask, you know, 'Would you mind showing me all the information?'*
>
> Mother, daughter 2-months, surgical ward

> *So, why is it so secret? I don't understand that part…it's my child. I'd like to know what is wrong, and what you're doing, and what you're giving, and why you're giving it, and why you keep coming back in every two hours to take [my child's] observations, and then why's it changed to four-hourly? All of that, um, is never explained why. You know, and having the, the, the paperwork about your child, as much as it's not discussed as the reasons why, you can pretty much work it out for yourself, seeing it in black and white.*
>
> Mother, daughter 9-years, medical ward

Both parents characterised the use of an iPad as making the vital sign observations a 'secret'. These parents valued looking at their child's chart to reassure themselves about their condition.

In this theme, the importance of children/young people, parents and nurses working in partnership has been highlighted. The recording of vital sign observations can put this this partnership under strain, particularly when monitoring is required overnight.

5.6 Discussion

This discussion section will include a review of the findings from the interview and focus group data and discussion of these in relation to the existing body of knowledge on vital sign monitoring and PTTS in children and young people. This will be followed by a review of the strengths and limitations of this qualitative study.

None of the children, young people and parents who participated in the study were aware of the local PTTS, the CEWS, although this system had been in place for a number of years. Developing meaningful partnerships with children, young people and families has been highlighted in the safe system framework[33] as an area which requires further development. Following an explanation of the PTTS function, parents reported that they found the use of a PTTS to be reassuring and none raised concerns about its use.

The findings of this study indicate that nurses and healthcare professionals may under-estimate the effects and consequences of vital sign observations recording on children, young people and parents. Whilst the results support previous research that children and young people view vital sign observation recording as a fundamental clinical skill which they considered to be important to them,[248] they also saw it as distressing and painful. Parents perceived that nurses were sometimes inflexible regarding the scheduling of vital sign observation recording. This was echoed by senior nurses, who highlighted that the inexperience of junior nurses sometimes resulted in poor planning of care, placing an extra burden and disruption on families. The recording of vital signs at night particularly appeared to add to parental burden and disrupt sleep, which led to feelings of exhaustion and frustration. Previous studies have reported that nurses may undertake vital sign observation recording at regular times rather than responding to the needs and preferences of children, young people and families.[93,249] Parents reported particular frustration with false alarms from continuous monitoring, which when ongoing appeared to undermine their partnership with nurses, especially if they perceived that nurses were dismissive of their concerns. Parents also spoke of the need for their child to '*behave'* whilst having observations taken. This appeared to have great importance for them, not only because they recognised vital sign observations as an important way of assessing their child's progress, but also because they wanted to be perceived by staff as being a good parent with a '*well-behaved child'*. Offering choice and allowing children and young people and parents a degree of control over the recording of vital signs may mitigate the adverse effects experienced by them. This has the potential to improve relations, not only between nurses and families but also between parents and their children. Moreover, with improved compliance comes the likelihood of improved accuracy of recordings.

Child and family participation in the recognition and response to deterioration has been identified in the safe system framework[33] as an area which requires growth (Table 1.5). A relatively small number of published PTTS explicitly encourage parental participation in the PTTS by inclusion of a dedicated parameter for parental concern.[40,47,140-142,173,176,181,250] Although none have specifically reported its efficacy as a predictor of deterioration, the parameter has been cited as offering potential benefits by drawing on the skills and knowledge of the person who knows the child best.[128] Inclusion of a parental concern parameter may act a vehicle for healthcare

professionals to discuss with families the aim and function of the PTTS. As such, inclusion may have benefits in terms of increased communication regarding the PTTS with children, young people and parents.

The data support the view that vital sign observation recording requires technical expertise, high-level communication and well-developed negotiation skills. Vital sign observations underpin the calculation of a PTTS score and have traditionally been perceived as a low impact activity that is a routine part of clinical care. As such, it is often delegated to the most junior and least experienced staff[111] and this may underestimate its importance.[111,115]

Some nurses expressed frustration about the requirement to document regular vital sign observations in patients perceived as being at low risk of deterioration. This was particularly true of the short stay ward where children and young people were admitted for elective investigation. Compliance to the requirement to document a PTTS score once per shift was perceived as time consuming for nurses and anxiety provoking for parents. Similar concern has been expressed by staff undergoing a workflow evaluation on a paediatric ward in a different hospital, who identified the majority of PTTS scores as normal or low.[115]

Whilst no nurses identified PTTS as causing harm, they did identify limitations in its use. The PTTS was not felt to be helpful with certain groups of patients. Neonates were highlighted as a particular group for whom the PTTS did not work well and was largely felt to be related to 'inappropriate' vital sign parameter thresholds resulting in over-triggering and false alerts. In a recent study, the distribution of heart and respiratory rate values of 14,014 hospitalised children were compared to two previously validated PTTS. The findings indicate that 12% to 54% of heart rate values and 32% to 40% of respiratory rate values would have resulted in an elevated PTTS score using the Bedside Paediatric Early Warning System[154] and the Paediatric Early Warning Score (PEWS) [177] Given that these children were on wards outside of the paediatric intensive care unit, it is highly likely that a significant number did not indicate a patient who went on to suffer a critical deterioration event.

Challenges in PTTS use were also identified for children who had long standing conditions or altered physiology in whom baseline PTTS values remained elevated, even when the child is experiencing a period of well-being. Although there was a

mechanism to deal with this, nurses reported that it was poorly used. Findings from a previous study indicate similar problems for adult patients who falsely triggered the National Early Warning System.[78] Registrars and consultants were reported as reluctant to adjust these thresholds despite the resultant additional workload for the bedside nurse.

Nurses in this study also described feelings of conflict when they were required to repeatedly escalate patients who falsely triggered the PTTS but they assessed to be 'well'. Repeated escalations were felt to undermine their own judgment and impacted on relationships with senior clinicians and the intensive care outreach team. Continued false positives resulted in ward nurses 'accepting' high PTTS values as 'normal' for the child. Responses from the intensive care outreach team and senior clinicians were reported to re-enforce this impression. Ward nurses expressed concern about the impression this might give to junior staff.

Repeated false positive PTTS scores might be considered to merely induce alarm fatigue,[251-253] where repeated exposure to non-actionable or false alarms reduces subsequent response times.[202] Whilst the relationship between isolated false alarms and reduced response times has been demonstrated in the paediatric setting,[202] the impact of repeated falsely high PTTS values appears more complex. The inter-professional communication between the alerted senior clinician or intensive care outreach team and the bedside nurse would appear to play a significant role. Nurses in this study reported reticence at escalating elevated PTTS values if they perceived they had previously been criticised or belittled. Escalations of children/young people with persistently high PTTS values were sometimes disregarded by the intensive care outreach team. This was despite staff indicating they *'knew the child'* and had concerns about their condition. This appeared to affect intra-professional relationships as staff characterised these responses as '*rude'.* Hierarchy, culture, nursing confidence and fear of criticism have all been reported to play a role but the relationship between these and other factors is poorly understood.[83,171] It is not known whether the experience and skills of the nurse is a mitigating or aggravating factor.

The findings suggest that the PTTS may be used by different staff in differing ways. Senior staff on the more acute medical and surgical wards staff described using the

PTTS to confirm, rather than detect, the signs of deterioration. This phenomenon has been previously described in adult wards, where the documentation of vital sign observations follows, rather than precedes, an escalation call.[111] Staff may place value on other indicators of deterioration which do not form part of the PTTS. Nurses in the focus groups spoke of a 'gut instinct' that a patient is deteriorating. The incorporation of a PTTS parameter for nurse concern may be a way of addressing this issue.

Nurses highlighted a number of benefits associated with the use of a PTTS. They reported that a PTTS could facilitate the early detection of children who are deteriorating and prompt referral to senior clinicians to instigate appropriate interventions. This accords with findings from a US study where nurses and physicians identified the PTTS as alerting them to significant vital sign changes and prompting them to think critically about the possibility of deterioration.[79] Nurses also identified the benefits for junior nurses, as the PTTS provided reassurance and guidance to indicate when they should seek senior help and guidance. For senior nurses, this eased the burden of supervision and helped them to manage their workload. Similar findings have been reported by doctors and nurses in similar children's hospital in the USA.[79]

5.6.1 Limitations

This study explored the understanding and use of a PTTS in clinical practice. It was conducted in a specialist children's hospital in three selected wards. Children/young people and parent participants were, to a certain extent, self-selecting. After being approached by the direct care team, potential participants put themselves forward to be approached by the candidate to discuss the research. Participants in the focus group were selected by the ward manager using the sampling matrix developed by the candidate. The manager may, consciously or unconsciously, have selected candidates who had a particular perspective on vitals sign monitoring and PTTS use. This may have introduced bias and resulted in findings which were not representative of the wider population. As a result, findings may not be generalisable to other settings, either within the same or different hospitals. Moreover, participants in each focus group were drawn from the same ward. Group dynamics are recognised to influence the discussion. There is a potential for consensus within the group to be misinterpreted, as participants may choose to give

similar answers or withhold their views dependent on the relationship and dynamics of the group.[254] The views of one person may dominate the discussion and this can exclude important and relevant findings from other participants. However these limitations were recognised by the candidate, who made a conscious effort to ensure equal participation by all participants. Focus groups appeared dynamic, discussion was free flowing and both positive and negative reflections on vital sign monitoring and PTTS emerged.

No data were collected on children and families who were approached by the direct care team but chose not to put themselves forward for participation. This was felt to have potential to be mis-interpreted as exerting additional pressure on candidates to participate. The need to ensure participant choice and unbiased participation was prioritised although it was recognised that this may limit the findings.

Participants were predominantly female. This may reflect the lower number of male paediatric nurses and the higher proportion of mothers who are resident with their child in hospital. However male participants may have a different perspective on vital sign and PTTS recording which could affect the findings of this study.

Analysis was undertaken by the candidate, who was also a nurse. Whilst this may offer greater insight into the findings, particularly from the focus groups, it may also have introduced bias into the data collection and data analysis.[254] The views of nurses may have been afforded greater weight over those of the children/young person and family. However this was recognised as a potential limitation by the candidate and care was taken to reflect on the findings with a supervisor from a different professional background.

Due to the small number of participants it was not possible to explore whether differences exist between surgical, medical and short stay wards. Further research is required to explore these factors.

5.6.2 Strengths

This study explored the views of nurses, families, children and young people on vital sign monitoring and use of a PTTS that is used and activated exclusively by healthcare staff. This is an area where there is limited research. Greater

participation by parents and children/young people has been highlighted as central to the effective management of the deteriorating hospitalised child.[33] Exploration of their views and understanding of PTTS use may facilitate greater participation in care and strengthen the partnership between children, families and healthcare professionals. The candidate drew on her extensive nursing experience to try and build a rapport with families and quickly put them at ease, which was felt to have facilitated the production of rich data.

Data were collected from children/young people, parents and nurses from the same three wards. This offered an opportunity to compare and contrast the findings and examine the relationship between the differing participants. This may offer greater insight into the dynamics and inter-personal relationships that contribute to the delivery of care. Different data collection methods were selected to meet the needs of participants. The data collection process was flexible to reduce the burden on participants and facilitate the opportunity for participation. This resulted in a rich data set.

5.7 Conclusion

In this chapter the understanding and experiences of children, young people, parents and nurses surrounding the use of a PTTS have been explored. The findings indicate that the use of PTTS is complex. Many factors influence the success or failure in clinical practice. However greater partnership between children, young people, families and healthcare professionals appears key.

The final chapter will discuss the findings presented in this thesis and make recommendation for future research and clinical practice.

Chapter 6 Discussion

6.1 Introduction

Selected aspects around the use of paediatric track and trigger systems (PTTS) to detect critical deterioration in hospitalised children have been reported in this thesis. Aspects were selected based on the candidate's experience of implementing a PTTS in clinical practice. They represented real-world problems and challenges faced by clinicians and explored areas where the existing research was identified as limited or weak.

6.1.1 Research objectives

Four main research questions were identified:

1. What are the number, nature and characteristics of published PTTS and what is the evidence on their validity, reliability and utility?
2. Does predictive validity, assessed by calculation of the area under the receiver operator characteristic curve (AUROC), vary between differing PTTS and can the substitution of percentile-derived thresholds for heart and respiratory rate improve performance?
3. When PTTS are used in clinical practice are they reliably recorded, accurately calculated and appropriately escalated?
4. What are the views of children/young people, their families and ward nursing staff on PTTS?

6.1.2 Summary of the main findings

A systematic review of the literature using the GRADE methodology[147] was presented in chapter two. Thirty-three different PTTS were identified from 55 publications. Twenty-one were classified as scoring systems and 12 as trigger systems. All included one or more vital signs however thresholds for prompting a positive score or trigger differed. Implemented without a rapid response team, PTTS did not demonstrate a statistically significant relative reduction in cardiac or respiratory arrest, or mortality. When implemented as part of a rapid response team there was a statistically significant reduction in the relative and absolute risk of death in hospital, death on the ward and death following transfer to the paediatric

intensive care unit (PICU). There was also a significant reduction in the relative risk of cardiac and respiratory arrest on the ward. Six studies examined inter-rater reliability. Four found good to high levels with a further study demonstrating excellent inter-rater reliability at scores of three and above. Eight quantitative and two qualitative studies examined the acceptability and usefulness of PTTS to staff. No studies evaluated the acceptability of PTTS to the children and their families.

An observational study of the predictive performance of 18 PTTS was presented in chapter three. A retrospective case-control methodology was selected as this allowed simultaneous comparison between multiple PTTS. Overall 297 case events and 311 control events were identified. The predictive performance assessed by the AUROC varied from 0.62 to 0.89. The Cardiff and Vale Paediatric Early Warning System (PEWS),[137] the Bedside PEWS[154] and the Modified PEWS III[172] performed better than the other PTTS, but there were no clear defining features that explained this. Incorporation of evidence based thresholds for heart and respiratory rate[184,185] did not improve the performance of the highest ranked PTTS.

In chapter four the findings from an observation study of real-world use of PTTS by clinicians were reported. The vital signs observation sets and PTTS scores recorded for case and control patients identified in chapter three were examined for accuracy, completeness and compliance to a monitoring and escalation protocol. Whilst case patients had a greater number of observation sets recorded (8543 vs 5273), they had a lower proportion of accurately calculated PTTS scores (73.2% vs 80.9%). Only 35.9% of observations sets had all the component vital signs recorded simultaneously. Compliance to the monitoring and escalation protocol was very poor. Only 6.4% of controls and no case patients fully complied with the monitoring and escalation protocol for the entire 48-hour study period.

An exploratory study into the experiences of children/young people, their families and nurses of their perceptions and experiences of vital sign monitoring and the use of PTTS was reported in chapter five. Three themes and 10 sub-themes emerged from the data. Vital signs and PTTS monitoring were associated with *benefits and burdens* by participants. In particular, children and young people reported that recording of their vital sign observations was sometimes a painful and distressing experience. *Watchfulness and wisdom* embodied the need by parents and nurses to

watch over the child/young person and offers explanations on how they made assessments and judgments on the child's progress. Both groups identified the benefits of knowing the child/young person. *Collaboration and conflict* encompassed the impact that PTTS use sometimes has on relationships between children/young people, their families and healthcare staff. Children and young people and their parents were unaware of the local PTTS although most could understand its concept and function after it was explained to them. The importance of their participation has been emphasised in the recent the safe system report.[33]

6.1.3 Original contribution of this thesis

Findings from the four studies provided original contributions to the evidence base on PTTS:

1. A systematic review of published PTTS which highlighted 33 differing PTTS with variable validity and reliability
2. A pooled analysis of published PTTS which identified very low level evidence for PTTS implementation and moderate to low evidence for PTTS implementation as part of a package of interventions such as a rapid response system
3. A comparative analysis of validity (as assessed by the AUROC) which identified significant differences in the performance of published PTTS
4. A comparative analysis of validity which identified that modifying published PTTS with percentile-derived vital sign thresholds does not significantly improve the performance of the best performing systems
5. An evaluation of nursing practice which identified that only 35.9% of observation sets had simultaneous recording of the six components required to calculate the PTTS score
6. An evaluation of nursing practice which identified that 7.3% of observation sets had no recorded PTTS value and 19.6% had a PTTS value which was incorrect
7. An assessment of adherence to a PTTS monitoring and escalation protocol using an 'all or nothing' approach which identified that no case patients and only 6.4% of controls fully adhered to the protocol.

8. A qualitative study with junior and senior nurses, parents and children and young people which elicited their perceptions and experiences of in-patient vital sign monitoring and the use of PTTS.

6.2 Supporting and conflicting findings across the four studies

Although the findings reported in this thesis relate to four separate studies, all explore differing aspect of PTTS use in a tertiary specialist children's hospital. As such the findings from one study may help explain and enrich our understanding of another. Findings may also conflict and this may highlight areas which require further study. The following section will discuss selected findings linked by two or more of the studies.

6.2.1 Recording of vital sign observations and paediatric track and trigger system scores

In chapter five parents spoke of how vital sign observations appeared to be recorded at regular times rather than being tailored to their child's individual needs. Nurses also reported the tendency, particularly by junior staff, to record observations at regular times. Night-time recording of vital sign observations and PTTS was highlighted as an area of particular challenge for both staff and parents. Parents described how staff would come to record their child's vital sign observations after they had just settled them to sleep. Staff spoke of occasions when parents restricted the taking of observations and as such they were perceived as '*awkward'*.

The data reported in chapter four would appear to support some of these perceptions. Examination of Figure 4.8 reveals a four-hourly pattern of recording around the hours of two, six and 10 o'clock. This pattern was seen for both case (Figure 4.9) and control patients (Figure 4.10) and persisted across the individual vital sign parameters. However comparison of vital sign recording frequency for the day and night revealed no statistical difference (paragraph 4.3.2.1). These finding differ those found in adult in-patients.[93] A pattern of two large peaks in the morning and evening were noted and the frequency of vital sign observation recording was significantly lower at night. The findings of this study indicate that the challenges and conflicts identified by both parents and nurses do not appear to affect the

underlying rate of recording. It may be that these episodes are infrequent and were not present for the patients in this sample. Staff may have successfully negotiated with parents and children times to take the observations at night. Alternatively, staff may have continued to record vital sign observations despite the protestations of families.

Assessment of the frequency of vital sign recording in the hours leading up to the case patients' critical deterioration event indicated a steady increase in the frequency of recording (Figure 4.15). Nurse participants in chapter five reported increasing the frequency of observations when they detected that a child's condition was deteriorating.[83] Parents also reported requesting that vital sign observations be performed when they sensed something was 'not right' with their child. However closer examination of Figure 4.15 shows that this increase was not sustained. At around three hours before the critical deterioration event the rate of recording for vital sign parameters decreased. Nurses in the focus groups described how the need to intervene in emergency situations out-weighed the documentation of vital sign recordings, creating 'gaps' in the chart.[111] Despite recognising the importance of recording, they cautioned that PTTS charts should not be relied upon in emergency situations.

6.2.2 Escalation of elevated paediatric track and trigger system scores

Findings from chapter three indicate that the local PTTS, the CEWS, performed moderately well, with an AUROC of 0.79 (95% confidence interval [CI] 0.75-0.82). This could be considered to indicate reasonable discrimination.[201] The optimal score was identified as four (Table 3.12) with sensitivity determined to be 0.60 (95% CI 0.54 - 0.66) and specificity of 0.85 (95% CI 0.80-0.88). The subsequent response to this score for 166 case patients and 32 controls was reported in Chapter four (Table 4.9). These 32 control patients could retrospectively be labeled as 'false positives'.

Nurse participants in chapter five identified 'false positives' as a concern and certain patient groups, such as neonates, were highlighted as particularly vulnerable. The challenges of using a PTTS in this population have previously been highlighted.[255] Participants recalled occasions where patients had repeatedly attained a high score, but had not gone on to suffer a critical deterioration event. They emphasised the importance of discretion in these situations and appeared to feel that their decision

not to escalate the patient was vindicated when the patient did not go on to deteriorate. However this still represented a failure to adhere to the protocol in a significant number of patients considered to be at moderate risk of deterioration.

Full adherence to the escalation protocol for all patients would considerably increase the workload for healthcare staff. In this case-controlled study over 10% of control patients achieved a CEWS of four. If this were applied to the hospital in-patient population as a whole, a considerable number of additional repeat PTTS recordings and clinical reviews would be required. Emphasis has traditionally been placed on achieving high levels of sensitivity for PTTS. The consequential lower level of specificity has received less attention. On the surface, this appears to be the 'safe' option. However there may be unintended consequences of low specificity which leads nurses to make decisions on whether or not to escalate a patient with an elevated score. The accuracy of this decision can only be determined with hindsight. As such elimination of false positives may be equally important because of the effect this may have on compliance to the escalation protocol.

6.2.3 Errors in paediatric track and trigger system scores

In chapter four a high rate of errors in PTTS score calculation was identified. Significantly more errors were under rather than over-scored. The majority of errors were ascribed to an incorrect or missing sub-score for one or more parameters (Table 4.9). Examination of the prevalence of scoring errors at differing scores revealed significantly more errors for CEWS scores of two and above (Table 4.2). Despite having a smaller number of elevated scores, control patients had a significantly higher rate of errors for medium and high CEWS scores when compared to cases. In control patients these scores would be considered to be a false positive.

Findings from chapter five may offer some insight into the possible reasons for this. Nurse participants in one focus group described their decision-making process when faced with a vital sign parameter which sat on the border between two parameter sub-scores. They explained how they selected the vital sign parameter sub-score which most closely matched their clinical impression of the patient. If they felt the patient was 'sick' they chose the higher score. If they assessed the patient

as ‘stable’ the lower score was selected. As such they used the PTTS as a mechanism to support rather than direct their decision-making.

When examined together, these findings may indicate that the mis-calculation of a PTTS score is not just ‘random error’. Rather, it may represent a deliberate choice by nurses to select a score which matches their clinical impression of the patient. A similar phenomenon, characterised as ‘manipulation of the score’, has been reported in adult patients with Legionnaires disease.[49] This may explain the higher prevalence of under rather than over-scoring errors.[54,90]

6.3 Strengths of the thesis

This thesis explored selected aspects around the use of PTTS in clinical practice. The research questions arose from problems encountered when implementing and using a PTTS in the clinical arena. They were considered clinically important based on these real-world experiences and challenges. As such, the findings may have a high degree of utility for other clinicians.

A strength of this thesis is the inter-relationship between the findings of the four component studies This offers an opportunity to compare and contrast findings and may enrich our understanding of PTTS use in the clinical environment. The findings may also add breadth to the research on PTTS. Collaboration with children/young people and their parents on PTTS use is an area which has received very little attention.

The research explored selected aspects of an established PTTS. A significant proportion of existing research is set in the period during or shortly after PTTS implementation. Relatively little attention has been paid to how these systems develop and change over time. Findings from adult studies indicate that mature rapid response systems behave differently to novel systems.[256-258] It is therefore possible that PTTS evolve and change over time. The findings from centres with a newly established system may differ from those where the PTTS has been established for a number of years. Given that the majority of hospitals in the UK have already implemented a PTTS, the findings reported in this thesis may have greater relevance.

6.4 Limitations of the thesis

The research in this thesis was performed in a specialist children's hospital without an emergency department. Many of the children suffer from rare and life-limiting disorders and as a consequence had experienced multiple episodes of hospitalisation. As such, findings from this study may not be generalisable to other settings.

The main outcome reported in chapter three and four was critical deterioration. This was a composite outcome of respiratory and cardiac arrest, unplanned admission to the PICU (paediatric intensive care unit) and unexpected death on the ward. The majority of case patients were classified as requiring an unplanned admission to PICU. Respiratory and cardiac arrests were less frequent and no participant was classified as suffering an unexpected death on the ward. Death on the ward and arrests were recognised as a more robust outcome measure. Admission to PICU is known to be influenced by many non-patient factors: bed capacity, staffing levels and skill mix in both the PICU and the ward, clinician preference, inter-professional relationships and local protocols to cite but a few.[16,259-261] However arrests and ward deaths are rare events, and it is likely that the numbers needed to achieve statistically significant findings would have exceeded the duration of the PhD. As such the outcome was selected for pragmatic purposes, whilst bearing in mind the significant number of PTTS studies which have utilised this outcome.[59,119,137,138,154,157,161,170]

The candidate was a senior nurse in the hospital where the research was conducted and was responsible for implementing the local PTTS which was central to the studies reported in chapters four and five. Her role in implementing the PTTS was known by all senior staff and many of the research participants. All data, with the exception of two focus groups in Chapter five and the data from 20 participants in Chapter four, were collected and analysed by the candidate. Hindsight bias may have influence the classification of compliance reported in chapter four.[262] Participants in chapter five may have been aware of the candidate's role in implementing the PTTS and felt pressure to report positive, rather than negative opinions on the PTTS. Whilst care was taken to remain objective, this may have introduced bias into the studies at either the data collection or the analysis stage.

Data were collected and analysed at different times over the course of the PhD. No attempt was made to standardise care across differing wards, but differences in clinical practice may have evolved over time.

6.5 Dissemination of findings

Findings from chapter two have been published and can be seen at Appendix 12.1. Findings from Chapter three have been peer-reviewed and accepted for publication. Selected findings from chapter three have also been accepted for presentation at the European Academy of Paediatric Societies (Appendix 12.2). The results from Chapter four are currently being prepared for publication. The qualitative study in chapter five will be prepared for publication later in the year.

The results from the studies have been shared with colleagues and managers at the candidate's host hospital. Some have already been incorporated into clinical practice and this is discussed below. Findings have also been shared with colleagues with similar research interests in other institutions.

6.6 Implementation of findings into clinical practice

Selected findings reported in this thesis have already been implemented in practice.

In chapter four, high levels of incomplete recording of vital sign observation sets and PTTS calculation errors were reported. Findings were shared with senior clinicians and managers at the hospital at an early stage. Software systems which electronically capture vital sign observations, accurately calculate the PTTS and automatically cascade an alert to a senior clinician were available, however funding could not be secured as the benefits were not clear. Early findings from this study supported the procurement of such a system as the high number of missing or erroneous scores and the failure to escalate some elevated PTTS scores were considered a patient safety risk. The system was implemented across the hospital in 2014.

In chapter three the comparative validity of 18 PTTS scores was reported. Considerable variation in the predictive validity of PTTS was identified. The local PTTS, the Children's Early Warning System (CEWS), performed only moderately, ranked ninth overall (Table 3.12). Findings were shared with the Medical Director

and the Deteriorating Children committee. The Bedside Paediatric Early Warning System,[154] ranked second in the Table, (PEWS) was felt to have advantages over the Cardiff and Vale PEWS[137] (ranked first) and the Modified PEWS III[172] (ranked third): it had previously been validated in a similar clinical setting, was being used in other UK centres and was currently subject to an international multi-centre cluster-randomised controlled trial.[10] Using the optimal score threshold identified in Table 3.10, implementation of the Bedside PEWS, ranked second in the table, would have led to correct identification of 36 more children who suffered a critical deterioration event over the two-year study period. It would also have prevented 13 false alerts for children who did not suffer a critical deterioration event. The deteriorating children committee recommended moving to the Bedside PEWS as it would facilitate more accurate discrimination between 'sick' and 'stable' patients. The group also highlighted increased opportunities for future collaborative research and potential reductions in staff training, particularly for staff that join the hospital from centres already using the Bedside PEWS. Based largely on the data presented in this thesis, the committee's recommendations were accepted and are currently being implemented into practice.

6.7 Implications for clinical practice

Managing the deteriorating child is complex. Although PTTS have been purported as a means to address some of the deficiencies in managing the deteriorating child, they have not delivered the anticipated benefits in terms of improved clinical outcomes. The findings reported in this thesis may go some way towards offering an explanation.

The recent report by NHS Improvement and the Royal College of Paediatrics and Child Health emphasises the need to make improvements across a number of domains.[33] The six core elements which characterised a 'safe system' were identified (Table 1.5). The findings reported in this thesis have implications, to a greater or lesser extent, for all six elements.

6.7.1 Core element: Recognising deterioration

Chapter two identified the diversity of published PTTS. However it is highly likely that many more unpublished systems are in use. The ability of these systems to

accurately support staff in recognising deterioration is variable. Whilst the findings reported in chapter three may not be directly transferable to other settings, they do highlight that locally derived PTTS may not necessarily perform better than those which have been externally validated. A poorly validated PTTS may decrease staff confidence in the PTTS and result in unintended consequences such as the failure of staff to escalate elevated scores. Regular assessment of the predictive validity of any local PTTS remains important so users can be reassured that the system is delivering improvements in care and not harm.

6.7.2 Core element: Responding to deterioration

Responding effectively to deterioration is essential if the child is to receive the appropriate help. However PTTS may not always be acted upon as intended. Technology has been proposed as offering a means to bridge this gap. Software systems with electronic calculation of PTTS values can eradicate the scoring errors identified in chapter four.[89] Inbuilt prompts can alert staff to the need for repeat vital sign observation recordings. Escalations to senior clinicians can be automated, without the nurse needing to generate a call. Early findings have been largely positive.[263-267] However these systems may be beyond the financial reach of many centres, particularly those caring for children in a predominantly adult environment.

Audit of elevated PTTS scores may offer clinicians and managers an opportunity to evaluate the robustness of their response.

6.7.3 Core element: Partnership with patients and family

Partnership with patients and families is seen as an essential component of the system and is highlighted as 'central' to all other elements.[33]

None of the parents or children recruited to the qualitative study were aware of the local PTTS despite the system being established for a number of years. Many had been in hospital before but did not recall the system from previous admissions. Some parent's spoke of their wish to know more about when and how to escalate. Nurses also spoke of parents alerting them to indicators of potential deterioration.

Nine of 33 PTTS systems identified in chapter two had a parameter for parental concern.[40,47,140-142,158,173,176,181,183] Incorporating parental concern into the PTTS may

act as a prompt to discuss its function with parents, allowing them to participate more fully in their child's care. Studies of parental activation of a rapid response system have suggested that parents are judicious in its use and concerns regarding over-activation have not, as yet, materialised.[128,217,268]

Some parents would appear to welcome more information on PTTS. Others were more reticent. Control, choice and negotiation were highlighted by children and families as important, particularly around the method and timing of vital sign recordings. Greater attention to these may strengthen the partnership between children, families and healthcare professionals and improve relationships and compliance to the PTTS protocol.

6.7.4 Core element: Open and consistent learning

The report highlights the need to regularly measure, monitor and report on the processes around detecting and escalating deterioration.[33] The findings from chapter four reinforce the need to continually monitor processes of care and evaluate the robustness of monitoring and escalation procedures. The report also emphasises the to need triangulate information and data. This series of linked studies has demonstrated that evaluation of differing aspects of PTTS use can be beneficial in promoting our understanding of these complex systems.

6.7.5 Core element: Education and training

The report highlights the importance of involving children and families in training and education and draws attention to the challenges they may experience in raising concerns about deterioration. For staff the benefits of training and learning as a team, both immediate and cross-boundary and teams are emphasised.

Findings from chapter five would appear to support these aims. Some parents recalled how they wished they had known more about how and when to escalate their child's condition. Others reported that their knowledge on vital signs was largely self-taught. Some expressed an interest in understanding more so they could better manage their child's condition. Findings would appear to indicate that education and training for parents and children are likely to be positively received.

Relationships between the ward staff and the intensive care outreach team occasionally appeared to be under strain. Staff sometimes reported a reluctance to escalate an elevated PTTS score, as there was a perceived reluctance by senior staff to attend the patient. Others reported that they had been retrospectively criticised for failing to escalate a PTTS score in a patient who later deteriorated. Cross-boundary training may promote a greater understanding of the challenges of each other's roles and facilitate a better working relationship between differing teams. This may also promote consistent escalation of elevated PTTS scores.

6.7.6 Core element: Patient safety culture

This element highlights the need for patient, parent and family engagement, open and robust communication and broad leadership for patient safety, such as monitoring progress and setting goals.

Whilst this was not explicitly addressed within the findings of this thesis, complex interventions which involve adjustments to systems and processes, working with differing teams and professional groups, and inter-departmental working inevitably involve a shift in people's ideas, beliefs and customs.[83,253,269,270] As such, these findings adjust the patient safety culture within an organisation.

6.8 Implications for research

The limitations of the outcomes reported in chapter three and four of this thesis have been highlighted. Looking forward, there is a need to develop novel and more pragmatic outcomes for research into PTTS. Greater consensus on these outcomes may offer opportunities to increase collaborative research and increase research outputs. This would also support multi-centre research and ensure that findings can be pooled. This is especially important for areas where the numbers of children who deteriorate significantly are small, such as district general hospitals. There is an urgent need to address the lack of research in secondary care, particularly given the high numbers of children admitted to these settings. Staff in these environments may not be paediatric specialists and as such, may be less familiar with signs of deterioration in children.

There are a number of areas which would benefit from future research:

- Prospective research on the effect of PTTS on clinical outcomes particularly for centres implementing a PTTS without access to a rapid response system
- Qualitative research using ethnography to explore the clinical decision-making by nurses in relation to the recording of vital sign observations and adherence to PTTS monitoring and escalation protocols
- Prospective research to identify the characteristics of high performing PTTS in a variety of settings
- Studies to examine less invasive and more reliable methods of capturing vital sign observations and their acceptability to children, their families and clinicians
- Examination of the clinical benefits of software facilitating electronic calculation of PTTS values with automated escalation
- Research examining the calibration of validated PTTS
- Studies exploring the role that parents and children can play in detecting and escalating critical illness
- Mixed methods research exploring the relationship between validity, reliability and utility

6.9 Conclusion

The aim of this thesis was to provide practice-based research that would have real-world applicability for children, young people, families and clinicians. A systematic review of PTTS was followed by three studies examining selected aspects of validity, reliability and utility. The findings indicate that managing the deteriorating child is complex. There appears to be a relationship between validity, reliability and utility which is, at present, poorly understood. The outcome for children and young people is unlikely to be significantly altered by improving validity, reliability or utility in isolation. Benefits may be more likely to emerge if the relationship between these factors and other core elements of the safe system framework[33] are explored and better understood.

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Appendix 1 Modification of PTTS published age-ranges to facilitate comparative analysis

Paediatric Early Warning System Name, first citation	Published age ranges	Age-ranges used in the comparative analysis
Bedside PEWS[154]	0 - 3 months 3 – 12 months 1-4 years 4-12 years >12 years	*0 - <3 months* 3 - <12 months 1-4 years *> 4-12 years* >12 years
Bristol PEW tool[42]	<6 months 6-12 months 1-5 years 5-12 years >12 years	<6 months 6-12 months *1-<5 years* 5-12 years >12 years
Cardiff and Vale PEWS[137]	<1 years 1-2 years 2-5 years 5-12 years >12 years	<1 years *1-<2 years* *2-<5 years* 5-12 years >12 years
Children's Early Warning System	<1 year 1 – 4 years 5-11 years ≥ 12 years	<1 year 1 – 4 years 5-11 years ≥ 12 years
Children's Early Warning Tool[67]	<1 years 1-4 years 5-11 years >12 years	<1 years 1-4 years 5-11 years *≥12 years*

Paediatric Early Warning System Name, first citation	Published age ranges	Age-ranges used in the comparative analysis
ITAT[162]	<3 months 3-12months 1-4 years 4-12 years >12 years	<3 months 3-12months *1-<4 years* 4-12 years >12 years
MET activation criteria I[40]	Term-3 months 4-12 months 1-4 years 5-12 y >12 years	Term-3 months *4-<12 months* 1-4 years 5-12 years >12 years
MET activation criteria III[141]	Term-3 months 4-12 months 1-4 years 5-12 years >12 years	Term-3 months *4-<12 months* 1-4 years 5-12 years >12 years
Modified Bristol PEWS[169]	<3 months 3-6 months 6-12 months 1-5 years 5-12 years >12 years	<3 months *3-<6 months* 6-12 months *1-<5 years* 5-12 years >12 years
Modified PEWS I[170]	Newborn – 3 months 3 months – 2 years 2 years- 10 years > 10 years	*0 – <3 months* *3 months – <2 years* 2 years- 10 years > 10 years

Paediatric Early Warning System Name, first citation	Published age ranges	Age-ranges used in the comparative analysis
Modified PEWS II[79]	<3 months 3-<12 months 1-<4 years 4-<12 years >/=12 years	<3 months 3-12 months 1-<4 years 4-<12 years ≥12 years
Modified PEWS III[172]	0 - 3 months 3 – 12 months 1-4 years 4-12 years >12 years	*0 - <3 months* 3 - <12 months 1-4 years *> 4-12 years* >12 years
NHSI PEWS[173]	0-11 months 1-4 years 5-12 years 13-18 years	0-11 months 1-4 years 5-12 years 13-18 years
PEW score III[176]	Neonate 1-11 months 1-2 years 3-4 years 5-7 years 8-11 years 12-15 years male 12-15 years female >15 years male >15 years female	Neonate 1-11 months 1-2 years 3-4 years 5-7 years 8-11 years 12-15 years male 12-15 years female >15 years male >15 years female

Paediatric Early Warning System Name, first citation	Published age ranges	Age-ranges used in the comparative analysis
PEW score IV[177]	0 – 1 month 1-12 months 13 months – 3 years 4-6 years 7-12 years 13-19 years	0 – 1 month <1-12 months 13 months – 3 years 4-6 years 7-12 years 13-19 years
PEW system score I[138]	<3 months 3-12 months 1-4 years 4-12 years >12 years	<3 months *3-<12 months* *1-<4 years* 4-12 years >12 years
PMET triggers[181]	Term-3 months 4-12 months 1-4 years 5-12 years >12 years	Term-3 months *4-<12 months* 1-4 years 5-12 years >12 years
THCS MET calling criteria [183]	Term-3 months 4-12 months 1-4 years 5-12 years >12 years	Term-3 months *4-<12 months* 1-4 years 5-12 years >12 years

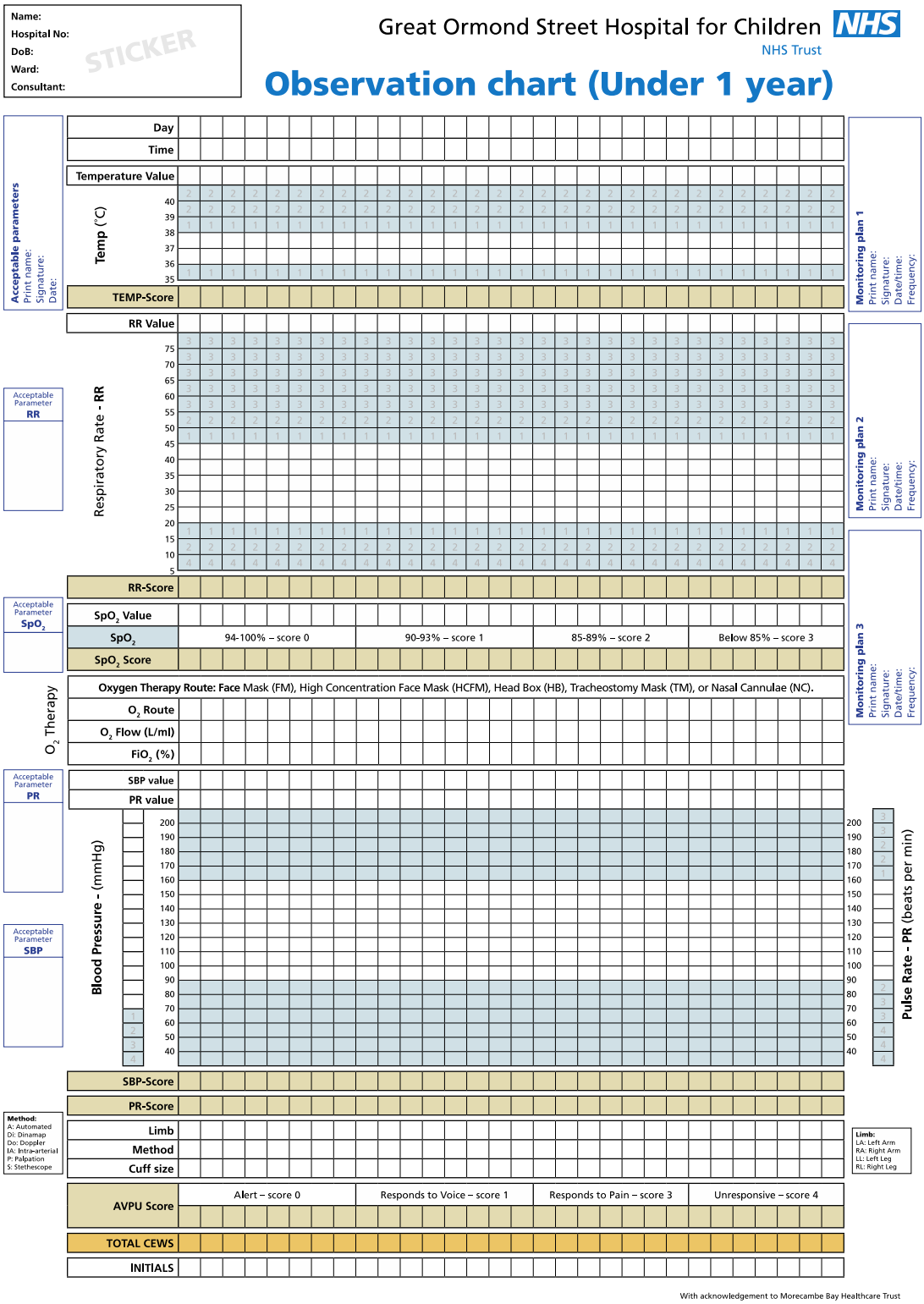
Key: Age-ranges that were modified are presented in *italics*

Appendix 2 Children's Early Warning Score (CEWS)

Appendix 2.1 Thresholds for CEWS

	Age range	Score								
		4	3	2	1	0	1	2	3	4
Heart rate	<1 year	<60	60-79	80-89		90-160	161-170	171-190	>190	
	1 – 4 years	<70	70-79		80-89	90-140	141-160	161-180	>180	
	5-11 years	<60		60-69	70-89	90-130	131-150	151-170	>170	
	≥ 12 years	<50		50-59	60-69	70-120	121-130	131-160	161-190	>190
Respiratory rate	<1 year	<10		10-14	15-19	20-45	46-50	51-55	> 55	
	1 – 4 years	<5		5-9	10-14	15-35	36-40	41-50	>50	
	5-11 years	<5		5-9	10-14	15-30	31-40	41-50	>50	
	≥ 12 years	<5		5-9	10-14	15-25	26-30	31-40	41-50	>50
Systolic blood pressure	<1 year	<40	40-49	50-59	60-69	≥ 70				
	1 – 4 years	<50	50-59	60-69	70-79	≥ 80				
	5-11 years	<50	50-59	60-69	70-89	≥ 90				
	≥ 12 years	<60	60-69	70-79	80-89	≥ 90				
Temperature	All				<36.0	36.0-38.0	38.1-39.0	>39.0		
Oxygen saturation	All					94-100%	90-93%	85-89%	<85%	
AVPU	All					A	V		P	U

Appendix 2.2 Example of CEWS chart for infant under one year



Name:
Hospital No:
DoB:
Ward:
Consultant:
STICKER

Great Ormond Street Hospital for Children NHS
NHS Trust

Observation chart (Under 1 year)

Acceptable parameters
Print name:
Signature:
Date:

Day
Time
Temperature Value
Temp (°C)
TEMP-Score

Monitoring plan 1
Print name:
Signature:
Date/time:
Frequency:

RR Value
Respiratory Rate - RR
RR-Score

Acceptable Parameter RR

Monitoring plan 2
Print name:
Signature:
Date/time:
Frequency:

Acceptable Parameter SpO2

SpO2 Value
SpO2
SpO2 Score

94-100% – score 0
90-93% – score 1
85-89% – score 2
Below 85% – score 3

Monitoring plan 3
Print name:
Signature:
Date/time:
Frequency:

O2 Therapy
Oxygen Therapy Route: Face Mask (FM), High Concentration Face Mask (HCFM), Head Box (HB), Tracheostomy Mask (TM), or Nasal Cannulae (NC).
O2 Route
O2 Flow (L/ml)
FiO2 (%)

Acceptable Parameter PR

SBP value
PR value
Blood Pressure - (mmHg)
Pulse Rate - PR (beats per min)

Acceptable Parameter SBP

SBP-Score
PR-Score

Method:
A: Automated
DI: Dinamap
Do: Doppler
IA: Intra-arterial
P: Palpation
S: Stethescope

Limb
Method
Cuff size

Limb:
LA: Left Arm
RA: Right Arm
LL: Left Leg
RL: Right Leg

AVPU Score
Alert – score 0
Responds to Voice – score 1
Responds to Pain – score 3
Unresponsive – score 4

TOTAL CEWS
INITIALS

With acknowledgement to Morecambe Bay Healthcare Trust

Appendix 3 The Children's Early Warning Score escalation algorithm

Children's Early Warning Score (CEWS) Action to be taken when a patient scores:	
0-1	No action needed
2	Report CEWS to **nurse-in-charge** Repeat observations within 30 minutes After 30 minutes if score still 2 inform **nurse-in-charge** and **Registrar**
3-4	Inform **Registrar** to review the patient Repeat observations within 30 minutes, agree monitoring plan, consider adjusting parameters If no improvement after 30 minutes inform the **CSP** (bleep 0313)
5-6	Inform **Registrar** and **CSP** with recommendation (SBARD) to attend
7+	Inform **Registrar** and **CSP** with recommendation (SBARD) to attend within **15 minutes**

If there is concern about the clinical condition of the patient at any time consider placing a 2222 call regardless of the CEWS

Appendix 4 Search strategy

Appendix 4.1 AMED: 27th May 2016

Search number	Search term	Search field	Result
1	Intensive Care Unit	Explode	0
2	Intensive Care	Explode	149
3	Critical illness	Explode	74
4	Emergency service, hospital	Explode	0
5	Emergency Medical Services	Explode	272
6	Acute disease	Explode	1747
7	“track”	Map term	484
8	“trigger”	Map term	682
9	7 and 8		1
10	1 or 2 or 3 or 4 or 5 or 6		2204
11	“rapid response”	Map term	25
12	Early warning	Map term	17
13	9 or 11 or 12		43
14	10 and 13		1
15	Limit 14 to “child” subjects		0
16	Limit 15 to 1990 – 2015.(sa_year)		0

Appendix 4.2 CINAHL Plus: 27th May 2016

Search number	Search term	Search field	Result
1	“early warning”	Abstract	686
2	“rapid response’	Abstract	1206
3	medical emergency team”	Abstract	224
4	“critical care outreach”	Abstract	66
5	“track”	Abstract	4873
6	“trigger”	Abstract	6874
7	5 and 6	All	43
8	1 or 2 or 3 or 4 or 7, limit to all infant/child/adolescent and dates: 1990 - 2015	All	208

Appendix 4.3 Cochrane: 27th May 2016

Search number	Search term	Search field	Result
1	“early warning”	Title, abstract, key words	146
2	“track and trigger”	Title, abstract and key words	7
3	“rapid response”	Title, abstract and key words	248
4	“critical care outreach”	Title, abstract and key words	7
5	“medical emergency team”	Title, abstract and key words	18
6	child	Title, abstract and key words	87890
7	1 or 2 or 3 or 4 or 5		409
8	6 and 7, limit to 1990-present		61

Appendix 4.4 Embase search: 27th May 2016

Search number	Search term	Search field	Result
1	Intensive Care Unit	Explode	107477
2	Intensive Care	Explode	544019
3	Critical illness	Explode	23988
4	Emergency service, hospital	Explode	77948
5	Emergency Medical Services	Explode	77948
6	Acute disease	Explode	94473
7	“track”	Map term	45384
8	“trigger”	Map term	86632
9	7 and 8		313
10	1 or 2 or 3 or 4 or 5 or 6		774492
11	“rapid response”	Map term	6127
12	Early warning	Map term	5166
13	9 or 11 or 12		11328
14	10 and 13		2407
15	Limit 14 to “child” subjects		210
16	Limit 15 to 1990 – 2015.(sa_year)		201

Appendix 4.5 OVID medline: 27th May 2016

Search number	Search term	Search field	Result
1	Intensive Care Unit	Explode	63429
2	Intensive Care	Explode	47573
3	Critical illness	Explode	20013
4	Emergency service, hospital	Explode	56973
5	Emergency Medical Services	Explode	107287
6	Acute disease	Explode	195927
7	“track”	Map term	33896
8	“trigger”	Map term	65363
9	7 and 8		193
10	1 or 2 or 3 or 4 or 5 or 6		404346
11	“rapid response”	Map term	4224
12	Early warning	Map term	3683
13	9 or 11 or 12		7958
14	10 and 13		906
15	Limit 14 to “child” subjects		100
16	Limit 15 to 1990 – 2015.(sa_year)		94

Appendix 5 Quality assessment

Appendix 5.1 Diagnostic testing studies

STUDY	RISK OF BIAS				Overall risk of bias
	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW/ TIMING	
Agulnik[160]	☹	☹	☺	☹	☹
Akre[177]	☹	☹	☹	☺	☹
Duncan[138]	☹	☹	☹	☹	☹
Edwards 2009[137]	☺	☺	☺	☺	☺
Edwards 2011[164]	☺	☺	☺	☺	☺
Fenix[175]	☺	☹	☺	☺	☹
Fuijschot 2014[172]	☹	☹	☹	☹	☹
Gawronski[157]	☹	☹	☺	☹	☹
Haines[158]	☹	☹	☹	☹	☹
Mandell[186]	☹	☺	☺	☺	☹
Mason[174]	☺	☺	☺	☺	☺
McLellan[162]	☹	☹	☺	☺	☹
Olson[154]	☹	☹	☺	☹	☹
Parsharum 2009[116]	☹	☹	☺	☺	☹
Parsharum 2011[121]	☹	☺	☺	☺	☹
Robson[170]	☹	☹	☹	☺	☹
Skaletsky 2012[144]	☹	☹	☺	☺	☹
Tucker[59]	☺	☺	☺	☺	☹
Tume[59]	☹	☹	☺	☹	☹

Key: ☺Low Risk ☹High Risk ? Unclear Risk

Appendix 5.2 Observational studies

Study	RISK OF BIAS					Overall Risk of Bias
	Lack of allocation concealment	Failure to develop and apply eligibility criteria	Flawed measurement of exposure and outcome	Inadequate control of confounding	Inadequate/ incomplete follow-up	
Anwar-ul-Haque[179]	☹	☺	☺	?	☺	☹
Bell[182]	☹	☹	?	☹	☺	☹
Bonafide[168]	☺	☺	☺	☺	☺	☺
Bonafide[155]	☺	☺	☺	☺	☺	☺
Brady[84]	☺	☺	☺	☺	☺	☺
Brilli[142]	☺	☺	☺	☺	?	☺
Demmel[176]	?	?	☹	☹	?	☹
Ennis[173]	☺	☹	☹	☹	?	☹
Hanson[152]	☺	☺	☺	?	☺	☺
Henderson[178]	☹	☹	☹	☹	☹	☹
Hunt[139]	☺	☺	☺	☺	☺	☺
Kinney[163]	☹	☹	☹	☺	☺	☹
Kotsakis[181]	☺	☺	☺	☺	☺	☺
Krmpotic[165]	☹	☹	☹	?	☺	☹
Lobos[167]	☹	☺	☹	☺	☺	☹
McKay[67]	☺	☹	☹	☺	☺	☹
McLellan 2014[158]	☺	☹	☺	☹	☹	☹

Study	RISK OF BIAS					Overall Risk of Bias
	Lack of allocation concealment	Failure to develop and apply eligibility criteria	Flawed measurement of exposure and outcome	Inadequate control of confounding	Inadequate/ incomplete follow-up	
Monaghan[39]	?	☹	☹	☹	☹	☹
Panesar[180]	☹	☺	☹	☹	☺	☹
Parsharam 2011[119]	☺	☺	☺	☺	☺	☺
Rahman[159]	☺	☹	☹	☹	☺	☹
Randhawa[118]	☹	☹	☹	☹	☹	☹
Sefton[169]	☺	☺	☹	☺	☺	☹
Sharek[143]	☺	☺	☺	☺	☺	☺
Skaletzky 2009[48]	☹	☹	☹	☹	☹	☹
Tibballs 2005[40]	☹	☺	☹	☹	☺	☹
Tibballs 2009[141]	☹	☺	☹	☹	☺	☹
Van Voorhis[126]	☹	☹	☹	☹	☹	☹
Watson[115]	☹	?	☹	☹	☹	☹
Zenker[153]	☹	☺	☺	☹	☺	☹

Key: ☺Low Risk ☹High Risk ? Unclear Risk

Appendix 5.3 Qualitative studies

Study	Design appropriate	Recruitment strategy appropriate?	Data collection appropriate?	Researcher-participant relationship	Ethical issues	Rigorous data analysis?	Clear findings	Value of the research	Overall risk of bias
Bonafide[79]	☺	☺	☺	☺	☺	☺	☺	☺	☺
Brady 2014[83]	☺	☹	☺	☺	☺	☺	☺	☺	☺
Roberts 2014[171]	☺	☺	?	☺	☺	☺	☺	☺	☺

Key: ☺Low Risk; ☹High Risk ? Unclear Risk

Appendix 6 Research Ethics Committee permission

NRES Committee South Central - Oxford B
Whitefriars
Level 3, Block B
Lewin's Mead
Bristol
BS1 2NT

Telephone: 0117 3421391
Fax:

08 January 2015

Dr Jo Wray
Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London
WC1N 3JH

Dear Dr Wray

Study title:	**Improving the detection of critical deterioration in hospitalised children: what do children and young people think about vital sign monitoring and early warning systems?**
REC reference:	**14/SC/1445**
Protocol number:	**1**
IRAS project ID:	**123276**

Thank you for your submission dated 7th January, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Elizabeth Hearn, nrescommittee.southcentral-oxfordb@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper [Letter to REC]	1.0	18 November 2014
Covering letter on headed paper [Letter to REC]	2	17 December 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2014-2015 Insurance certificate]	1	01 August 2014
Interview schedules or topic guides for participants [Interview schedule Parents]	1	01 August 2014
Interview schedules or topic guides for participants [Interview schedule children and young people interviews]	1	01 June 2014
Interview schedules or topic guides for participants [Interview schedule child draw and write session]	1	01 June 2014
IRAS Checklist XML [Checklist_05122014]		05 December 2014
IRAS Checklist XML [Checklist_05012015]		05 January 2015
Other [Mark Peters UCL Jan 2014 MJP CV]	1	01 January 2014
Other [Tertiary supervisor CV Kate Oulton 2013]	1	31 December 2013
Other [Appendix 1 Overall PhD proposal summary]	1	15 August 2014
Other [Screen shot of question B1]	1	24 December 2014
Participant consent form [Consent form for parents/guardians]	1.1	17 December 2014
Participant consent form [Consent form (Parents of child participants)]	1.1	17 December 2014
Participant consent form [Assent form (Child participants)]	1.1	17 December 2014
Participant information sheet (PIS) [Information sheet (4-8 years old)]	1.0	01 November 2014
Participant information sheet (PIS) [Information sheet (Parents)]	1.1	17 December 2014
Participant information sheet (PIS) [Information sheet (Child 8-18 years)]	1.1	17 December 2014
REC Application Form [REC_Form_05122014]		05 December 2014
Research protocol or project proposal [Vital signs interviews proposal]	1	01 August 2014
Summary CV for Chief Investigator (CI) [Jo Wray Short CV]	1	01 May 2014
Summary CV for student [Short CV Susan Chapman]	1	01 July 2014
Summary CV for supervisor (student research) [Jo Wray Short CV]	1	01 May 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/SC/1445	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Chair

Email: nrescommittee.southcentral-oxfordb@nhs.net

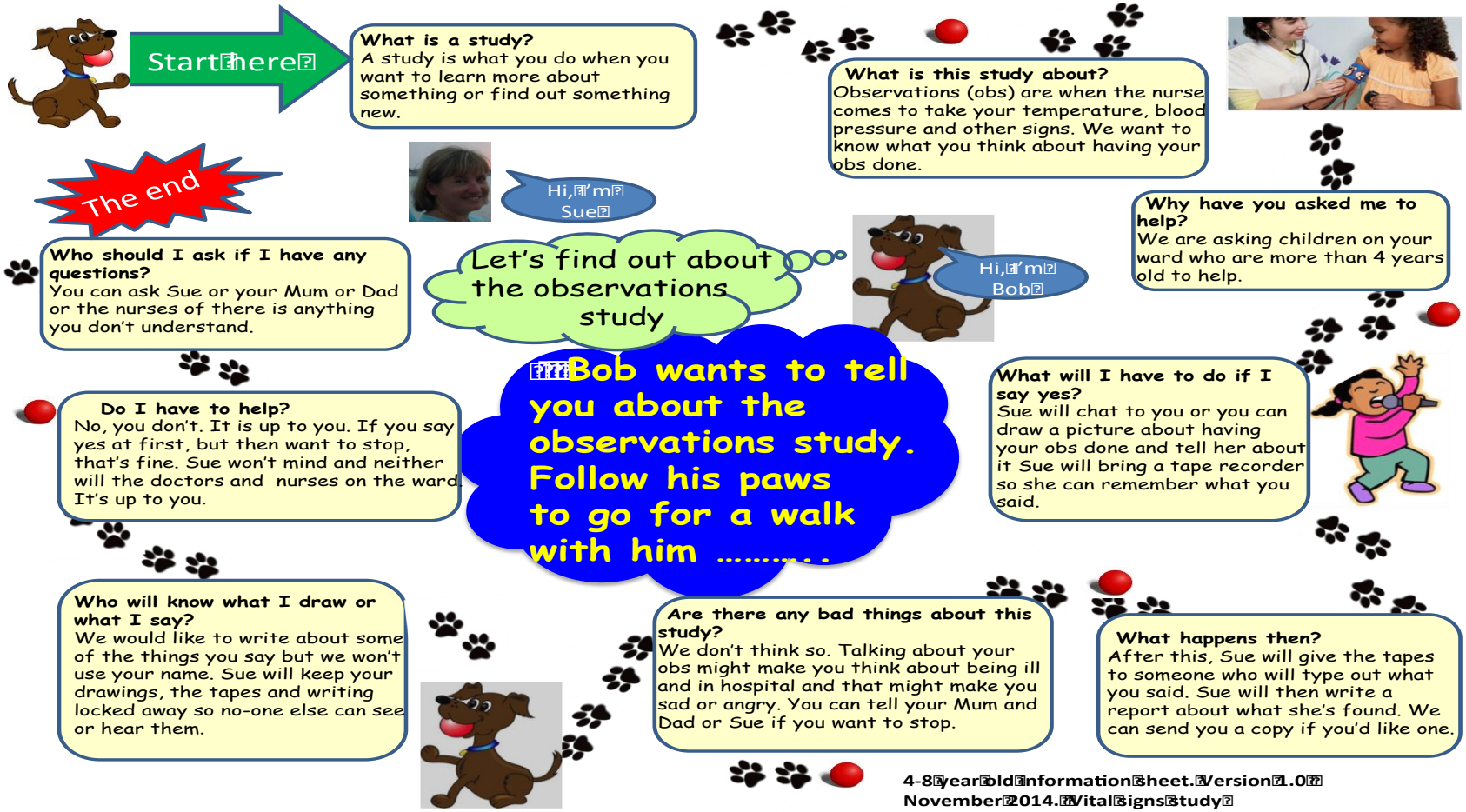
Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Ms Emma Pendleton*

Dr Thomas Lewis, UCL Institute of Child Health

Appendix 7 Information leaflets

Appendix 7.1 Leaflet for children aged four to eight years



Appendix 7.2 Leaflet for children/young people over the age of eight years

Q: What will Sue do with the tapes afterwards?
A: When the study has finished, Sue will make sure that the tapes are destroyed so no-one can hear what you said.

Q: What about afterwards? Will anyone be able to tell from Sue's writing that she was talking to me?
A: Sue will be really careful to make sure that no-one can tell it was you she was speaking to.

Q: What happens when the study has stopped?
A: Sue will write to you and your Mum and Dad to let you know what she found out.

Q: Do I have to help?
A: No, you do not have to say yes. It is up to you and your Mum and Dad whether you say yes. If you say yes at the beginning, but decide later you don't want to take part, you can change your mind. Sue won't mind and neither will the doctors and nurses on the ward. Its your choice.

Q: What should I do now?
A: Now you have read about the study, you need to think about whether you want to take part or not. You can talk with other people about it….your Mum and Dad, friends, or the nurses and doctors.

Q: How should I tell Sue if I want to take part?
You can tell your Mum or Dad that you want to talk with Sue or not. Sue will come and speak to them later. If you don't want to take part, that's fine. If you do want to take part, that's also fine. Its your choice.

Q: If I have some more questions, what should I do?

A: You can ask your Mum or Dad. Or you can ask the nurses to get in touch with Sue. She can come back to see you when you are ready and feel well enough to talk to her.

If you want to talk to someone else you can talk to your nurse or doctor or see the PALS (Patient Advice and Liaison) team.

My name is Sue

My telephone number is:
020 7813 8374

My e-mail address is:
Sue.Chapman@gosh.nhs.uk

Great Ormond Street Hospital for Children NHS
NHS Foundation Trust

What do children and young people in hospital and their families think about having vital sign observations taken?

Information leaflet

For children and young people over the age of 8 years

Version 1.1 December 2014
Information sheet for children and young people

We would like to invite you to take part in a study on what children and young people in hospital and their families think about having their vital sign observations taken.

Q: What is a study?
A: A study is what you do when you want to learn more about something or find out something new

Q: What is the observations study about?
A: Observations (obs) are when the nurse comes to take your temperature, blood pressure, pulse and other signs. We do this so we can watch out for signs that you might be getting sicker or so we can tell if you are getting better. Although we do these a lot, we haven't studied what you think about having this done. We want to know what you think about having your obs done.

Q: Who will be in the study?
A: We are talking to other children who are in hospital, Mums and Dads and nurses too.

Q: Who will be in charge of the study?
Sue is in charge of the study. Sue is a nurse, but she is also studying at the University College London Institute of Child Health, which is next door to the hospital. This study is part of her learning, a bit like when you have to learn something new for a test at school.

Q. Why have you asked me to help?
A: We want to talk with 9-15 children who are in hospital at GOSH and who are between 4 and 16 years old. You fit in here, so that is why Sue would like to speak with you.

Q. What will I have to do if I agree to take part?
If you agree to take part, Sue will arrange to come and chat to you whilst you are in hospital. Sue will come at a time that suits you and when you are feeling well enough to talk. Your Mum and Dad can be with you if you want and can also stay while you chat.

When you feel ready, Sue will ask you some questions or get you to talk about what it is like when the nurses take your obs. Sue will tape your talk so she can later write down what you said. If you prefer, you can draw Sue a picture to explain what its like for you.

Q:.How long will the study last?
A: Sue will speak to you this one time. She won't come back unless you ask to speak to her.

Q: What happens then?
A: After you have finished talking, Sue will give the tapes to someone who will type out what you said. This person will not know your name or who you are. When they have finished typing what you said, they will give the tapes and the writing back to Sue.

Q: How will joining in help me or other children?
A: Joining in may not help you directly, but it will help us understand what it is like for you when the nurses take your obs. We can then use this information to make sure we take obs in the best way possible for children like you.

Q: Can anything bad happen in the study?
We don't think so. You may think about the obs you have taken or how it feels when you are ill. You might ask the nurses more about taking the obs and that is fine. If you want to talk about anything else that is worrying you, that is fine.

Q: Who will know if I say yes to joining the study?
Only Sue and her three supervisors will know you are taking part. You can, of course, tell anyone you like about the study.

Q: Who will see the information I give or hear what I talk about?
A: Sue will get someone to type out everything you say on the tapes. This person knows that it is important not to talk to other people about what you and Sue said. After that, only Sue will listen to the tapes of you talking.

Sue will keep the tapes and the writing in a cabinet that is locked inside her office, which is also locked. So everything will be kept safe and secure and only looked at by Sue and her supervisors.

Appendix 7.3 Leaflet for families

Q: Will the information I give be kept confidential?

A: What you and your child say during the interview will be treated very carefully. All information will be kept in a secure office in a locked filing cabinet. You and/or your child will be given a unique research code number known only to the lead researcher and all information will be anonymysed. The tapes will be transcribed by a professional health research transcription service and erased at the end of the study.

Q: What will happen to the results of the study?

The results of the study will form part of the lead researcher's PhD. They will also form part of an internal report which will be published on the GOSH website. The results will also be published in a scientific journal and presented at a healthcare conference. In all instances, you and your child's details will be anonymysed. If you wish to receive details of publications and presentations, you will be asked permission for the researcher to hold your personal details on file so you can be contacted when the research is published or presented.

Q: Who has reviewed the study?

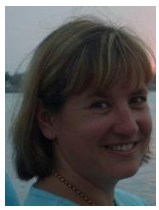
The study has been reviewed and approved by a research ethics committee as well as the Research and Innovation department at GOSH.

Q: If I have some more questions, what should I do?

A: You can discuss the research with a member of your clinical care team or contact the researcher directly. She will be happy to attend the ward and discuss any aspect of the study with you. Her contact details can be found below.

The PALS team are also available to discuss any aspects of the study in confidence.

Sue Chapman—Lead researcher



Telephone number:
020 7813 8374

E-mail address:
Sue.Chapman@gosh.nhs.uk

Great Ormond Street Hospital for Children NHS
NHS Foundation Trust

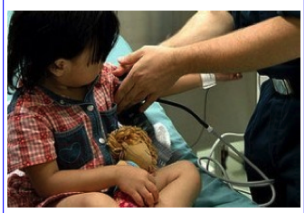
What do children and young people in hospital and their families think about having vital sign observations taken?

Information leaflet for families

Version 1.1 December 2014
Information sheet for families of children and young people

We would like to invite you and your child to take part in a research study on what children and young people in hospital and their families think about having their vital sign observations taken.

Q: What is the study about?
A: This study is looking at what children and young people in hospital and their families think about having their vital sign observations taken. Vitals sign observations include temperature, blood pressure, heart rate and other similar recordings that are used to monitor children's progress whilst in hospital. Although they are taken frequently, we know little about what children and their families think and feel about having them taken.



Q: Who will be in the study?
A: We are recruiting children who are in hospital, and their families. A related study is also conducting focus group interviews with nurses about their experiences of taking the observations of children.

Q: Who is in charge of the study?
The lead researcher, Sue Chapman, is an experienced paediatric nurse who is studying for a PhD at the UCL Institute of Child Health, The study will be overseen by three supervisors who are all experienced health care researchers.

Q. What will I have to do if I agree to take part?
We want to conduct interviews with children/young people and parents about their experiences of vital sign observations.

Parents will take part in a short interview with a researcher. Children/young people will be offered the choice of participating in an interview or a 'draw and write' session. Draw and write is a technique which has been successfully used in research with children. The child will be asked to draw a picture of what it is like when they have their vital signs taken. The researcher will then discuss the picture with them.

Both the interviews and drawing sessions will be recorded and later transcribed and analysed.

Interviews will take place at a time of you and/or your child's choosing and will take approximately 20-30 minutes. If you or your child are interested in participating, the lead researcher will visit and explain in more detail about the study.

Q: Should I take part?
It is entirely your decision whether you or your child take part in the study. If you do decide to take part you will be given this information leaflet to keep and be asked to sign a consent form. If you decide to allow your child to participate, they will be informed about the study, provided with age-appropriate information and asked to sign an assent form. You will be asked to consent to their participation and sign the assent form. If your child does not want to participate, they will not be entered into the study, even if you consent to their participation.

Q: What are the benefits to me or my child?
A: Participating may not help you directly, but it will help us understand what it is like for you as a parent and your child when the nurses take vital sign observations. We can then use this information to make sure we take observations in the best way possible in the future.

Q: What are the potential disadvantages or risks of taking part?
We believe the risks and disadvantages or taking part are minimal. Participation in the study may stir up unpleasant or distressing memories for you or your child. If you have any questions or concerns, the researcher is happy to discuss these with you before you decide whether you or your child would like to take part.

Q: What if something goes wrong?
As the research just involves you and/or you child talking to the researcher, there is very little to go wrong. If you wish to talk to your family or clinical care team about the research, you are free to do so.

Appendix 8 Consent forms

Appendix 8.1 Parent/guardian of chid/young person participants

Great Ormond Street Hospital for Children NHS Foundation Trust

Consent form for parents/guardians of child/young people participants

Study title: What do children and young people in hospital and their families think about having vital sign observations taken?

		Please initial inside the box
1	I confirm that I have read and understood the information sheet for the study titled above and have had the opportunity to ask questions and have had these answered satisfactorily.	
2	I confirm that I have had sufficient time to consider whether or not I want my child to take part.	
3	I understand that my participation is voluntary and that I am free to withdraw my child at any time, without giving reason, without my child's medical care or legal rights being affected	
4	I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from UCL Institute of Child Health, regulatory authorities and Great Ormond Street Hospital. I give permission for these individuals to have access to my child's records.	
5	I agree to data about myself being collected and securely held by the research team at Great Ormond Street Hospital and UCL Institute of Child Health.	
6	I understand that any direct quotations from interview between the researcher and my child will be completely anonymous and confidential, and I agree that quotations can be used in professional publications, reports and academic studies.	
7	I agree to my child's taking part in the above study	

_____ _____ _____
Full name of parent/guardian Date Signature

_____
Full name of child

_____ _____ _____
Full name of researcher Date Signature

When completed, 1 copy for parent, original for researcher file

Study title: What do children/young people in hospital and their families think about having vital sign observations taken?
Consent form (parents) December 2014 version 1.1

Appendix 8.2 Assent form for children and young people

Patient Assent Form

What do children and young people in hospital and their parents think about having their observations done?

Tick the yellow box ☐ if you agree

I have read the information sheet ☐

I was able to ask questions about the study ☐

I was told what I wanted to know ☐

All my questions have been answered ☐

I know I can stop the study anytime and it won't make a difference to how the nurses or anyone else looks after me ☐

I know that Sue is going to tape record our talk ☐

To be completed by both the child and the parent/guardian

I/We agree to take part in the study

.....sign

.....name

.....sign

.....name

Date.....

To be completed by the researcher

.....name

Signed by the researcher

.....

Date.....

Enter the allocated participant number ☐

Appendix 8.3 Parent/guardian participants

Great Ormond Street Hospital for Children NHS Foundation Trust

Consent form for parents/guardians

Study title: What do children and young people in hospital and their families think about having vital sign observations taken?

		Please initial inside the box
1	I confirm that I have read and understood the information sheet for the study titled above and have had the opportunity to ask questions and have had these answered satisfactorily	
2	I confirm that I have had sufficient time to consider whether or not I want to take part	
3	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason, without my child's medical care or legal rights being affected	
4	I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from UCL Institute of Child Health, regulatory authorities and Great Ormond Street Hospital. I give permission for these individuals to have access to my child's records.	
5	I agree to data about myself being collected and securely held by the research team at Great Ormond Street Hospital and UCL Institute of Child Health	
6	I understand that any direct quotations from questionnaires and/or interview between the researcher and me will be completely anonymous and confidential, and I agree that quotations can be used in professional publications, reports and academic studies.	
7	I confirm that if I decide to stop taking part in the study any questionnaires or interviews I have already been involved in will be included in the study unless I ask for them to be withdrawn.	
8	I agree to take part in the above study	

_____	_____	_____
Full name of parent/guardian	Date	Signature
_____	_____	_____
Full name of researcher	Date	Signature

When completed, 1 copy for parent, original for researcher file

Study title: What do children/young people in hospital and their families think about having vital sign observations taken?
Consent form (parents) December 2014 version 1.1

Appendix 8.4 Focus group participants

Dear colleague

We are working on improving the care of the deteriorating child across GOSH and your ward has agreed to participate as a pilot site. Vital sign monitoring is an essential part of detecting deterioration in children but little is known about nurses perceptions of vital sign monitoring and CEWS.

To increase our understanding and improvement our current system we would like to invite you to participate in a focus group on vital sign monitoring and CEWS. The focus group will be recorded and then transcribed and analysed. You will be provided with a summary of the overall findings.

Your participation in this focus group is voluntary and you can withdraw from the group at any time. By participating today, you are giving your consent for the recording and analysis of this interview.

Your personal details will not be divulged and the findings will be anonomysed. The details below will be used to assess any differences between registered/non-registered staff and senior/junior staff.

Name_____ Band_____

If Registered Nurse, years since qualifying_____

If Healthcare Assistant/Clinicians Assistant, years working as HCA/CA_____

Years working on Rainforest ward_____

I understand that this interview will be recorded and I give my consent.

Signature

Appendix 9 Interview and focus group question schedules

Appendix 9.1 Interview schedule: younger children

Great Ormond Street Hospital for Children NHS Foundation Trust

What do children and young people in hospital and their families think about having vital sign observations taken?

Interview schedule: Draw and write session

Equipment:
Blood pressure cuffs
Tempadots
ECG electrodes
Vital sign monitoring charts
Pens, pencils, crayons and paper

Preparation:
Allow the child to play with the vital sign monitoring equipment to familiarise themselves with it. When they are ready, proceed into the session.

Draw and write session:
Can you draw me a picture of what it is like when you have your vital sign observations taken?

Probes:
Tell me about what you have drawn here?
How does that make you feel?

What do children and young people in hospital and their families think about having vital sign observations taken?

Draw and write session interview schedule (child) Version 1, June 2014

Appendix 9.2 Interview schedule: older children

Great Ormond Street Hospital for Children NHS Foundation Trust

What do children and young people in hospital and their families think about having vital sign observations taken?

Interview schedule: Child/young people interviews

I would like to ask you about what it is like having vital sign observations taken. By vital sign observations I mean things like temperature, pulse, blood pressure and breathing rate that nurse take.
[Explanation will be supported by the equipment used to take vital signs such as blood pressure cuffs, tempadots and vital sign charts].

1. Tell me what it is like having your vital signs taken?

2. Why do you think nurses and doctors take your vital sign observations?

3. And when nurses take your vital sign observations, do they tell you what they found?
   Probe: Why do you think they do/do not?
   Probe: What would you like to know about your observations?

4. Do the nurses show you your observation chart?
   Probe if no: Would you like them to show you?
   Probe if yes: What do you look at?

5. If the nurse monitors your vital signs more often than before, how does that make you feel?

6. Are there any times when the nurses have come to take your vital sign observation and you don't want them to?
   Probe: Can you tell me about that?

7. Do the nurses take your vital sign observations at night?
   Probe: If yes, what is it like? Does it ever wake you up?

8. Have you heard of the Children's Early Warning Score?
   Probe: If the answer is yes, can you tell me about it?
   Probe: If the answer is no: The children's early warning score or CEWS is a tool to help nurses and doctors monitor how you are doing. After they have take your vital sign observations, the nurses give each vital sign a score. All the vital sign observations scores are then added up and this is the CEWS. If the score is 2 or above,

the nurses will come and take your vital signs more often, to keep an eye on how you are doing.

What do you think about the CEWS?
Probe: Does using the CEWS worry you?

9. Is there anything else you would like to tell me about vital sign monitoring or CEWS that you think I should know to make it better for you or other children?

Appendix 9.3 Interview schedule: parents

Great Ormond Street Hospital for Children NHS Foundation Trust

What do children and young people in hospital and their families think about having vital sign observations taken?

Interview schedule: Parent interviews

1. First, I want to ask you some information about you and your child. Can you tell me how old your child is?

2. And why is your child is in hospital?

3. How often have they been in hospital before this admission?

4. Has your child ever been admitted to intensive care?
When was that?
And how long were they in intensive care?

Thank you

I would now like to ask you about vital sign observations. By vital sign observations I mean the recordings like temperature, pulse, blood pressure and breathing rate that nurse take.

1. Can you tell me why you think nurses and doctors take vital sign observations?

2. And when nurses take your child's vital sign observations, do they tell you what they found?
Probe: Why do you think they do/do not?
Probe: What would you like to know about the observations?

3. Do you look at your child's observation chart?
Probe if no: Is there any particular reason why you don't look at it?
Probe if yes: What do you look at?

4. If the nurse monitors your child's vital signs more often than they have, how does that make you feel?

5. In terms of how often the nurses take your child's vital sign observations, do you ever discuss this with them?
Probe if no: Why do you think that is?

Probe if yes: Can you tell me about a time you did this?

6. Are there any times when the nurses have come to take your child's vital sign observation and you have asked them not to?
   Probe: Can you tell me about that?

7. When you are staying overnight with your child, is he/she ever woken up when the nurses take his/her vital sign observations?
   Probe: Can you tell me about that?

8. Are you ever woken up in the night when the nurses take your child's vital sign observations?
   Probe: Can you tell me about that?

9. Have you heard of the Children's Early Warning Score?

If the answer is no: The children's early warning score or CEWS is a tool to help nurses and doctors monitor if your child's condition is stable. Each of your child's vital sign observations are checked to see if they are in the normal range for their age. If they are, each observation is given a score of 0. If it is not in the normal range, the vital sign is given a score of between 1 and 4, depending on how far away from normal it is. All the vital sign observations scores are then added up and this is the CEWS. If the score is 2 or above, this helps to give the doctors and nurses an 'early warning' that you child may be getting sicker and to monitor them more closely.

10. How does the fact that we at Great Ormond Street use the CEWS make you as a parent feel?
    Probe: Can you give me an example?

11. Would like to have been given more information on the CEWS when your child was admitted?
    Probe: Why is that?

12. Is there anything else you would like to tell me about vital sign monitoring or CEWS that you think I should know?

Appendix 9.4 Focus group questions:

1. Do you find CEWS helpful in detecting clinical deterioration? Why?
2. Tell me about a time when you found CEWS useful?
3. Tell me about a time when you found CEWS unhelpful? Are there any situations where you think CEWs may have had a negative impact when a child was deteriorating?
4. Do you always act on elevated CEWs scores? Why/why not?
5. Tell me about the role parents have in detecting deterioration
6. How you decide how frequently to take observations? What influences this?
7. How do you decide if vital sign observations are ‘acceptable’? What do you do if obs are ‘not acceptable’?
8. What would improve our current CEWS?

Appendix 10 Framework for qualitative analysis

Heading	Category	Sub-category
1. The Value and Limitations of vital sign observations and PTTS	1.1 Overall Benefits and Limitations	1.1.1 The perceived purpose of VS and PTTS
		1.1.2 The perceived benefits/positive aspects of VS and PTTS
	1.2 Disadvantages and limitations	1.2.1 The perceived negative/disadvantages aspects of VS and PTTS
		1.2.2 The perceived limitations of VS and PTTS
		1.2.3 Do VS and PTTS have a negative/harmful impact?
	1.3 Suggestions for improvement	1.3.1 Suggestions for improvement
2. Recording and using vital sign observations and PTTS in clinical practice	2.1 Taking and documenting PTTS	2.1.1 Taking VS and PTTS
		2.1.2 Documentation of VS, PTTS and unexpected events
	2.2 Acting on PTTS	2.2.1 Dealing with abnormal VS and high PTTS scores
		2.2.2 Communicating about VS and PTTS
		2.2.3 Modifying PTTS to individual children
	2.3 Training, support and experience	2.3.1 Training, support and experience
3. Making decisions	3.1 Making decisions on recording	3.1.1 Making decisions on recording VS and PTTS
	3.2 Making decisions on escalating	3.2.1 Making the decisions to act on VS and PTTS
		3.2.2 Managing children with deranged physiology/persistently high PTTS
4. Experiences, impact and consequences of VS monitoring and PTTS	4.1 The experiences of VS monitoring and PTTS	4.1.1 The experiences of VS monitoring and PTTS for nurses
		4.1.2 The experiences of VS monitoring and PTTS for other healthcare professionals
		4.1.3 The experiences of VS monitoring and PTTS for children
		4.1.4 The experiences of VS monitoring and PTTS for families/carers
	4.2 Perceived impact and consequences of vital sign and PTTS monitoring	4.2.1 The perceived impact and consequences for nurses
		4.2.2 The perceived impact and consequences for other healthcare professionals
		4.2.3 The perceived impact and consequences of for children
		4.2.4 The perceived impact and consequences for families/carers

Appendix 11 Participants

Appendix 11.1 Child participants

Identifier	Gender	Parent participant	Age	Ward type	LOS (days)	Number of previous admissions	Previous PICU admission	Interview length (minutes)
C1	Male	P3	5 years	Medical	8	19	Yes	35
C2	Female	P5	10 years	Short stay	2	10	No	16
C3	Male	Did not participate	5 years	Short stay	3	3	No	37
C4	Female	P6	12 years	Short stay	2	22	No	16
C5	Female	P7	9 years	Medical	5	4	No	15

Identifier	Gender	Parent participant	Age	Ward type	LOS (days)	Number of previous admissions	Previous PICU admission	Interview length (minutes)
C6	Male	P9	11 years	Medical	5	10	Yes	34
C7	Female	P12	7 years	Medical	24	7	No	85
C8	Male	P13	7 years	Surgical	4	0	No	16
C9	Male	P14	5 years	Surgical	8	2	No	18
C10	Female	P15	14 years	Surgical	6	6	Yes	20

Appendix 11.2 Characteristics of parent/guardian participants

Identifier	Relationship to child	Ward type	Age of child	Gender of child	LOS (days)	Number of previous admissions	Previous PICU admission	Interview length (minutes)
P1	Mother	Medical	14 years	Female	127	5	No	33
P2	Mother	Medical	5 years	Male	12	28	Yes	17
P3	Mother	Medical	5 years	Male	8	19	Yes	35
P4	Mother	Short stay	5 years	Female	3	3	No	6
P5	Mother	Short stay	10 years	Male	2	10	No	16
P6	Father	Short stay	12 years	Male	2	22	No	16

Identifier	Relationship to child	Ward type	Age of child	Gender of child	LOS (days)	Number of previous admissions	Previous PICU admission	Interview length (minutes)
P7	Female guardian	Surgical	11 years	Male	18	1	No	15
P8	Mother	Medical	9 years	Female	5	4	No	43
P9	Mother	Medical	11 years	Male	6	10	Yes	34
P10	Mother	Surgical	2 months	Female	24	0	Yes	21
P11	Father	Surgical	2 months	Female	24	0	Yes	21
P12	Mother	Medical	7 years	Female	24	7	No	85

Identifier	Relationship to child	Ward type	Age of child	Gender of child	LOS (days)	Number of previous admissions	Previous PICU admission	Interview length (minutes)
P13	Mother	Surgical	7 years	Male	4	4	No	16
P14	Mother	Surgical	5 years	Male	8	8	No	18
P15	Mother	Surgical	14 years	Female	6	6	Yes	20

Length of stay is the number of days in hospital before the interview/draw and write session.

Appendix 11.3 Focus group participants

	Ward type	Grade of staff	Number of participants	Number of male participants	Interview length (minutes)
FG1	Surgical	Junior	4	1	42
FG2	Surgical	Senior	4	0	56
FG3	Surgical	Senior	7	0	46
FG4	Medical	Junior	8	1	38
FG5	Medical	Senior	5	1	32
FG6	Short stay	Junior	8	0	24

Appendix 12 Publications, presentations and abstracts

Appendix 12.1 Publications

Chapman SM, Grocott MPW, Franck LS. Systematic review of paediatric alert criteria for identifying hospitalised children at risk of critical deterioration. Intensive Care Med 2010;36:600–11. doi:10.1007/s00134-009-1715-x.

Chapman SM, Wray J, Oulton K, Peters MJ. Systematic review of paediatric track and trigger systems for hospitalised children. *Resuscitation*. 109:87-109 December 2016. doi:10.1016/j.resuscitation.2016.07.230.

Chapman SM, Wray J, Oulton K, Pagel C, Ray, S, Peters MJ. "The Score Matters": Wide Variations in Predictive Performance of 18 Paediatric Track and Trigger Systems. Archives of Disease in Childhood (accepted for publication 25th January 2017).

Appendix 12.2 Presentations

6th Congress of the European Academy of Paediatric Societies – EAPS 2016 Geneva, Switzerland | October 21-25, 2016

S Chapman, J Wray, K. Oulton, C. Pagel, S. Ray, M. Peters. Evidence-based vital signs do not improve predictive performance of effective paediatric track and trigger tools. Session 21: Before and after PICU: Oral presentation.