MASTER OF SCIENCE BY RESEARCH

A descriptive analysis of the routinely collected physiological observations of children and young people in a tertiary UK Children's hospital

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Award date:
2019

Awarding institution:
Coventry University

Master of Science by Research in

Clinical Practice:

A descriptive analysis of

the routinely collected physiological observations

of children and young people in a tertiary UK

Children's hospital.

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September 2018

Coventry University

Master of Science by Research.

A descriptive analysis of the routinely collected physiological observations of children and young people in a tertiary UK Children's hospital.

This thesis is submitted in partial fulfilment of the University's requirements for the degree of Master of Research

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September 2018

Certificate of Ethical Approval

Applicant:

Nicola Taylor

Project Title:

A longitudinal analysis of routinely collected physiological observations of children, and young people (CYP) in a tertiary UK Children's hospital.

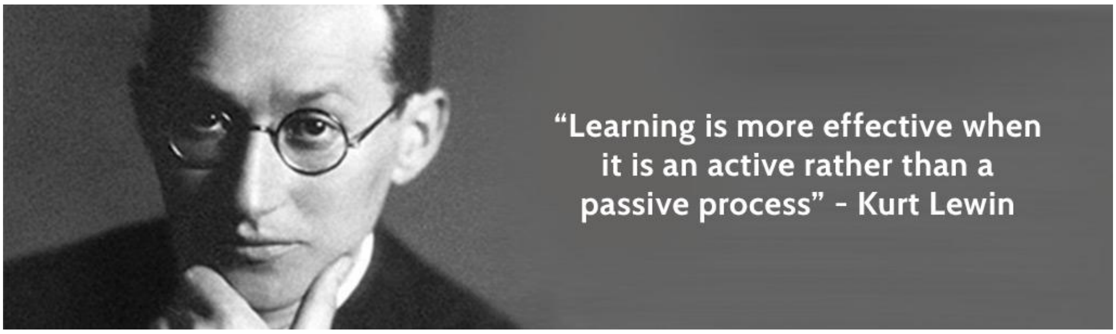
This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Low Risk

Date of approval:

04 April 2018

Project Reference Number:

P67183



Acknowledgements

I would like to thank my supervisory team for sharing their wonderful knowledge and for providing me with such excellent support. Their guidance and encouragement has been invaluable, keeping me focused and enthused throughout.

My family have given me encouragement, love and the time to complete the MScR, for which I will always be grateful. Thank you for believing in me.

ABSTRACT

Background

As part of standard care, all CYP require routine assessment of their physiological observations. Physiological observation reference ranges have historically been based on expert opinion rather than solid evidence (Fleming et al. 2012:1011). Research is therefore required to ensure that these tools are based on robust, evidence based physiological observation thresholds, to ensure they are both sensitive and specific.

Research objectives

1. To describe using summary statistical analysis, the characteristics of physiological observations by age, sex and diagnosis, of all CYP admitted to a tertiary children's hospital in the UK, between 2014-2017.
2. To compare the physiological observations of CYP admitted to a tertiary children's hospital in the UK (between 2014-2017), with standardised reference ranges from key clinical texts and guidelines.

Method

In this study, the researcher undertook secondary analysis of routinely collected data. The physiological observations of CYP were captured electronically as part of normal patient assessment.
Sample - the physiological observations (respiratory rate, heart rate, and blood pressure) of 22,584 CYP were analysed to produce age specific centile charts for each variable. Only the discharge observation were used for the centile development to try and reflect 'normality'.

Results

The vital signs of CYP in hospital appear to differ from 'well' CYP.
APLS 6th Ed. reference ranges for respiratory rate and blood pressure poorly align to the centiles derived in this study, although the centiles for heart rate align well.
Data was also interrogated to compare the respiratory rate and heart rate centiles of the study population with centiles developed in three clinical papers (Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015). Variance was demonstrated between these centiles and the study group, with most variance seen in the upper centiles. Similar to the comparison with APLS reference ranges, heart rate showed best alignment.
The study group stood out as having the least aligned heart rate data – this is potentially due to outliers (who were febrile) not being excluded from the study data, which was in contrast to both the Bonafide et al. (2013) and O'Leary et al. (2015) data.

Conclusion

APLS reference ranges for respiratory rate and blood pressure do not appear representative of contempory inpatient CYP population.
Most variance is seen when comparing the respiratory rate centiles, particularly in the younger age groups (>3yrs). Conversely, heart rate centiles demonstrate better agreement.
Although four studies have now developed centiles for vital sign of CYP, evidence must be cautiously interpreted due to the heterogeneity across the studies making comparing the centiles difficult.

CONTENTS

CHAPTER SIX - Conclusion

TABLES

FIGURES

REFERENCES

APPENDICES

1. Critical Appraisal Checklists for the seven studies included in the literature review

2. Data preparation, data code book and coding summary

3. Case Summaries for heart rate respiratory rate, temperature and systolic blood pressure

4. Respiratory Rate, Heart Rate and Systolic Blood Pressure Centiles on Discharge.

5. Boxplots - Heart rate and Respiratory rates by age

6. Graphs comparing vital signs to main diagnosis codes

7. Email NUH Trust

Abbreviations and key words

BP – Blood pressure

CRT – Capillary refill time

CYP – Children and young people

CIRAL – Centre for Innovation Research Across the Life Course

CU – Coventry University

EBP – Evidence Based Practice

EPR – Electronic patient record

EWS – Early warning scoring

e-Obs – Electronic capture of observations

HR – Heart rate

ICD10 – International classification of disease (10)

IRAS – Integrated Research Application System

LOS- Length of Stay

NUH – Nottingham University Hospital Trust

NCH – Nottingham Children's Hospital, Nottingham University Hospitals NHS Trust

NHS – National Health Service

PEWS – Paediatric early warning scoring

PAS – Patient administration system

RR – Respiratory rate

SBP- Systolic Blood Pressure

SpO_2 – Peripheral oxygen saturation

WOB- Work of Breathing

CHAPTER ONE

1. Introduction

1.1 Background

Each year in the United Kingdom, approximately 1.5 million children and young people (CYP) are admitted to hospital (NHS Digital 2017), all requiring routine assessment of their physiological observations, also called vital signs (Royal College of Nursing 2017). In the context of this study vital signs include respiratory rate, heart rate and blood pressure.

The recording and interpretation of physiological observations are core essential skills for all health care professionals, which the RCN (2017) describe as the 'art' of observation and monitoring. Here the health professional weaves together the broader picture, taking into consideration the CYP's development, non-verbal communication and interaction; as well as the (physiological) numbers.

Consequently, observations have an impact throughout the patient journey. Whether this is to form a baseline assessment, evaluate the impact of an intervention, or as a quantifier of the individual's physiological status (RCN 2017). Assessing the patient's observations also assists in making a diagnosis and may also contribute to differential diagnoses (O'Leary et al. 2015). Sequentially recording observations helps monitor the growth and development of the CYP as well as the effectiveness of ongoing treatment interventions (RCN 2017:4).

Observations therefore assist the health care professional to determine how 'well' the patient is, as much as how 'sick' they are. This helps determine not only the workload of the individual patient, but also informs planning to manage and mitigate risk. Whether this is patient centric, or wider hospital risk relating to capacity, flow and resource. Observations also have a part to play in wider health surveillance and health promotion, such as screening for obesity (Saner et al.2016). Accurate contemporary reference ranges therefore are imperative to support clinicians in their decision making.

1.2 Deteriorating patient

Acute clinical deterioration is the cause of approximately 85% of admissions into Paediatric Critical Care, these children either present in the emergency department or on hospital wards (Paediatric Intensive Care Audit Network 2017). Unanticipated deterioration is a contributing factor to many of the 1500 avoidable paediatric deaths in UK hospitals each year. Deaths that are potentially preventable, if the deterioration is recognised, escalated, and acted upon sooner (Deighton et al. 2016:1; Royal College of Paediatrics and Child Health 2016:2; Sidebottom, Fraser and Fleming 2014:907).

Consequently, assessment, monitoring and measurement of vital signs are core essential skills. Physiological assessment is a crucial element of timely recognition of acute deterioration (Bonafide et al. 2013). Fundamental to this assessment is the recording and interpretation of the patient's observations (Royal College of Nursing 2017). These standalone observations historically referred to as 'TPR' (temperature, pulse and respirations) are now used as part of complex tools or systems that act as rapid 'measures' of acute or developing critical illness (Roland, Oliver and Edwards 2014). These tools are known as Paediatric Early Warning Scores (PEWS) and incorporate a much broader range of patient observations. PEWS includes assessments such as the patients' work (effort) of breathing, their skin colour/perfusion and assessment of their behaviour in the context of alertness and/or lethargy (table 1). The reference ranges that contribute to PEWS have historically been based on expert opinion or settings outside the context of the hospital, rather than empirical evidence for the inpatient population (Fleming et al. 2011:1011). Key clinical texts, such as Advanced Paediatric Life Support guidelines (APLS) also use a wide variety of observation reference ranges (Van-Kuiken and Huth 2016). Together this has resulted in the development of multiple reference ranges, making it difficult for the clinician to ascertain what 'normal' observations are (Fleming et al. 2012, Tarassenko et al. 2011: 101).

Table1. Example of The Physiological Variables That Make Up PEW Score

Variables (Physiological Observations)	Unit of Measurement
Respiratory rate (RR)	Breaths / minute
Work of breathing	Categories 1. Poor effort 2. Normal 3. Mild effort 4. Moderate effort 5. Severe effort
Oxygen requirement	Categories 1. Minimum (<40%) 2. Moderate (40-60%) 3. High (>60%)
Peripheral Oxygen saturations (SpO_2)	Percentage (%)
Heart rate (HR)	Beats /minute
Blood pressure (Bp)	mmHg
Capillary refill time (CRT)	Categories 1. <2 seconds 2. 2-4 seconds 3. >4 seconds
Skin Colour (perfusion)	Categories 1. Normal 2. Pale 3. Grey/mottled 4. Cyanosed
Temperature	Degrees Celsius
Behaviour	Categories 1. Behaviours normally 2. Lethargy 3. Not responding normally 4. Rousable, but unable to stay awake 5. Unresponsive
AVVPU (incl. lethargy = V)	Categories 1. Alert 2. Responds to voice 3. Lethargy 4. Responds to pain 5. Unresponsive
Posture	Categories 1. Normal 2. Abnormal 3. floppy
Pain	Categories 1. No pain 2. Mild 3. Moderate 4. Severe

1.3 Changing inpatient population

The health of CYP in the UK has generally improved over the last three decades, but compared to Western Europe, the UK falls behind in measures of child health, wellbeing and mortality (Royal College of Paediatrics and Child Health 2015). The number of CYP with complex and long-term health needs has increased and up to 50% of childhood deaths are now attributed to life limiting disorders (Keeble and Kossaroval 2017, Sidebottom, Fraser and Fleming 2014). Consequently, inpatient care is becoming more complex as patient acuity rises (Keeble and Kossaroval 2017).

Advances in technology and societies expectations mean that CYP with life limiting illnesses are regularly treated for acute illness, which due to advances in medicine and technology would previously not have been available (Keeble and Kossaroval 2017).
The clinician's ability therefore to intervene successfully has improved substantially (Larcher et al. 2015). Therefore, inpatient population has changed, and physiological reference ranges based on healthy children may not be representative of today's inpatient population (Bonafide et al. 2013).

In the UK, unplanned emergency admissions and short stay admissions are rising and although overall hospital length of stay is reducing, there is an ever-increasing pressure on capacity and flow in both primary and secondary care (Heys, Rajan and Blair 2017, Clarke et al. 2017). Physiological observations are used as an intrinsic part of the decision-making process for both admission and discharge. There is pressure on existing NHS beds, with maximum occupancy frequently an issue during winter (Health Foundation 2018). Health professionals therefore need to be able to make effective decisions regarding admission and timely discharge. Providing access to contemporary reference ranges, that are reflective of the hospital population, will help the clinician ensure primarily the safety of the patient, but also best use of resources.

1.4 Justification

Research ideas often emerge from a researcher's personal experience and practice (Bryman 2016:17). A key motivator for this study has been the authors own experience as an educator, a lead nurse for a Paediatric Critical Care Outreach team and also one of the developors and facilitators of a local Paediatric Early Warning system (PEWSystem). On reflection this development was driven by the art, rather than the science of healthcare. Where the authors knowledge and experience rather than empirical findings dominated the development of the PEWS tool. As the tool was revised and better understanding of acute deterioration gained, the physiological reference ranges stood out as inadequately evidenced.

The majority of CYP with long-term conditions, disability and complex care needs are surviving into young adulthood (RCN 2013). Although children's inpatient services normally care for CYP < 17 years of age, most tertiary Children's hospitals look after CYP who are transitioning to adult care (Royal college of Nursing (RCN) 2013, National Institute for Health and Care Excellence (NICE) 2016). Consequently, most Children's hospitals care for young people up to the age of 19 years. The observations of these young people will therefore be included in the study to ensure they are represented in the data, and their physiological observations appropriately explored.

The physiological observations of children and young people (CYP) in hospital, in the UK, has previously not been described. This study therefore aims to explore these observations and compare them to several standard references ranges that are currently used in clinical practice. It is anticipated that this study will determine what 'normal' parameters are for CYP in hospital. Currently in the UK there are no robust, contemporary evidence based physiological reference ranges on which to base this patient assessment. Research is therefore required to ensure that these tools are based on robust, evidence based physiological observation thresholds, to ensure they are both sensitive and specific. With the innovation of e-Obs (electronic capture of observations), comes a greater opportunity to interrogate large datasets, which will enable a comprehensive analysis of CYP inpatient physiological observations.

1.5 Research question

What are the characteristics and distribution of physiological observations of children and young people (CYP, aged 0-19 years) in a UK tertiary children's hospital, between 2014-2017, compared to standard references ranges?

1.6 Dissertation structure

This thesis will begin by presenting a review of the current literature pertaining to physiological observations. The underpinning methodology will be explored, the research paradigms and the philosophical underpinnings will then be discussed. A detailed description of the research study design will follow, outlining the key decision making surrounding ethical considerations as well as the steps taken to maximise the validity and reliability of the statistical analysis plan. The results chapter will provide a descriptive analysis of the demographics and the physiological observations and compare these to published reference ranges. Study results will then be discussed in the context of the relevant literature. Study strengths and limitations will be expounded prior to drawing conclusions and making future recommendations.

CHAPTER TWO

2. Literature Review

2.1 Introduction

This chapter provide the reader with a synthesis of what is known about the physiological observations of CYP in hospital. The chapter will begin by outlining the systematic approach adopted to identify and review the available evidence. This evidence will then be critically appraised and the synthesis of the findings, into themes, will be presented.

2.1.2 Evidenced-based practice

The words 'evidence-based' are used synonymously across many disciplines. In healthcare this is interpreted as decision making that is based on informed, valid and reliable scientific evidence (Hewitt-Taylor 2002). The information on which practice is based comes in many guises - clinical exposure and experience, education, knowledge gained through books and journals, and the world around us (Egerod 2006). Evidenced based practice involves diverse and careful decision-making based not only on the available evidence but also on patient characteristics, situations, and preferences (Hewitt-Taylor 2002).

The physiological observations of CYP have not been adequately described in a contemporary context (Bonafide et al. 2013). Presently, clinical experience and tacit knowledge have played a pivotal role in the development of many observation reference ranges (Bonafide et al. 2013).

This scoping literature review aims to provide an overview of the existing literature, by exploring what is already known regarding children's observations, the experiential knowledge set out by expert opinion and link this with information about contemporary healthcare practice. Scoping reviews examine the landscape of the available evidence, often focusing on broad research questions. Gathering this background information has been done in a structured way. This has helped the researcher refine the research question by mapping out the existing literature and exposing the gaps in knowledge (Armstrong, Hall, Doyle and Walters 2011).

2.2 Approach to identifying relevant evidence

The search commenced with the construction of the research question, this helped the researcher identify the appropriate literature, as it guided the search strategy (Aveyard, Payne, Preston 2016:61). The first step of the search was to use mind-mapping to breakdown the PEO (Person, Environment, Outcome) framework into keywords and phrases; identify synonyms, alternative spellings and plurals (Schardt et al. 2007). These terms were then used to search three online bibliographic databases (SCOPUS, MEDLINE, CINHAL) together with internet medical search engines Science Direct and PubMED. These databases were selected for their connections to both international and specialist health and life science journals (Cronin, Ryan, Coughlan 2008).

In addition, a GOOGLE Scholar search ensured alternative 'grey' literature was not excluded. Caution is required when evaluating this type of information as it may not have been peer reviewed and may not be valid (Aveyard, Payne, Preston 2016:72).

Table 2. Keywords and Search Criteria

Key words and phrases • Vital signs OR (physiological observations) AND • Heart rate AND • Respiratory rate AND • Blood pressure AND • Paediatric Early Warning OR (PEWS OR POPS OR PAWS OR CEWS) • AND (Child*OR Pead*)
Inclusion criteria • Literature 1998 -2018 • Human • English language • Peer reviewed articles
Exclusion criteria • Literature pre-1998 • Non-human studies • Disease specific • Newspaper articles • Exercise and diet • Obesity • Adults (>19years of age)

2.2.1 Search Approach

Initial scoping of the literature identified several studies that focused on CYP observations that backdate to the 1950's (Fleming et al. 2011). PEWS first became an entity in paediatrics in the late 1990's, and clinical papers, focusing on paediatrics early warning scores, becoming more prevalent from the mid 2000's (Lambert et al. 2017). As the foundation of these tools are observation ranges, it was appropriate to focus the search to the last two decades, as the project aims to determine contemporary reference ranges appropriate for today's CYP. Age included CYP up to the age of 19 years, this takes into account those young people who have not transitioned to adult healthcare and are cared for within a paediatric speciality. These young people often have complex health needs (RCN 2013, NICE 2016), it was therefore important to include this age group in the literature search.

2.3 Search Results

Using the strategy outlined above, a total of 732 articles were initially identified, as shown in figure 1. Through screening the articles using the inclusion and exclusion criteria (table 2) and removing any duplicates, 12 full text articles were reviewed. This led to a further five studies being excluded as their focus was disease specific or related to diet, exercise, or obesity. Seven empirical studies therefore were included in this literature review (table 3).

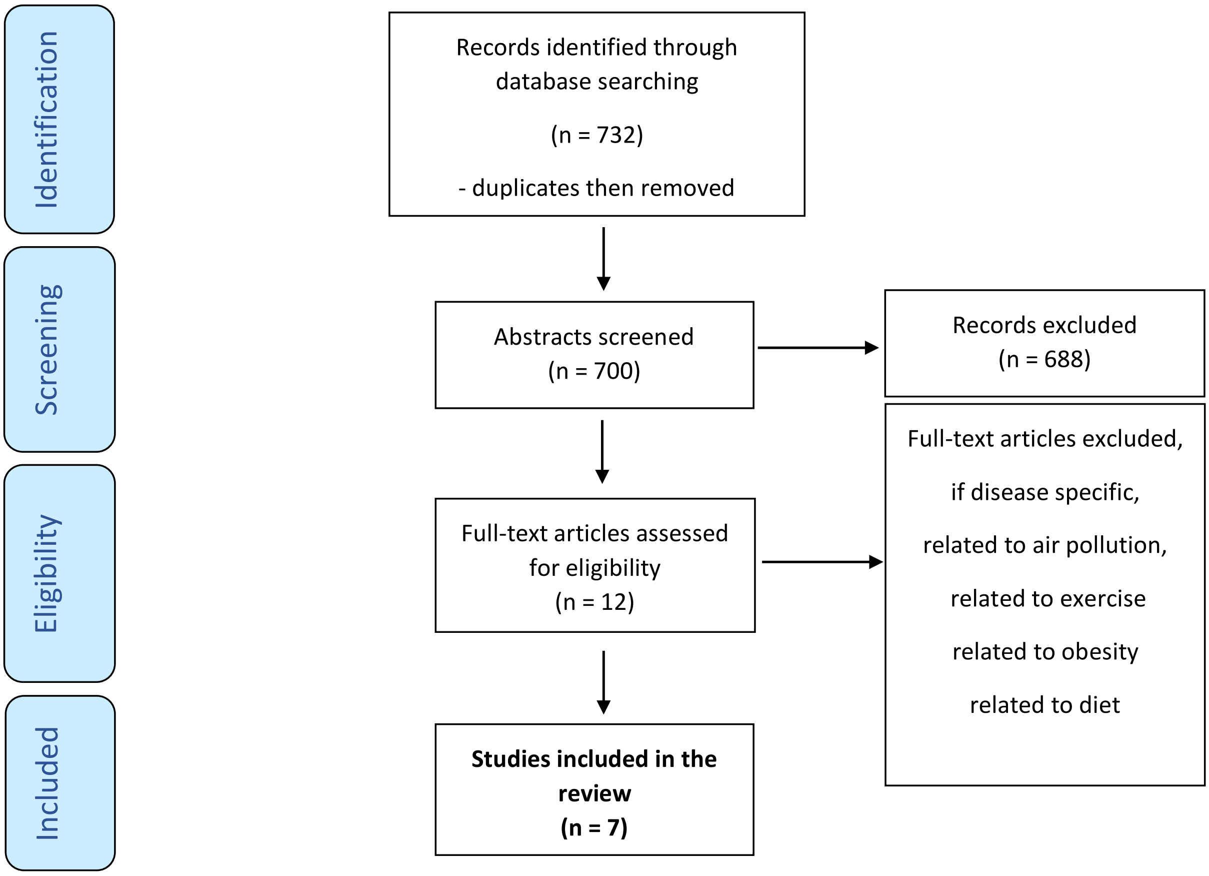


Figure 1. Search Results

Table 3. Studies Included in The Literature Review

Author	Title	Publication & country	Year
Wallis L, Healy M, Undy M, Maconochie I	Age related reference ranges for respiratory rate and heart rate for 4 to 16 years	Archives of Disease in Childhood. UK	2005
Chan S, Cattermole G, Leung P Mak P, Graham C, Rainer T	Validation of the APLS age-based vital signs reference ranges in a Chinese population	Resuscitation China	2011
Fleming S, Thompson M, Stevens R, Henegan C, Pluddermann A, Maconochie I, Mant D	Normal ranges for heart rate and respiratory rate in children from birth to 18 years old: A systematic review of observational studies	Lancet UK	2011
Bonafide C, Brady P, Keren K, Conway P, Marsolo K, Daymont C	Development of Heart Rate and Respiratory Rate Percentile Curves for Hospitalized Children	Pediatrics [online] USA	2013
O'Leary F, Hayden A, Lockie F, Peat J	Defining normal ranges and centiles for heart rate and respiratory rate in infants and children: a cross-sectional study of patients attending an Australian tertiary hospital pediatric emergency department	Archives of Disease in Childhood. Australia	2015
Van Kuiken D, Martz Huth M	What is Normal? Evaluating Vital signs	Nephrology Nursing Journal Netherlands	2016
Paliwoda M, New K, Davies M, Bogossian F	Physiological vital sign ranges in newborns from 34 weeks' gestation	International Journal of Nursing studies Australia	2017

2.3.1 Quality appraisal tools

The Joanna Briggs Institute (2014), Critical Appraisal checklists were used to assist the researcher to undertake robust critical reviews of the literature. The author selected these design specific tools as having the structure and prompts ensured that key design questions were not missed. Through identifying the strength and weakness of the papers the researcher was able to determine how the papers would influence their own project (Aveyard, Payne, Preston 2016:109). A critical review of each paper can be found in appendix 1. The themes from the evidence were synthesised and are debated within the following literature review.

2.4 Literature synthesis and discussion

A total of seven papers were selected for inclusion in this review, these included three systematic reviews and four cross-sectional studies. They were undertaken in the UK, USA, Netherlands, China and Australia. All seven papers focus on the normal ranges of vital signs for CYP, aiming to define age related reference ranges. Four studies developed age specific respiratory rate and heart rate percentile charts for CYP.

From the synthesis of the literature, it was evident that the findings could be grouped under three main themes that included: (1) Clinical decision making; (2) What constitutes normal vital signs? and (3) Research considerations. These will be discussed sequentially in the next section.

2.4.1 Clinical decision making

It is evident from the literature that vital signs are an integral part of a patient's general clinical examination and are pivotal to clinical decision making (Fleming et al. 2011). For the health care professional, formulating a meaningful clinical assessment, physiological observations are considered and compared against previous recordings and standard reference ranges (Roland and Snelson 2018). In most health care scenarios this aspect of clinical assessment is used to assist in determining the patient's pathway, whether in primary or secondary care. Bonafide et al. (2013) refers to the 'afferent' reliance healthcare has on reference ranges and how the interpretation of these vital signs impacts throughout the CYP hospital stay, recognising the 'well 'child as much as the 'sick' child.

Recognition of acute or chronic deterioration is just one aspect of care that relies heavily on vital signs, whether as part of an EWS, or to set monitor alarms, or to determine alerts in patient health records (Bonafide et al. 2013, Roland et al. 2014). Vital signs also play a key role in assessing the impact of treatment interventions such as drug therapies and surgery (Bonafide et al. 2013). They are used to set admission and discharge criteria and likewise used in the development of policy and procedures (Bonafide et al. 2013).

However, vital signs are just one piece of the jigsaw and over reliance may cause harm or error through failure to interpret their meaning within the clinical context (Lambert et al. 2017, Lillitos and Maconochie 2017). Roland (2017), eloquently describes the 'myths and misconceptions' relating to PEWS, and that abnormal observations do not always equate to high severity of illness and conversely, normal observations don't always indicate the 'well' child. Vital signs therefore need to be assessed and interpreted in context, and also in relation to the duration, frequency and trends of any changes or abnormal observations (Roland 2017).

Bonafide et al. (2013) discusses how the widespread implementation of Rapid Response Systems[1] in the United States of America (USA), brought to the forefront the importance of accurately interpreting vital signs, particularly regarding the recognition of serious illness and its ongoing surveillance. Although reference ranges for vital signs are frequently used in clinical practice, there is agreement among several authors that most appear to be based on clinical consensus with minimal contemporary empirical evidence (Wallis et al. 2005, Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015).

Wallis et al. (2005) reviewed the literature on vital signs prior to undertaking their own empirical cross-sectional study. They provide a synopsis of the evidence and although they state that there is good evidence for temperature and blood pressure, they found a paucity of literature to support the reference ranges for respiratory and heart rate. Concluding, that there is no reliable, contemporary evidence on which to base heart rate and respiratory rate parameters (Wallis et al. 2005).

In a systematic review of 69 observational studies, Fleming et al. (2011) suggest that empirically developed physiological norms may improve this clinical conjecture. However,

[1] RRSs identify seriously ill and at-risk patients and those whose condition is deteriorating, using abnormal vital signs and observations that trigger an urgent response by staff who can deal with a medical emergency.

similarly to Wallis et al. (2005), their review found a paucity of evidence, with only two reference ranges citing a source. One cited clinical text, but when explored by Fleming et al. (2013) the text itself did not cite any supporting evidence (Fleming et al. 2011). The other was cited by the World Health Organisation, this reference range was devised from data collected in developing countries (Fleming et al. 2011), making any generalisation outside this context problematic.

This systematic review included data from 1950-2000 and although the search strategy was comprehensive and well documented, it could be argued that the early studies (from the 1950's) should not have been included in this meta-analysis. Although the health of CYP has generally improved the since the 1950's (RCPCH 2015, Keeble and Kossaroval 2017), the in-hospital population have more complex, long term and life limiting health care needs (Keeble and Kossaroval 2017, Larcher et al. 2018). Consequently, CYP in hospital are much sicker and for observations reference ranges to reflect this, they need to be based on contempory evidence (Bonafide et al. 2013).

When discussing the development of their centiles Fleming et al. (2013) clearly articulate that further studies were required to test the generalisability of the centiles with in-patient CYP population. The results from the study have been adopted, for example into the Advanced Paediatric Life support guidelines (ALSG 2016), and the authors own local PEWS tool without detailed testing, even though this had been a clear study recommendation.

Appropriate decision making not only depends on the accuracy of these observation references but also on their application. Chan et al. (2011) introduces the concept that ethnicity should be considered when devising reference ranges. Drawing on the evidence of

Jafar et al. (2005) who found that ethnicity impacted on blood pressure, Chan et al. (2011) undertook a cross sectional study to compare the vital signs of CYP of Chinese ethnicity to Advanced Paediatric Life Support (APLS) reference ranges. This study was based on the vital signs of healthy CYP and had clear inclusion and exclusion criteria. CYP with current symptoms of illness or any history of chronic or congenital issues were excluded. The exposure measurements were well controlled by having standard operating procedures and standardised equipment. Reliability was further enhanced by using researchers trained to undertake the observations. Chan et al. (2011) hypothesised that there would be significant differences between vital signs in Chinese children and the APLS reference ranges. Their study identified that approximately half of the vital signs they recorded fell outside APLS 5th Ed.[2] ranges, suggesting that vital signs reference ranges need to not only be age specific, but also context specific and should therefore account for ethnicity.

A recent systematic review aimed to identify vital signs reference ranges for newborns (≥ 34 weeks' gestation). The rationale for including this neonatal paper is that all newborns discharge home at birth, (or who have an uneventful birth at home) who then go on to have an acute illness, would be admitted to children's ward and not a neonatal unit. This is irrespective of their gestation or if they are still within the neonatal period. Therefore, similar to the older CYP waiting to transition to adult care, it is important that this study captures the nuances relating to the physiological observations of these infants.

In the first four weeks of life newborns undertake a process of transition to extra uterine life, during this period several significant physiological changes occur (Morton and Brodsky 2016).

[2] APLS reference ranges have been amended and are now in their 6th iteration.

Paliwoda et al. (2017) found that although several Early Warning Scores (EWS)[3] tools for neonates had been developed, there was a paucity of empirical evidence to support the vital signs components of the tools and suggested that they do not reflect the complexities of the transition period of the new-born. For effective decision making in situations where the new-born is clinically at-risk, what is emerging from the evidence is that tools should potentially be reflective of gestational maturity (Paliwoda et al. 2017), although this would need to be empirically tested.

Although vital signs play a significant role in clinical decision making, they appear to be driven by policy, tradition and expert opinion rather than grounded in empirical evidence (Van Kuiken and Huth 2016). To ensure that effective clinical assessment can be undertaken reference ranges for vital signs need to be evidence based. A number of studies have endeavoured to identify normal ranges for CYP but there remains a lack of largescale population-based studies, that account for setting, ethnicity and sex (Parslow, 2015).

2.4.2 What constitutes normal vital signs?

Several systematic reviews regarding the vital signs of CYP have been undertaken (Fleming et al. 2011, Van Kuiken and Huth 2016, Paliwoda et al. 2017). The consensus being that there is little empirical evidence to support the reference ranges frequently used in practice, whether nationally recognised guidelines such as APLS, local policy or professional clinical text.

In their systematic review, Van Kuiken and Huth (2016) aimed to determine the normal vital signs parameters for one to five-year olds. Even though a clear research question is proposed there is inconsistency between the question and the purpose of this review. The question is

[3] EWS is a physiological track and trigger systems that is used to monitor patients in the hospital setting and provide an early warning of deterioration

focused on inpatients whereas the purpose of the review is to find evidence relating to healthy children. The number of CYP with complex and long-term health needs has increased and consequently inpatient care is more complex as patient acuity rises (Keeble and Kossaroval 2017). Therefore, there may be a disparity between the observations of so-called healthy children compared to their counterparts in hospital. Clarity is required, as these groups are different and therefore their vital signs may be different.

Key aspects of the methodology are missing, and description is minimal, therefore it is difficult to make judgement on the robustness of the study to provide reliable and valid data that is without bias (Aveyard, Payne, Preston 2016:104). This article appears more aligned with a critical review, although it describes data from empirical and theoretical studies, it is doing so without systematicity. Studies are not combined and there is no evidence of any meta-analysis (Grant, Booth 2009:93). While, the review has its limitations it does give some generic insights into the availability and development of reference ranges.

One such insight is that single observation ranges, developed for a specific purpose, can readily be extrapolated into reference ranges for vital signs (Van Kuiken & Huth 2016). The example cited is blood pressure centile charts (developed by the Working Group on High Blood Pressure in Children and Adolescents 2014) used to diagnose pre-hypertension in CYP, these now form the basis of many standard blood pressure reference ranges (Van Kuiken & Huth 2016). With no empirical evidence, assessing the transferability of the ranges to another patient group may have significant patient safety consequences.

Text books appear to be particularly poor with both age range classification and reference ranges (Van-Kuiken, Huth 2016). Bonafide et al. (2013) found that 54% of vital signs were abnormal compared to clinical text books. This has relevance in education where text books are often a key source for this type of information. As with the previous studies, this review concludes that there is little agreement and empirical evidence as to what constitutes normal vital signs.

These findings are also reflected in an earlier systematic review conducted by Fleming et al. (2011). This meta-analysis analysed 150,808 heart rate measurements and 7565 respiratory rates to create centiles and compare these to published reference ranges. Age is an important determinant in creating centiles, Fleming et al. (2011), constructed their age range by devising groups based on incremental increases in heart and respiratory rates[4] and is the only study in this review to describe age in this way. Age groups vary in many studies describing normal vital signs ranges, which makes interpreting and comparing the ranges difficult (Fleming et al. 2011, Van-Kuiken, Huth 2016). Although a novel approach to developing age bandings, further empirical testing in contempory practice is required.

Fleming et al. (2013) compared their centiles to APLS 5th Ed. and Paediatric Advanced Life Support (PALS) reference ranges, both of which are nationally accredited advanced resuscitation courses and therefore widely used and taught in the UK. Findings showed that there was little alignment between their centiles, and those from APLS and PALS. Using ten-year olds as an example, they suggest that 40% would have abnormal heart rates when compared to APLS ranges. Subgroup analysis also found higher heart rates ($p<0.001$) in community settings compared to when measurements were recorded in a clinical or laboratory setting. Although his shows statistical significance, it is difficult to extract the

[4] Five beats/minute for heart rate and two breaths for /minute for respiratory rate.

relevance to today's clinical practice as the different setting would indicate different patient groups, there is also potential for inconsistency in how measures were obtained and recorded hence measurement validity maybe also be a confounding variable.

This study also identified that heart rates were statistically higher ($p<0.0001$) when captured by automated techniques compared to manual, this is not a surprising find. Automated devices are often used by untrained staff whereas manually obtaining a blood pressure recording requires specific skills and training, Using the wrong size cuff , not pre-setting inflation pressures are common causes of inaccurate measurement (Riley and Bluhm 2012).

A small but significant trend in increasing median heart rates (when compared sequentially) was also highlighted by Fleming et al (2013) in their findings. Again, it is difficult to attribute this finding due to the heterogeneity of the studies. As this data included studies from as far back as the 1950's the change in heart rates may potentially be linked to increasing levels of obesity. One in five children in the UK are now overweight by the time they start school with poor diet and a sedentary life style causative factors (Public Health England (2015), factors that would have a direct effect on cardiovascular function. Other confounds may be changes in practice and also the equipment used to capture the heart rate measurements.

In a systematic review to identify vital signs parameters for newborns (≥34 weeks' gestation), Paliwoda et al. (2017) hypothesised that the effectiveness of new-born EWS would improve with age specific vital signs parameters. The motivation for their study was inconsistency in the vital signs reference ranges used in the new-born EWS. This made any subsequent validation of these tools difficult (Paliwoda et al. 2017). This review, like much of the current literature, concluded that there is inconsistency with recommended vital signs reference ranges. It is also highlighted that for neonates there is a lack of consideration of gestation in many of the studies, and where reported, gestation is only described as either term or preterm. Paliwoda et al. (2017) point to the growing evidence that late pre-terms are not just small newborns and that the impact of transition to extra-uterine life should be considered (Morton and Brodsky 2016). Therefore, to ensure a good level sensitivity and specificity, reference ranges and EWS should account for neonatal gestation (Paliwoda et al. 2017).

Several observational studies have compared vital signs with either known standard reference ranges or previously reported studies (Wallis et al. 2005, Chan et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015). Collectively these studies also indicate that there is limited empirical data available to inform vital signs reference ranges for CYP; most ranges have been developed using consensus opinion, generally using 'well' children and that there is even less evidence regarding these ranges in the context of the hospitalised CYP. Further confirming the views of Fleming et al. (2011) and Van-Kuiken and Huth (2016).

Wallis et al. 2005, aimed to describe the normal values of heart rate and respiratory rates of CYP in a school setting. This is the only study within this literature review that considered the impact of sex on the vital sign's measurements. They stated that they found only a small difference (although the size difference was not clarified), between the heart rates and respiratory rates of male and female CYP, providing a methodological insight for future studies.

When comparing their data to APLS reference ranges, Chan et al. (2011) found that their reference ranges for heart rate, respiratory rate and systolic blood pressure differed significantly from APLS ranges in both pre-school and school aged children, but similar in small toddlers (≤11months). In this cross-sectional study, approximately 38% of the study population had lower heart rates than the APLS heart rate lower range and approximately

50% had higher systolic blood pressures than the upper equivalent APLS range. Chan et al. (2011) conclude that they found that the vital signs of Chinese CYP differ significantly from APLS reference ranges and suggest that ethnicity impacts on vital signs and should be a consideration in future research. Several other studies have demonstrated that their populations vital signs also do not align to APLS (Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015) but rather than ethnicity being the only cofounding, the assumptions made were that the ranges were just not reflective of contemporary CYP. The reasons for this are complex and multifactorial; whether due to setting (well child versus sick child), due to socio economic changes impacting on the health and wellbeing, rise in obesity or mental health (Bonafide et al. 2013, Royal College of Paediatrics and Child Health 2015 and Parslow 2015).

Few studies have attempted to define the normal ranges of vital signs of CYP in hospital. Bonafide et al. (2013) claim to be the first study to describe the distribution of heart rates and respiratory rates for hospitalised CYP in the USA, they go on to develop and validate heart and respiratory rate centiles. This cross-sectional study used paired heart and respiratory rates from hospital electronic records and compared them to several recognised reference ranges. The study details a comprehensive data plan, which included, data sourcing, sampling strategy, quality measures and a clear analysis plan. Data integrity measures were well documented and ascertainment bias was addressed by dividing each admission into six-hour intervals. One paired heart rate and respiratory rate was then randomly selected from each interval, reducing bias from individual patients with lengthy hospital stay and frequent observations. This strategy has not been documented in any other studies in this review.

When comparing their data to the meta- analysis by Fleming et al. (2011), the ranges again did not align, with the studies upper centiles being higher than the comparable centiles in the meta-analysis.

In a similar study, O'Leary et al. (2015) analyse 111,696 heart rates and respiratory rates of CYP in an Australian Children's Emergency department. The participating CYP had to be afebrile and have a low priority triage score, i.e. no obvious risk factors for serious illness or injury (O'Leary et al. 2015). The aim of this study was to devise age adjusted centile charts to be compared with previous studies and APLS ranges. This study had a comprehensive and clear study design and analysis plan. When comparing data, O'Leary et al. (2015) found that their data differed considerably from that of Fleming et al. (2011) - Infants and children <3years old had lower respiratory rates, but after this age, respiratory rates were higher. The heart rates centiles over 12 months of age were also higher than those produced by Fleming. The data from both the Bonafide et al. (2013) and O'Leary et al. (2015) studies were produced from measurements taken from CYP in hospital compared to the centiles devised by Fleming et al. (2011) which were reflective of healthy CYP as set out in the studies inclusion/exclusion criteria.

Fleming et al. (2013) are the only study to describe their date as normally distributed, all the other studies (that have produced physiological data) in this review have either described data as skewed, or their methods as nonparametric. This difference between the population samples may perhaps explain why the data does not align. Other associated confounds include that 6% of the data Fleming et al. (2011) used was extracted from studies conducted pre-1980. The more contemporary studies in this systematic review used more automated measurement techniques and these studies reported higher heart rates (Fleming et al 2011). Measurement type (i.e. automated or manual) may therefore impact on the measurement.

When comparing the centiles developed by both Bonafide et al. (2013) and O'Leary et al. (2015) their data for heart rates align on the 50th percentile but the corresponding 1st – 99th centiles devised by Bonafide et al. (2013) are much wider, possibly due to the ward population being 'sicker' than the 'well' triage patients. The respiratory centiles (5th, 50th and 95th) do differ but are more closely aligned, particularly when compared to the centiles developed by Fleming et al. (2011).

Comparing the evidence is problematic due to the methodological heterogeneity of the studies, and although three data sets for normal values for heart rate and respiratory rate centiles have been described (Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al . 2015), it is still unclear which one, if any, can be generalised to the UK CYP in hospital patient population.

2.4.3 Considerations for future research

In their systematic review, Fleming et al. (2011) discuss the difficulties in appraising and assessing quality within the studies, due to diversity in design type, size, and population. New studies therefore need to be mindful of these to ensure any future result can be extrapolated into the wider population CYP in hospital.

The literature to date implies that heart rates and respiratory rates are possibly context specific (Chan et al. 2011, Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015), and that the observations of CYP in hospital differ from those of 'well' CYP recorded in a school or laboratory setting (Chan et al. 2011, Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015). Insights from these studies need to be considered in any future research to better understand the impact of age, ethnicity and setting have on the vital signs of CYP.

Further subgroup analysis may also be helpful to establish a better understanding of the impact specific illness has on vital signs. Bonafide et al. (2013) removed variables of any participants with a respiratory diagnosis as sensitivity analysis exposed higher respiratory and heart rates the 90-99th centiles, but minimal changes on the 50th centile or below. Respiratory disease is known to effect respiratory and heart rates (Cretikos 2008), but the effect has not been quantified. Having a better understanding of the effect specific diseases have on these physiological observations should have a positive impact on policy and guidelines developments.

2.5 Summary

This review of the literature has identified that the physiological observations of CYP have not been adequately described in a contemporary context. Presently, clinical experience and tacit knowledge have dominated the development of many observation reference ranges (Bonafide et al. 2013). Several studies have attempted to develop centiles for normal heart rate and respiratory rates (O'Leary et al. 2015), yet there is no consensus as to what constitutes ‘normal’ for CYP in hospital. Therefore, there is definite need for further empirical work in this field to quantify the characteristics of physiological observations of CYP in the UK.

CHAPTER THREE

3. Methodology and Methods

3.1 Introduction

This chapter will outline the principle philosophical assumptions, methodology and methods that have been employed by this study in order to address its research question and objectives. The chapter will begin by presenting the research question and objectives for this empirical study that aim to address some of the aforementioned deficits within the literature (Chapter Two). The selected philosophical orientation, study design, data analysis approach, and ethical framework will be presented with rationale. Methods to mitigating issues of validity and reliability will also be discussed.

3.1.1 Formulating the research question

The research question has been formulated using a PEO (Patient, Exposure and Outcome) framework (table 4), this helped keep the question focused and specific (Schardt et al. 2007). Having a well-focused question enabled the researcher to more efficiently and effectively identify and source the relevant literature, it also governed the development of the research methodology (Aveyard, Payne, Preston 2016 pg. 12).

TABLE 4. PEO FRAMEWORK

Framework item	Project focus
Patient Problem (or Population)	CYP 0-19yrs, UK tertiary children's hospital.
Exposure	Acutely unwell. Potentially deranged physiological observations.
Outcome	Greater understanding of what 'normal' observation parameters are for children in hospital.

From the literature (Chapter two) it is evident that there are considerable deficits in a contemporary understanding of the characteristics and distribution of physiological observations of CYP admitted to hospital. Therefore, the research question for this study was:

3.1.2 Research question and objectives

What are the characteristics and distribution of physiological observations of CYP (age 0-19 years) in a UK tertiary children's hospital, between 2014-2017, compared to standard reference ranges?

From this research question two objectives were proposed:

1. To describe using summary statistical analysis, the characteristics of physiological observations by age, sex and diagnosis, of all CYP admitted to a tertiary children's hospital in the UK, between 2014-2017.

2. To compare the physiological observations of CYP admitted to a tertiary children's hospital in the UK (between 2014-2017), with standardised reference ranges from key clinical texts and guidelines.

3.2 Methodology

Within the field of applied health research there are a constellation of methodologies available (that transcend the quantitative and qualitative paradigms) underpinned by different philosophical assumptions. The quantitative researcher views information as objective, measurable and gathered systematically - data is often numeric and quantifiable. This paradigm is grounded in the philosophy of logical positivism, the foundations of which are built on rules of logic, measurement and prediction (Polit and Beck 2009:9). The philosophy positivism assumes that reliable knowledge can only be achieved through quantifiable observations. The aim is to establish scientific laws through exploring data in search of facts and the relationship between these 'truths' (Bryman 2106:24). The positivist researcher views themselves as independent to the study and maintains an objective approach which aims to describe and predict a phenomenon, rather than give meaning. Positivist driven science is therefore judged only by fact rather than supposition or the personal views and values of the researcher (Bryman 2016:24). However, the selection of a particular methodology and position is dependent upon the focus of the research and the approach most congruent with meeting the specified question and objectives. The aim of this study is to explore the physiological observations of CYP in hospital and compare these to several standard reference ranges that are currently used in clinical practice. Hence this study is not concerned in the complexities of the patient's experience and only requires objective factual data to answer the research question. By employing positivism, this study has taken a deductive approach to its exploration of the physiological observations of CYP in hospital, generating quantifiable data that is objective and measured.

3.3 Study design

In this study, the researcher undertook secondary analysis of routinely collected data. Using secondary data analysis is an increasingly population research method that utilises existing data, which can be both time and cost saving for the researcher (Cheng and Phillips 2014). Although using secondary data, this method remains an empirical exercise that applies the same principles as primary research (Cheng and Phillips 2014). The disadvantages of using this method is that the researcher has no control over what data is collected, how the data is collected, and therefore has limited control over data integrity. This can potentially limit aspects of both the research question and data analysis (Cheng and Phillips 2014). When using secondary analysis, the available data set and a broad research question are often used iteratively, to develop a more focused question (Song and Chung 2010, Cheng and Phillips 2014).

The data for this study was routinely collected from clinical practice without any manipulation or interventions by the researcher. The physiological observations of CYP are captured electronically as part of normal patient assessment rather than recorded for the sole purpose of the research study. Using secondary data has some limitations for this study, particularly in respect of any analysis of ethnicity and gestation, both research insights highlighted in the literature review (Chapter two).The researcher also had no control over how the physiological observations were measured and recorded. The advantage of using this secondary data was that a large, electronically captured, data set was readily available to the researcher. The data was prepared and cleaned prior to the analysis, this was carried out by the researcher and overseen by the supervisory team (a detailed description of data cleaning process, along with data coding book can be found in appendix two).

It was anticipated that by analysing the data from the whole cohort and following them through the trajectory of the admission, the researcher would gain a better insight into the physiological observations of CYP in hospital (Hennekens and Buring 1987:22, Caruana et al. 2015).

3.3.1 Setting

The study used existing data routinely collected at a tertiary children's hospital in the United Kingdom (UK). The hospital has 116 inpatient beds across 12 ward areas, an 18-bedded Children's Critical Care facility, Children's Outpatients, Children's Day-care and Children's Emergency Department. The Children's Hospital is a tertiary referral centre for many specialities, including neurology, neurosurgery, spinal surgery, orthopaedics, ear nose and throat, oncology, rheumatology, renal, respiratory and surgical specialties. In the year 2017/18 the hospital cared for approximately 157,000 CYP (data generated by Nottingham University NHS Trust Business data analyst 2018). The Children's hospital is one of 26 children's hospitals in the UK (Paediatric Intensive Care Audit Network 2017). It is a moderately sized facility when compared to one of the UK's largest Children's Hospitals which has approximately 300 beds and 250,000 patient visits per year (Birmingham Women's and Children's NHS Foundation Trust 2017).

3.3.2 Sample and sampling

Total population sampling was used for this study. This non-probability purposive form of sampling allowed the researcher to strategically determine a sample due to its relevance to the research question, rather than by randomisation (Bryman 2016:408). Utilising this sampling technique enabled the entire population of CYP admitted to the study site (who met the inclusion criteria) to be included in the study.

Table 5. Inclusion and Exclusion Criteria

Inclusion criteria
CYP aged 0-19 years admitted to the study hospital who have observations recorded electronically. This age range was used as the Children's hospital is a tertiary centre that looks after CYP who are transitioning to adult care and regularly cares for young people up to the age of 19 years
Exclusion criteria
The physiological observations of CYP during inpatient episodes on Neonatal or Paediatric Critical Care. (These patients were excluded as the very nature of their admission to critical care would indicate that their observations would be abnormal and therefore potentially bias the study results.)

3.3.3 Data source

The study site has approximately 23,500 inpatient admissions per year (Nottingham Children's Hospital, nd) which equates to 1.6% of the 1.5 million CYP that are admitted to hospital yearly in the UK (NHS Digital 2017). The participant's data required for this study is routinely collected using an electronic observation capture platform (e-Obs). This then directly links to the electronic patient records (EPR) for the patient's demographic details. As the observations and demographic details are recorded electronically, all admitted patient's data was available for analysis.

3.3.4 Data analysis

The demographics and physiological data were explored using descriptive statistics, univariate and bivariate analysis.

Demographic data (table 6) were analysed using descriptive statistics to determine:

- Frequencies (counts and percentages)
- Measures of central tendency (mean, mode and median)
- Levels of variation (range, deviation from mean and quartile ranges).

Where data is not normally distributed the median has been used as the most representative level of central tendency as it is not as vulnerable to outliers (Bryman 2016:338).

Diagnosis is described at ICD-10 chapter heading levels to reduce the potential for any patient re-identification. Discharge diagnosis coding was used as it was anticipated that this would give an accurate reflection of the patient episode, as coding on admission would potentially contain provisional and unsubstantiated information (e.g. a working or differential diagnosis).

Table 6. Demographic Variables

Demographic Variables	Level of Measurement
Age (months & years)	Interval and Ordinal
Sex	Nominal
Working diagnosis (ICD10) **ICD-10 - International Statistical Classification of Diseases and Related Health Problems (Tenth Revision)**	Nominal
Acute deterioration (defined as an unscheduled admission from a ward to the Paediatric Critical Care Unit)	Binary

The admission pathway and outcome are also described to give context to the demographic variables and will determine:

- Admission by type - elective or non-elective
- Admission pathway into hospital - Emergency department, Outpatients clinic, General Practice or Transfers from another health care provider
- Outcome - including, transfer to Paediatric Critical Care and hospital length of stay (LOS)

3.3.4.1 Analysis for objective 1

The physiological variables (table 7) recorded on admission, on discharge, and the minimum and maximum value during the inpatient stay were obtained for analysis. The data distribution will be explored using histograms, bar charts and boxplots for ranges.

Analysis will determine:

- Frequencies (counts and percentages)
- Measures of central tendency (mean, mode and median)
- Levels of variation (range, deviation from mean and quartile ranges).

For those variables that are not normally distributed the median will be used as the most representative level of central tendency.

3.3.4.2 Analysis for objective 2

Using the discharge respiratory rate, heart rate and systolic blood pressure observations, age and sex specific centile charts for the variables, were produced. The discharge observation has been used as it is anticipated that the patient's observations on discharge reflect 'normality'. For the patient to be discharged there is an expectation that the patient's condition has improved, and observations should therefore have returned to their baseline. From personal experience the researcher is aware that a small number of CYP on discharge will have been transferred for continued care. Therefore, for these individuals their observations may not be reflective of a normative state. The data does not identify which CYP this applies to, consequently, the researcher was unable to remove them as part of the data cleaning process.

Table 7. Physiological Variables

Variables (Physiological Observations)	Unit of Measurement	Level of Measurement
Respiratory rate (RR)	Breaths / minute	Continuous
Work of breathing	Categories 1. Poor effort 2. Normal 3. Mild effort 4. Moderate effort 5. Severe effort	Ordinal
Oxygen requirement	Categories 1. Minimum (<40%) 2. Moderate (40-60%) 3. High (>60%)	Ordinal
Peripheral Oxygen saturations (SpO_2)	Percentage (%)	Continuous
Heart rate (HR)	Beats /minute	Continuous
Blood pressure (Bp)	mmHg	Continuous
Capillary refill time (CRT)	Categories 1. <2 seconds 2. 2-4 seconds 3. >4 seconds	Ordinal
Skin Colour (perfusion)	Categories 1. Normal 2. Pale 3. Grey/mottled 4. Cyanosed	Ordinal
Temperature	Degrees Celsius	Interval
Behaviour	Categories 1. Behaviours normally 2. Lethargy 3. Not responding normally 4. Rousable, but unable to stay awake 5. Unresponsive	Ordinal
AVVPU (incl. lethargy = V)	Categories 1. Alert 2. Responds to voice 3. Lethargy 4. Responds to pain 5. Unresponsive	Ordinal
Posture	Categories 1. Normal 2. Abnormal 3. floppy	Ordinal
Pain	Categories 1. No pain 2. Mild 3. Moderate 4. Severe	Ordinal

Data were plotted to visually compare the observations to the following standard reference ranges:

- Advanced Paediatric Life Support Guidelines (ALSG 2016).
- Bonafide et al. (2013) Centile charts for children's heart rates and respiratory rates (USA).
- Fleming et al. (2011) Normal heart rates and respiratory rates in children (systematic review UK).
- O'Leary et al. (2015) Defining normal ranges and centiles for heart rate and respiratory rates in an Australian paediatric emergency department.

3.4 Validity and Reliability

Within this study, areas have been highlighted that may impact on the reliability and validity of the data. The strategies employed to mitigate for these were considered and then built into the study protocol (as set out in table 8).

3.4.1 Heterogeneity and violation of statistical assumptions

The more heterogeneous the variable, the more difficult it becomes to detect relationships; therefore, it was important to interrogate and describe the data fully prior to any analysis (Shadish, Cook and Campbell 2002:46). To minimise the risk of violating any statistical assumptions the researcher developed a data analysis plan that began with a comprehensive descriptive analysis of all the variables. This ensured that there was clarity and consistency in all levels of measurement and that when appropriate, the distribution (either parametric or non-parametric) was defined. This enabled the most appropriate statistical tests to be employed.

Table 8 Strategies employed to maximise the reliability and validity of the research.

Potential areas of concern	Strategy used to maximise validity and reliability
Patients not having observations recorded and attrition	The hospitals observation policy mandates a minimum of 4 hourly observations for 24 hrs, then a minimum of 12 hourly for the duration of inpatient stay. Once a patient is admitted to the hospital the electronic observation system alerts the nurse in charge of the admission (via an iPod device), this alert remains highlighted on the system until the observations are inputted. All admitted patients therefore have their observations recorded, this also ensures that there is no attrition due to lost documentation.
Inconsistencies with data entry	All staff who record observations (registered or non-registered nurses) have undertaken standardised training on patient assessment and the recording of physiological observations. Student nurses are under the direct supervision of a registered nurse. There is a Hospital Paediatric Early Warning Score (PEWS) policy in place for the assessment and the recording of a patient's physiological observations, these mandates best practice for the measuring and recording of vital signs.
Inaccurate documentation of observations	Safety netting is built into the e-Obs system that flags erroneous observations (i.e. outside of normal parameters, such as a respiratory rate of 300) and ensures that a complete set of observations are recorded, the system will not allow the observation to be submitted if a mandatory observation is omitted.
Missing data	As the data is captured electronically there were very few missing entries, these were deleted case wise as discussed in section 3.3.4. The greatest potential for lost data is during any system downtime, where staff go back to manual recording the patient's data on paper, capturing this data was not achievable within the constraints of this study.
Equipment failures and use of non-standardised equipment	Although the researcher has no direct control over this aspect of reliability, all ward equipment is centrally procured which ensures standardisation of the machinery, its maintenance and the specific training and competency requirements. Each ward has a designated medical devices trainer who is responsible for training and assessing staff locally. The NHS Trusts policy dictates that staff do not use equipment unless formally assessed as competent and their Medical Equipment Service Unit maintain all the medical devices.
Poor understanding of the constructs being measured	This is alleviated ensuring that there was clear explication of the constructs being measured (Shadish, Cook and Campbell 2002:69). This includes the demographics of the sample population (table 6) and all outcome measures, which in this case are the CYPs physiological observations (table 7). Physiological observations (heart rate, respiratory rate, blood pressure etc.) and the demographic characteristics (age, sex and diagnosis) are universally accepted constructs, that are inherent to the CYP hospital stay. In this study this is addressed through local hospital policy and mandatory staff training in regard to measuring and recording physiological observations.

3.4.2 Data Phishing

Having a pre-defined data analysis plan the researcher ensured that the analysis was focused around the research questions. This was to prevent data phishing, where researchers seek statistically significant associations among variables without setting clear research questions or hypothesising the effect first. This can lead to spurious findings that although are statistically significant have no underlying true effect (Smith and Ebrahim 2002).

3.5 Ethical considerations

Conducting clinical research ethically, requires integrity, transparency, and respect for privacy (UK Government Legislation 1998, Burns and Grove 2009:184, Medical Research Council 2012, Coventry University 2013, MRC 2017). Ethical review was undertaken with Coventry University (certificate of ethical approval page 3). Following Health Research Authority (HRA) guidance, a review by NHS Ethics was not required, however the NHS Trust's Research and Innovation department and Data Guardian granted permission for the research.

The research project was built around an ethical framework ensuring that the morality of any decisions or actions were considered in all settings and every situation (Burns and Grove 2009).

The Anonymisation Network for Decision Making Framework UK (Elliot et al. 2016) has been used to guide the ethical considerations within this project (table 9). This MRC (2017) recommended resource was chosen as it specifically focuses on information 'about people', which is appropriate for this project as data will be generated entirely from the participant's medical record.

Table 9. Ethical Considerations

Frame Work Principles	Considerations	Study Mitigation
Describe your data situation	Patient data Routinely collected Secondary data analysis	Data will be anonymised by the NHS Trust prior to being exported to the researcher.
Understand your legal responsibilities	Common law Data protection laws (1998 & 2018) Vulnerable population (safeguarding)	Ensure data storage and handling controls in place. Data will be stored on a secure server and will be password protected. No patient identifiers or any highly sensitive data will be requested as part of the study. Maintain anonymity through study and dissemination of findings. Data will be reported at group level rather than individual data.
Know your data	Potential for (re)identification	Diagnosis will be requested at the ICD-10, three-digit grouping level to help prevent re identification. As a second layer of protection once data analysis is complete, any small cohorts i.e. 5 children in one category will be merged into a larger age cohort or be removed to further reduce the risk of any (re)identification.
Understand the use case	Having a clear reason why the data needs to be collected and what /how it will be disseminated	Findings will be used to refine PEWS by producing evidence-based observation reference ranges for CYP.
Meet your ethical obligations	Seek appropriate organisational approval	Agreement from NHS Trust data guardian. NHS Ethics (via IRAS) and CU Ethics approval will be obtained. Research Team trained in Good Clinical Practice (GCP)
Identify the disclosure control processes that are relevant to your data situation	Potential data breech and lost data. University and NHS process	Ensure data storage and handling controls in place. - Anonymised data - Data held securely and protected with encryption - Research supervisor access to data for verification and validation purposes only.
Identify who your stakeholders are and plan how you will communicate	CYP admitted to hospital Staff using PEWS	Discuss the study with the hospital Youth group and a staff workshop

3.5.1 Consent

The data used in this study was collected routinely and has been de-identified. Processing this retrospective (routinely collected) data will cause minimal /no harm to patients. The research team adhered to Good Clinical Practice guidelines and the new General Data Protection Regulations that came into effect May 2018 (MRC 2017). Data was anonymised by the NHS site with no linkage to any patient identifiers, prior to being shared with the researcher. The processing of the data, for the purpose of attaining anonymisation, was the responsibility of NHS Trust and remains subject to data protection laws.

To ensure the Common Law Duty of Confidentiality was upheld, reducing the identifiability of any data, and minimising the risk of (re)identification has been considered (MRC 2017). To protect the privacy of the research participants and prevent any unintended disclosure of confidential information, diagnosis was requested at the three-digit ICD-10 level grouping.

3.5.2 Using children's data

Children may be less aware of any risks, consequences, but also their rights in relation to the processing of their personal data. As the data for this study was anonymised, it was exempt from the GDPR consent requirements, the researcher though was interested in the view of CYP regarding the research study and the use of anonymised data. With assistance of the Children's Hospital youth forum the researcher ran an engagement event to gauge their views. This was an extremely inspiring opportunity. The CYP were very positive about the research and felt that it was an appropriate study to conduct. When discussing how they felt about the use of anonymised data they were again very positive and felt that in this situation it was acceptable, but with one caveat; 'remember that the data is not '**just data'**, but it belongs to a person and that person has outcomes'. This statement affirmed the importance of handling data ethically, with care and dignity, keeping in mind the CYP's rights and wellbeing should be central to any decision making in the study.

3.5.3 Data storage and security

In keeping with Good Clinical Practice, Coventry University Data Policies, General Data Protection Regulation (2017), Data Protection Act (1998) and NHS Data Management Guidelines, a data management plan was developed and implemented to manage and protect data (figure 2). No patient identifiable data was held by the study team or transferred out of the study site, data was held securely and encrypted at Coventry University maintaining General Data Protection Regulation (Information Commissioners Office 2018). Access to the data was limited to the researcher and the research supervisors, for verification purposes and to validate the study findings. The research data will be archived at the end of the project to fulfil the legal, ethical, and organisational requirements as dictated by Coventry University. The data will be kept intact for 10 years, in a format that would enable recovery of the data as required, but that would maintain the principles of confidentiality, in line with Medical Research Councils Good Research Practice Guidelines (2012).

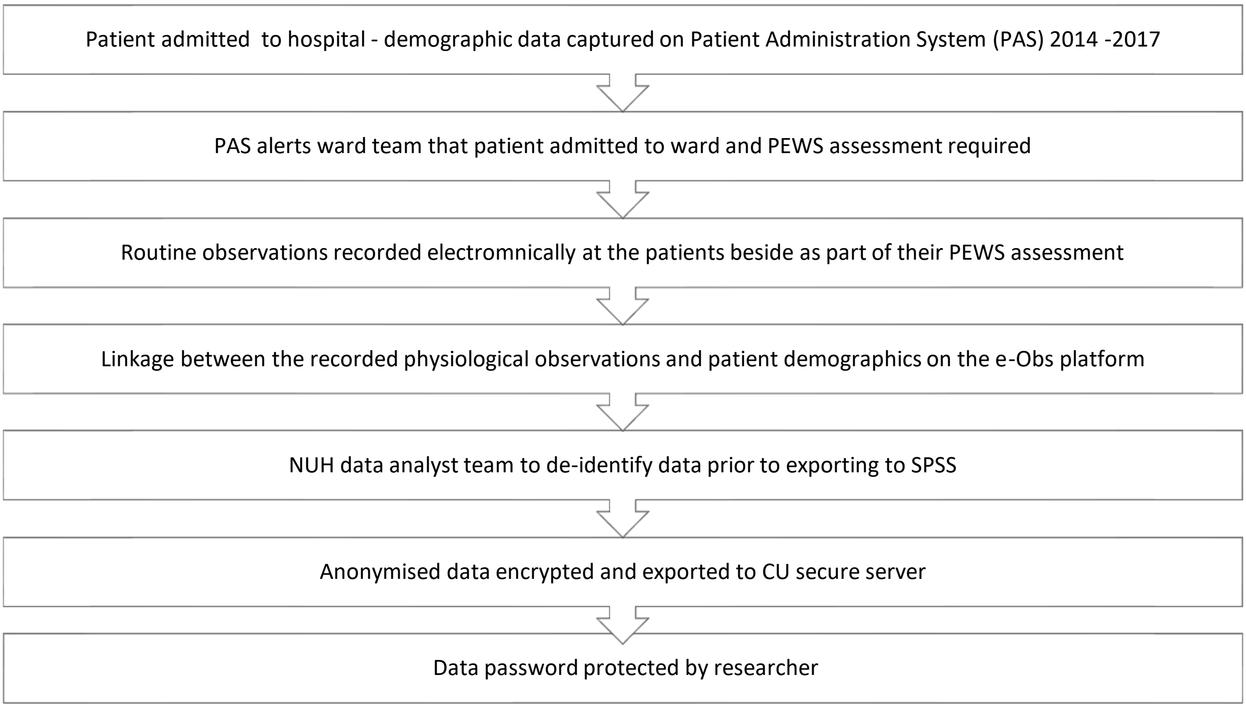


Figure 2. Data Handling Schematic

3.6 Governance

Monitoring of the study was undertaken through bi-monthly research supervisory meetings. The research team must comply with Coventry University Research Policy and make available any documentation necessary for any spot check audit. The NHS Trusts Data Guardian and Information Governance lead have agreed the research. The protocol has been shared with the NHS Trusts Patient Safety Lead and has the support from the Trusts Recognise and Rescue (Patient safety) Committee (appendix 7. for correspondence).

3.7 Dissemination.

Within the project's development phase, it was necessary to consider and plan how findings will be disseminated. Understanding knowledge translation; the process by which research findings inform or are adopted into clinical practice has been an important aspect of the researcher's journey (Curtis et al. 2016).

Being cognisant of the audience to ensure that both the medium and content are appropriate is another important aspect when considering how the research is to be disseminated (Curtis et al. 2016). Within this study the researcher will use the Knowledge to Action Cycle as described by Curtis et al. (2016), as a framework to determine how the research findings will be disseminated at a local and regional level. The application of these findings will potentially impact on the entire care pathway, whether this is to form a baseline assessment, to evaluate the impact of an intervention, as a quantifier of the individual's physiological status or in making a diagnosis. Therefore, the knowledge gained will help inform policy, hospital admission/discharge processes and educational programs. This will ensure that the findings are presented in a variety of formats that will aid both translation and sustainability in practice (Graham et al. 2006).

The researcher also intends to present the findings at national level to ensure a comprehensive dissemination. This will be through poster presentations at appropriate healthcare conferences such as the Paediatric Intensive Care Society or European Society of Paediatric and Neonatal Intensive Care. Although this will not disseminate initially to a wide audience, it is an influential audience, important if findings should to be translated into guidelines or policy.

The researcher also aims to publish the project findings in a relevant peer reviewed journal but one that has a wide readership and is not over specialist such as Nursing Children and Young People. The project findings will be of interest to all children's nurses as physiological observations are fundamental to all areas within the specialty.

Chapter Four

4. Results

4.1 Introduction

This chapter will present the analysis and findings of the study. Firstly, it will describe the demographics and the physiological data as set out in the objectives. The data for heart rate, respiratory rate and blood pressure will then be compared to known reference ranges.

4.2 Sample characteristics

The study included 22,584 CYP (aged 0-19 years) who had observations recorded electronically between September 2014 to December 2017. During this period 40,990 admission episodes were logged, anonymised and exported for analysis. Following the cleaning of the data, as described in Chapter three, 40,802 admission episodes were available for analysis.

4.2.1 Age

The participant ages ranged from newborns (excluding those in the Neonatal Intensive Care Unit) to 19 years old. Considering the evidence from the literature review (Chapter 2), identify the gestation of the infants ≤ four weeks old (n=820) would have enabled the researcher to gain valuable insight into the effect gestation has on the vital signs of the new born. Unfortunately, a limitation of using secondary data meant that this information was not available. The total number of young people included in the study who were transitioning to adult services, and therefore ≥ 17years was 824.

As shown in figure 3, participant age was not normally distributed and is bimodal. It has two modes, one at 0-10mths and the other at 180mths, around which the observations are concentrated. Interrogating the distribution has identified that although there are more admissions in the younger age groups, there is also a second peak in admissions at approx. 15years old (180mths).

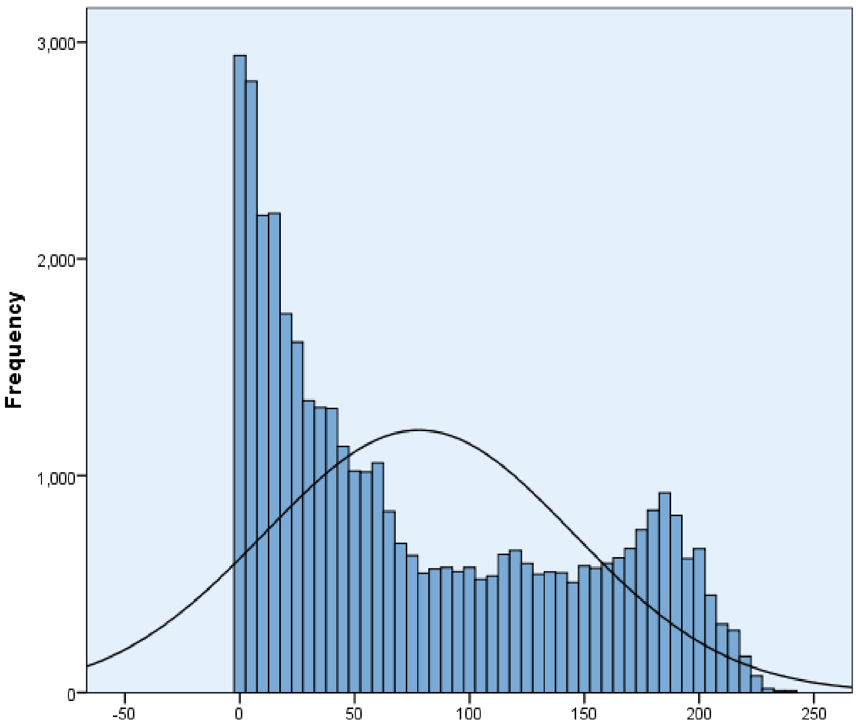


FIGURE 3: AGE OF CYP ADMITTED TO A UK CHILDREN'S HOSPITAL (2014-2017), SHOWING BIMODAL DISTRIBUTION

4.2.2 *S*ex

Of the 22,584 participants included in the study, the majority were male (56%, n=12,647). This division was very similar in the proportions between male (55.5%, n=22646) and females (44.5%, n=18156) for admission episodes.

4.2.3 Diagnosis

Diagnosis, as described by ICD-10 chapter heading levels, is shown in table 9. Respiratory disease (n=6354), infections (n=6202), neoplasm (n=4980), and injury/poisoning (n=4649) were the four most prevalent diagnosis groups. When reviewing diagnosis by age and sex, six diagnosis groups (shaded on table 10) appear to show approximately a 20% difference between the sexes, in all other groups this difference is smaller.

Table 10. Diagnosis by Median Age in Years and Sex

Diagnosis		Age in years				Sex (%) per ICD 10	
ICD 10 Chapter Headings	n= (%)	**Median**	**IQR**	**25th centile**	**75th centile**	**Female**	**Male**
Infectious and parasitic diseases	6202 (15.2%)	7	4	5	9	40 %	60%
Neoplasms	4980 (12.2%)	10	4	8	12	49%	51%
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	1392 (3.4%)	10	4	8	12	47%	53%
Endocrine, nutritional and metabolic diseases	664 (1.6%)	11	3	9	12	48%	52%
Mental, Behavioural and Neuro-developmental	205 (0.5%)	13	1	12	13	60%	40%
Diseases of the nervous system	1422 (3.5%)	10	3	8	11	48%	52%
Diseases of the eye and adnexa	354 (0.9%)	10	4	7	11	51%	49%
Diseases of the ear and mastoid process	480 (1.2%)	9	4	7	11	45%	55%
Diseases of the circulatory system	244 (0.6%)	11	4	8	12	42%	58%
Diseases of the respiratory system	6354 (15.6%)	6	6	3	9	43%	57%
Diseases of the digestive system	2465 (6.0%)	11	7	5	12	40%	60%
Diseases of the skin and subcutaneous tissue	599 (1.5%)	9	5	6	11	42%	58%
Diseases of the musculoskeletal system and connective tissue	1863 (4.6%)	12	2	11	13	63%	37%
Diseases of the genitourinary system	1322 (3.2%)	11	4	8	12	36%	64%
Certain conditions originating in the perinatal period	1151 (2.8%)	1	0	1	1	46%	54%
Congenital malformations, deformations and chromosomal abnormalities	1957 (4.8%)	6	9	2	11	39%	61%
Symptoms, signs and abnormal clinical and laboratory findings not elsewhere classified	3612 (8.9%)	9	7	5	12	48%	52%
Injury, poisoning and certain other consequences of external causes	4649 (11.4%)	11	4	8	12	49%	51%
Factors influencing health status and contact with health service	874 (2.1%)	9	4	7	11	43%	57%
Unknown – not coded	13 (0.0003%)	11	3	9	12	46%	54%
Totals	n=40802	**4**	-	-	-	**n= 18156 (44.5%)**	**n=22646 (55.5%)**

4.3 Admission pathway

During the study period there were more non- elective admissions (63% n=25703) than elective admissions (37%, n=15094). Over half of the non-elective patients were admitted from the emergency department (51%, n=20810), with a smaller percentage (12%, n=4898) admitted directly to the wards from primary care, clinic or direct transfer from another hospital**.** When further reviewing the admission pathway, 96% (n=39170) of the CYP required a single consultant episode (referral). The other 4% (n=1632) required 2-64 consultant episodes per admission. A consultant episode being a new referral to a specialist consultant.

The 40802, admission episodes were accounted for by 22584, patients. Most patients required a single admission (74%, n=16771). The median number of admissions per patient is one (IQR 1-2, range 93). The median in this situation was the most representative level of central tendency, due to the presence of a long right-hand tail in the distribution.

4.4 Outcome

Survival to discharge was 99.9% (n=40791), 16 CYP died during the study period. Therefore, the mortality rate for CYP admitted to the wards was 0.39/1000 admissions. Table 11. shows that the majority of patients remained on a ward for the duration of their admission, with only two percent (n=874) transferred as unscheduled admissions to Paediatric Critical Care Unit (PCCU).

Table 11. Outcome of Admission Episodes

Stayed on ward	**Escalated to Critical Care**	**Survived to discharge**	**Died**
98% (n=39928)	2% (n=874)	99.9% (n=40786)	0.04% (n=16)

Median LOS for CYP on the wards was one day (IQR 0-2, range 358), this increased to two days (IQR 1-3, range 191) for those transferred to critical care.

Table 12. illustrates the percentage of ward patient stays by LOS. Over 80% of all ward admissions were for up to 48 hours, with only 8% staying 5 days or more.

Table 12. Length of Stay for Ward Patients at Study Site

Ward patient stays	Length of stay
41%	Less than 24hours
40%	1-2 days
11%	3-5 days
8%	>5days

4.5 Physiological observations of CYP in hospital

4.5.1 Respiratory rate

The case summary for respiratory rate by age can be found in appendix 3. The Scatterplot (figure 4) visually demonstrates the direction of the relationship between respiratory rate and age, which in this case is that as age (independent variable) increases, respiratory rate (dependant variable) decreases. A boot strapped Spearman's Rho correlation was run to determine the relationship between age and respiratory rate.

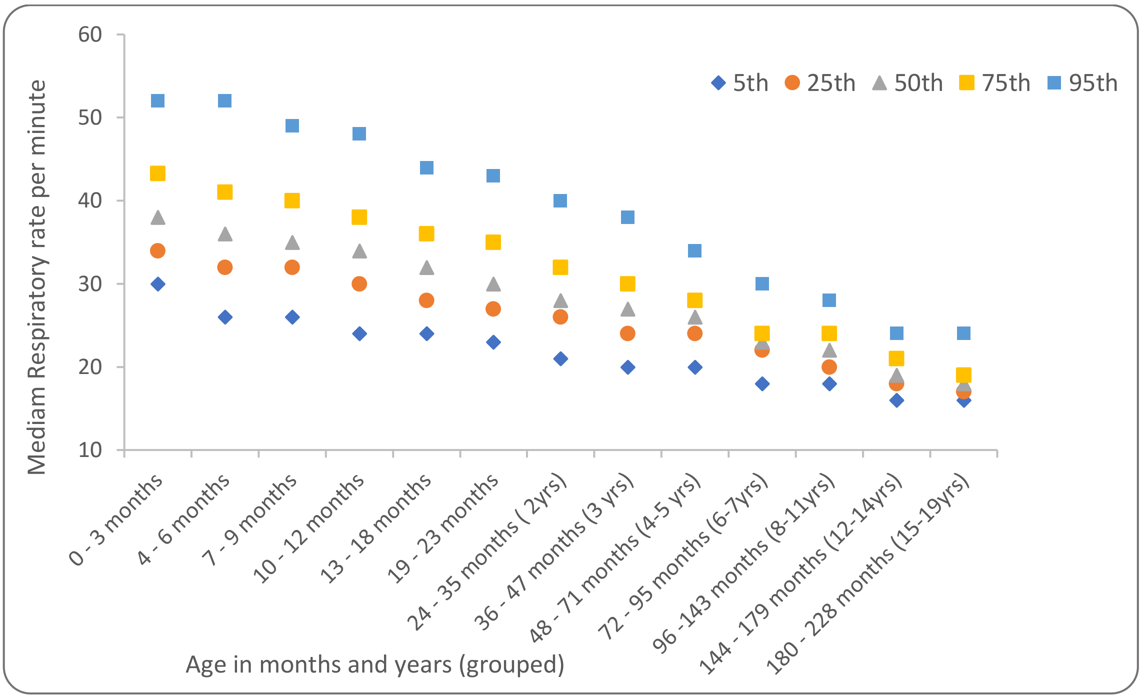


Figure 4. Scatterplot Showing Respiratory Rate Centiles by Age

There is a strong, monotonically inverse correlation between age and respiratory rate, which is statistically significant (r_s = - 0.840, n = 40802, p< 0.001). Respiratory rate and age are scale and ordinal measures, respectively. Therefore, the Spearman's Rho correlation was used to determine the strength and direction of relationship**,** rather than the strength and direction of the linear relationship (Kim & Mallory 2017 p.196).

Table 13. Spearman's Rho Correlation for Respiratory Rate and Age.

				Respiratory rate	Age
Spearman's rho	Respiratory rate	Correlation coefficient		1.000	-0.840 **
		Sig.			0.001
		N		40802	40802
		Bias		0.000	0.000
		Std. Error		0.000	0.002
		95% Confidence interval	Lower	1.000	-0.843
			Upper	1.000	-0.836

*** Correlation is significant at the 0.01 level. Bootstrap results are based on 1000 bootstrap samples*

The boxplots (appendix 5) show there is greater variance in respiratory rate in the younger age groups. The interquartile (IQR) range decreases as age increases, even though the age grouping broadens as age increases, for example 0-3 mths the IQR is 9 compared to an IQR of 2 at 15-19years. From 0-3 years old, the outliers sit above the upper quartile whereas after this age the outliers can be seen either side of the IQR, although the vast marority of the outliers, even in the older groups sit above the upper values. The middle 50% of repiratory rates in the CYP ≥ 4 years old also occur within a much smaller range (IQR, 2-4 compared to 6-9 in the younger CYP).

4.5.2 Work of breathing

Table 14. shows that most participants (88% n=35966) had no increased WOB prior to discharge. Mild effort accounts for 11.5% (n=4710) and a very small percentage (<0.5% n=126) had poor, moderate or severe respiratory effort.

During the hospital stay, the WOB assessment altered for a number (n=7021) of participants. On admission 15.3% (n=6230) were assessed as having mild increased

WOB, which increased to 17% (n=7021) during the hospital stay and then reduced to 11.5% (n=4710) on discharge. In contrast, poor, moderate or severe respiratory effort was recorded in approxiametly 7% (n=2726) of participants during the hospital stay, compared to <0.5% (n=126) on discharge.

Table 14. Work of Breathing

Work of Breathing	Percentage (number)
Normal	88.1% (35966)
Mild Effort	11.5% (4710)
Moderate Effort	0.3% (114)
Severe Effort	<0.1 % (9)
Poor Effort	<0.1% (3)

4.5.3 Peripheral oxygen saturations (SpO_2).

Peripheral oxygen saturation monitoring was not a mandatory observation in the study hospital and was recorded as clinically indicated (such as in participants requiring oxygen therapy). Twelve percent (n=4982) of participants did not have a SpO_2 recorded with their discharge observations.

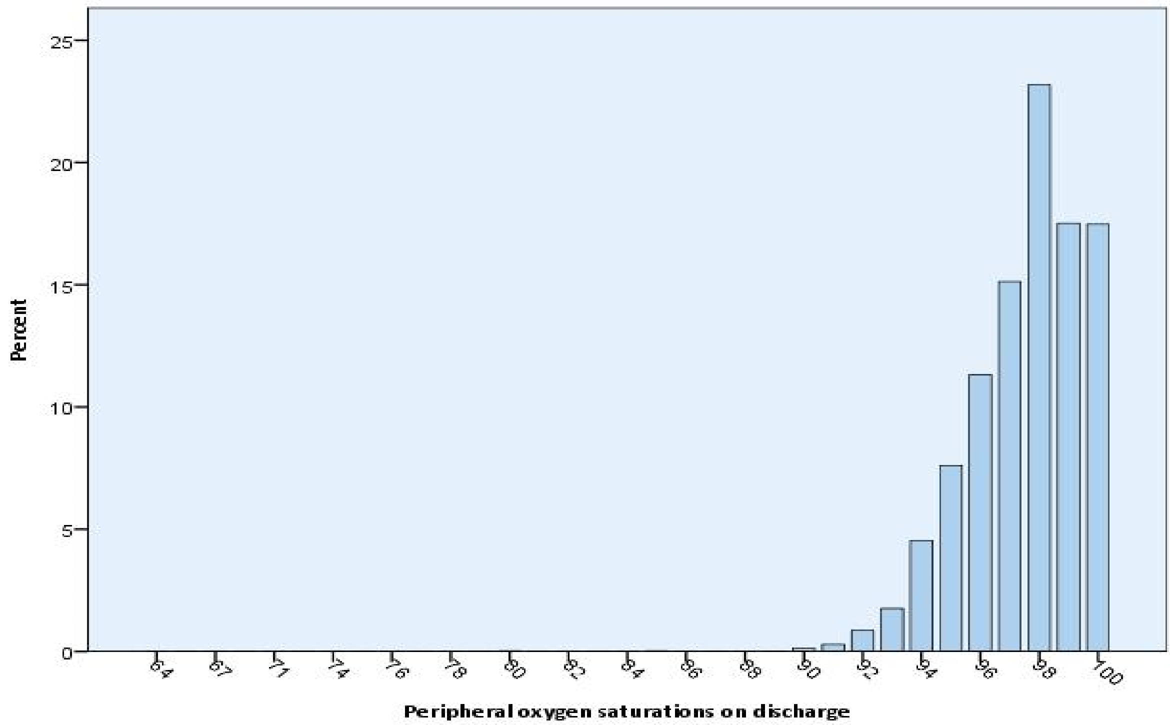
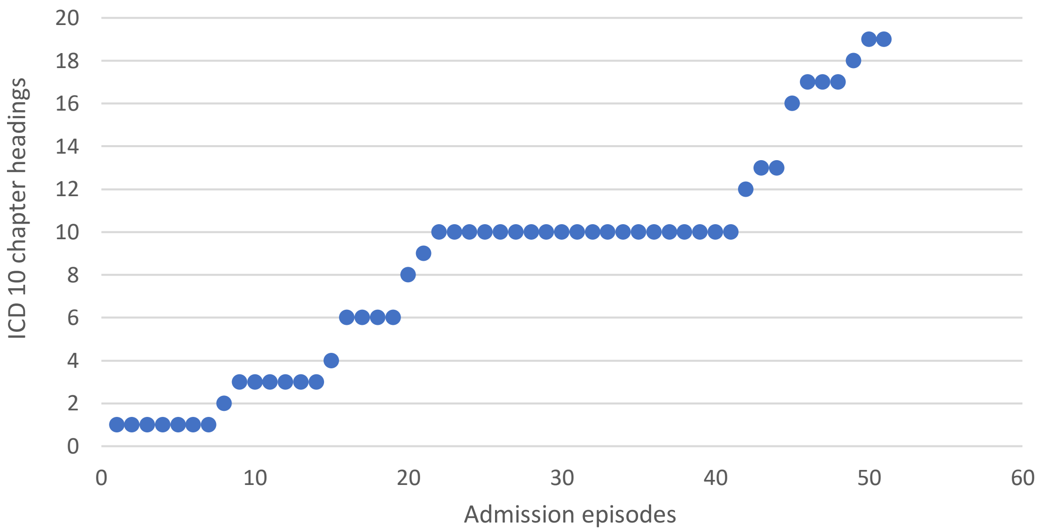


Figure 5. Peripheral Oxygen Saturations on Discharge

The data in figure 5. shows that on discharge, where SpO_2 was recorded, the majority of participants had an SpO_2 was above 94% (n=34,500, 96%). Only 0.5% (n=204) had a SpO_2 ≤89%.

4.5.4 Oxygen requirements

On discharge from hospital 99% (n=40388) of the CYP did not require any supplemental oxygen. However, for those participants that had an oxygen requirement this included: 0.4% (n=154) required 24% oxygen; 0.4 % (n=144) required 28% oxygen; and 0.3% (n=116) required >28% oxygen (ranged from 30%-100%). These figures show that only a very small percentage of participants had an oxygen requirement on discharge. Of the 116 CYP that required >28% oxygen, 51 were documented as requiring a high concentration (≥60%) of oxygen and 31 had a documented requirement of ≥80%. For the researcher the number of CYP requiring significant concentrations of oxygen on discharge is somewhat counterintuitive. The data therefore was further interrogated to uncover the main diagnosis codes for these CYP. The scatter plot (figure 6) shows the ICD 10-chapter headings for patients requiring high percentage of oxygen (≥60%) on discharge. The predominant chapter heading is respiratory disease (10), followed by infections (1), diseases of the blood (3) and diseases of the nervous system (6).



ICD 10 chapter headings
1- Certain infections and parasitic diseases
3- Disease of the blood and certain disorders of the immune mechanism
6 - Disease of the nervous system
10 - Diseases of the respiratory system

Figure 6. ICD 10-Chapter Headings for Patients Requiring High Percentage of Oxygen (≥60%) on Discharge.

Both hospital LOS and admission to PCCU was explored for this group of patients. Approximately 50% had had a LOS ≥5 day (median 3) and 26 CYP required admission to PCCU where the median LOS was 5 days.

4.5.5 Heart rate

Scatterplots (figure.7) show the relationship between heart rate and age. The case summary for heart rate by age can be found in appendix 3.

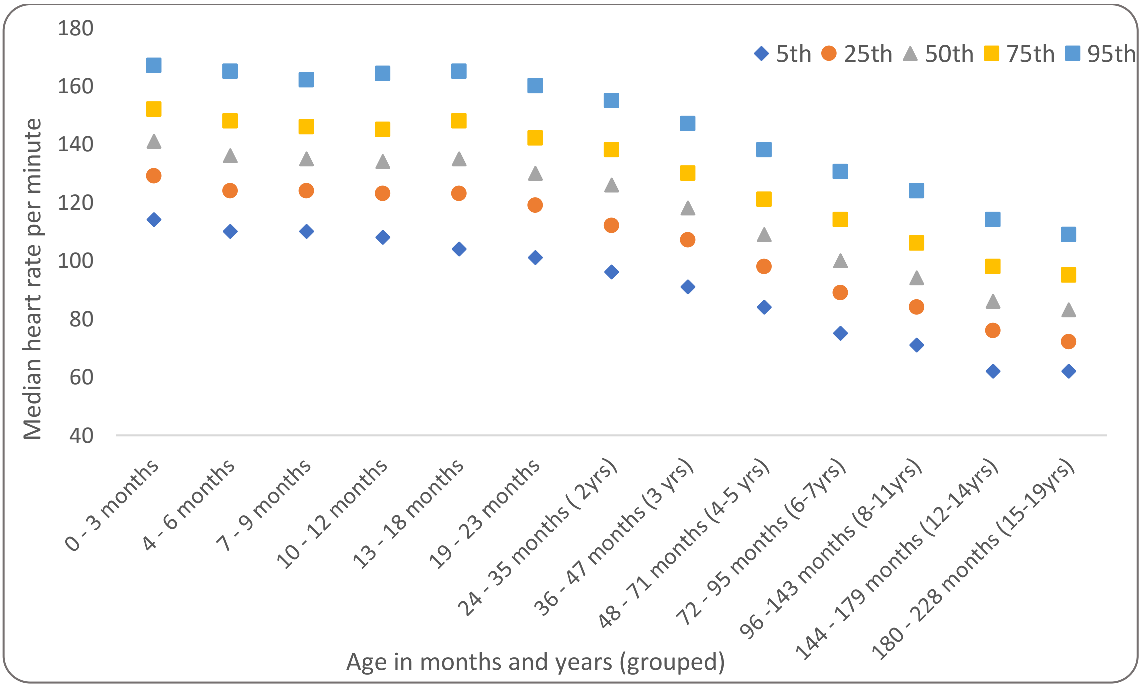


Figure:7 Scatterplot Showing Heart Rate Centiles by Age

A relationship between the two variables (heart rate and age) can be seen, showing as age increases, heart rate decreases. A Spearman's Rho correlation was run to determine the relationship between age and heart rate (Table 15). This nonparametric test is used as one of the variables did not fulfil the assumption of normality required for a parametric test (Kim & Mallory 2017:196). Analysis showed a strong, monotonically inverse correlation between age and heart rate, which was statistically significant (r_s = -0.778, n = 40802, p< 0.001).

Table 15. Spearman's Rho Correlation for Heart Rate and Age

			Heart rate	Age in months
Spearman's rho	Heart rate	Correlation Coefficient	1.000	- 0.778**
		Sig. (2-tailed)		0.001
	Age in months	Correlation Coefficient	-0.778**	1.000
		Sig. (2-tailed)	0.001	.

**.Correlation is significant at the 0.01 level (2-tailed). Listwise N = 40802

Boxplot for heart rate (appendix 5) demonstrates that the IQR does not decrease with age as in all but three age groups the IQR sits between 22-23. The 24-35mth age group had the widest spread of data with an IQR of 26. There were fewer outliers below the minimum data values across all the age groups; with the 4-6mth age groups having the smallest number of outliers either above or below the normal data values. The anomaly in the data set appeared to be in the 13-18mth age group as the median heart rate raised (from 96bpm to 102bpm) instead of following the downward trend.

4.5.6 Systolic blood pressure (SBP)

The SBP of participants is presented in figure 8. It is not a mandatory observation at the study site. The boxplots represent the median, quartiles and outliers for SBP by age. Approximately 30% of participants had their SBP recorded on discharge, consisting of a total of 12,066 measurements, with a minimum of 118 measurements for each age group. A case summary for SBP on discharge can be found in appendix 3.

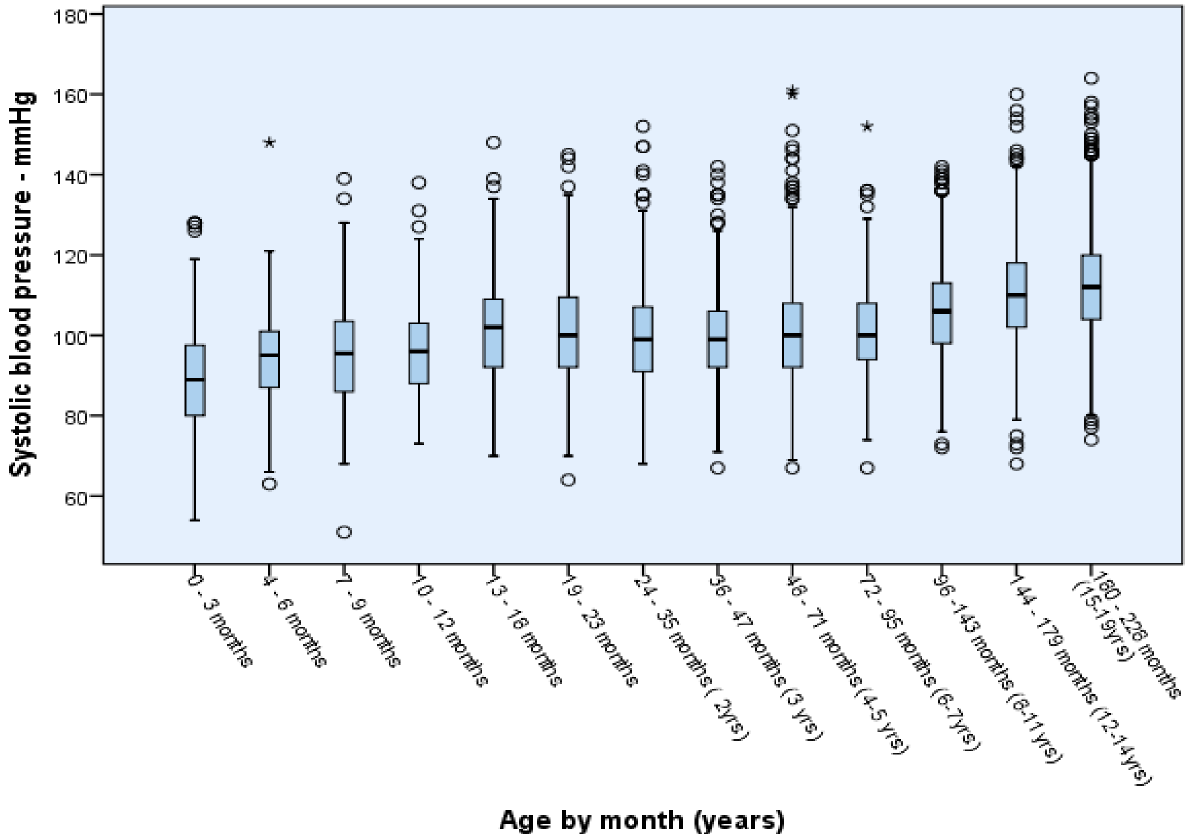


Figure 8. Boxplot Showing Median Systolic Blood Pressure, Quartiles and Outliers

Data showed that SBP increases incrementally with age, but with some degree of plateauing between the step changes, for example between 4-9months, 24-47 months and 48-95 months. There appeared one anomaly for participants aged 13-18months where there is a steeper rise in SBP with a corresponding drop back down to what appears a more normal incremental step at 19-23months. This 5 mmHg rise in median SBP corresponds to a 6 bpm increase in heart rate as highlighted in section 4.5.5 , but this was not reflected in respiratory rate. Outliers are seen in all age groups, they predominately sit above the upper data values and are more prevalent in the CYP ≥ 4 years old.

4.5.7 Skin Colour (perfusion)

This visual assessment is a mandatory observation at the study hospital and is used as a marker of skin perfusion. On discharge from hospital 99% (n=40471) of CYP are assessed as having normal skin colour. Two (n=2, <0.01%) CYP was classed as grey/cyanosed and 0.8% (n=329) as having a pallor.

During the hospital stay, the assessment of skin colour changed for a number of participants. On admission, 3% (n=1225) were assessed as having poor skin colour, which increased to 8% (n=3282) during the hospital stay, and then reduced to 0.8% (n=331) on discharge. The abnormal assessments for skin colour was seen across all age groups and there were no significantly predominant age groups.

4.5.8 Temperature

As temperature is not a mandatory observation only 79 % of CYP had their temperature recorded on discharge. This included 32,197 temperature measurements, with a minimum of 985 measurements within each age group. A case summary for temperature on discharge can be found in appendix 3.

The median temperature on discharge was 36.6 °C (SD 0.45, min 33.3, max 40.3). Although most participants (97%, n=40534) had a temperature within normal limits, there was a proportion of the population (3% n=1268) that appear to be discharged with a significantly high (>38 °C), or low (< 36°C) temperature.

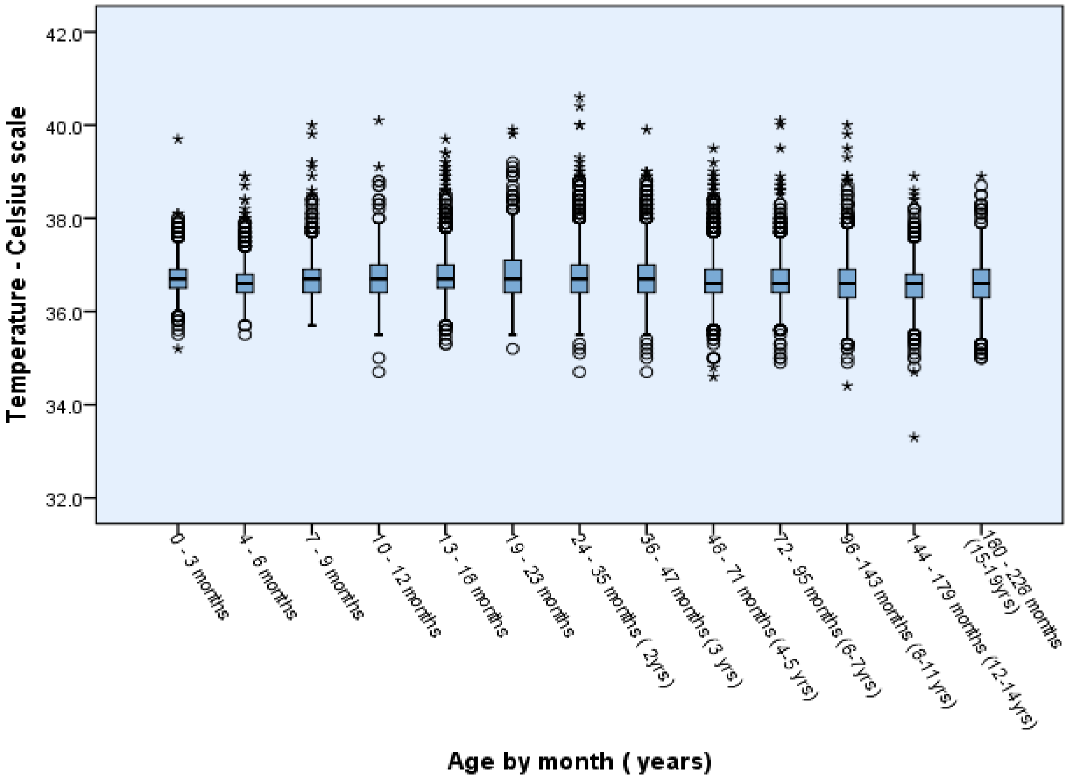


Figure 9: Boxplots Showing Median Temperature, Quartiles and Outliers

Outliers were seen in all age groups; they predominately were above the upper data values. The 4-12 months and 19-23 months' age groups had ≤ 1 outlier below their lowest data range.

4.5.9 Neurological Status

Neurological assessment in the study hospital was determined by assessing the participant's behaviour which included their response to social cues, interventions and their posture. This was assessed both in context of what is normal for the individual and their developmental level.

4.5.9.1 Behaviour and Posture

On discharge the majority (84%, N=34,172) of participants were alert or reported to behave normally (table 16).

The remaining participants were recorded as asleep (15%, n=6,363) or as having significant behavioural changes and were recorded as lethargic (<1% n=247), not responding normally, unable to stay awake or unable to respond (> 1% n=20).

Table 16. Behaviour and Posture on Discharge

Behaviour Assessment	Percent (number)
Behaviours Normally/ Asleep	99.4% (40535)
Lethargy	0.6% (247)
Not responding normally	> 0.1% (15)
Unable to stay awake if roused	> 0.1% (4)
Unable to rouse	> 0.1% (1)
Posture Assessment	**Percent (number)**
Normal	99.9 % (40784)
Abnormal/floppy	> 0.1% (18)

During the hospital stay, the assessment of behaviour changed for a number of participants. On admission 4% (n=1772) were assessed as having abnormal behaviour, which increased to 11% (n=4605) during the hospital stay and then reduced to <1% (n=267) on discharge. The abnormal assessments for behaviour were seen across all age groups, with no significantly predominant age groups.

On discharge only 18 (<1%) CYP had an abnormal posture recorded, the rest (n=41784, 99%) were assessed as having a posture that was normal for the individual. During the hospital stay, the assessment of posture changed for a small number of the CYP. On admission 0.2 % (n=88) were assessed as having abnormal posture, which increased to 0.9% (n=382) during the hospital stay and then reduced to <0.1% (n=18) on discharge. The abnormal assessments for posture were seen across all age groups and with no predominant age group.

4.6 Comparing respiratory rates and heart rates with diagnosis

In order to establish whether the variables respiratory rate and heart rate differed according to participant diagnosis, respiratory and heart rate centiles were analysed against five of the most prevalent ICD-10 codes (infection, respiratory, neoplasm, congenital abnormality and injury). The five diagnoses[5] chosen accounted for approx. 60% of all admissions. Each was compared to the study population through the 5^{th}, 50^{th} and 95^{th} centiles, the graphs for the individual diagnosis codes can be found in appendix 6.

[5] Although the code for 'symptoms, signs and abnormal clinical findings' did account for 8.9% of the admissions this was not analysed separately due to the broadness of this category.

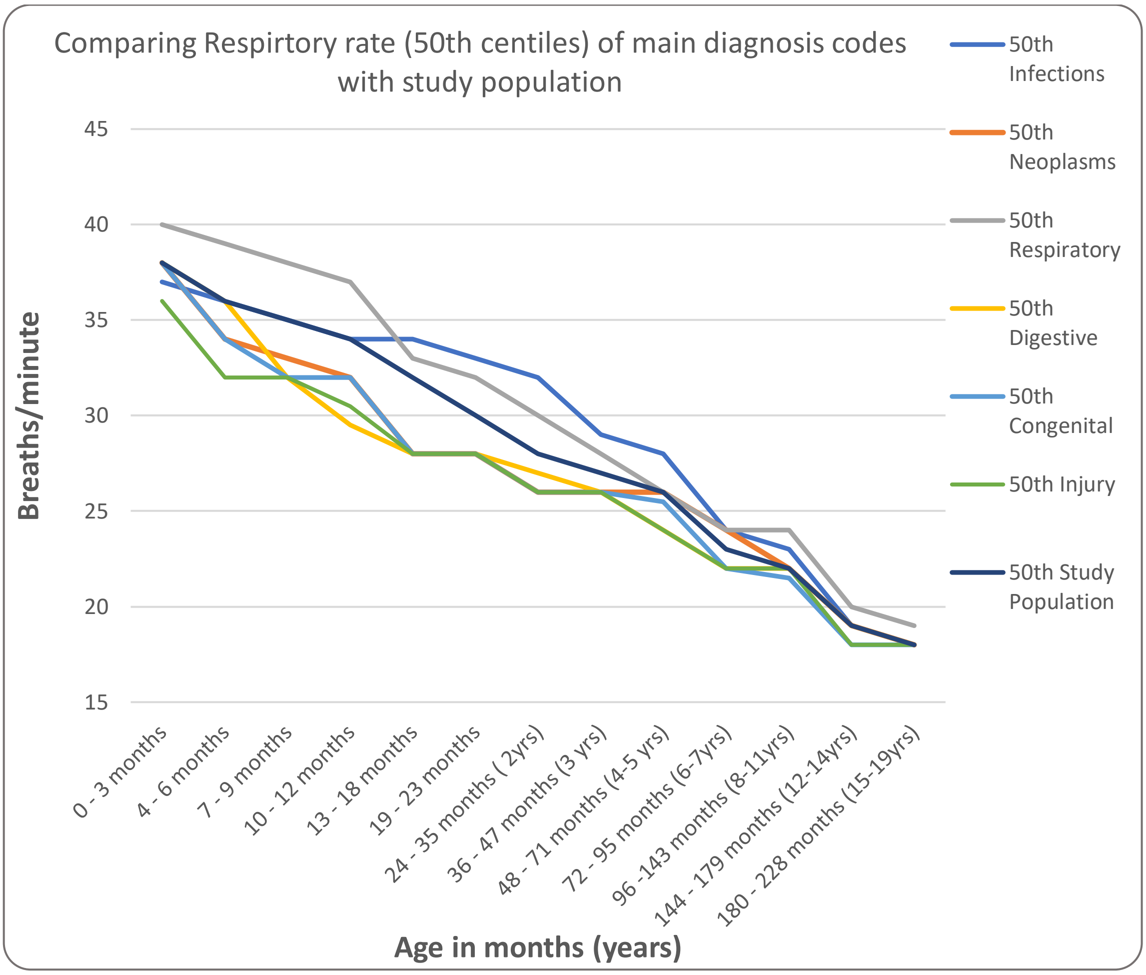


Figure 10. Comparing 50th Centile Respiratory Rates with the Six Most Prevalent Diagnosis Codes

Figure 10 shows the respiratory rate 50th percentile for each code alongside the 50th percentile for the study population. Respiratory disease and infections have the highest median respiratory rates. The difference between the centiles and the study population though is relatively small (1-4 breaths/minute). Between all groups there is greater variance between six months and two years where the difference can vary from five to seven breaths/minute.

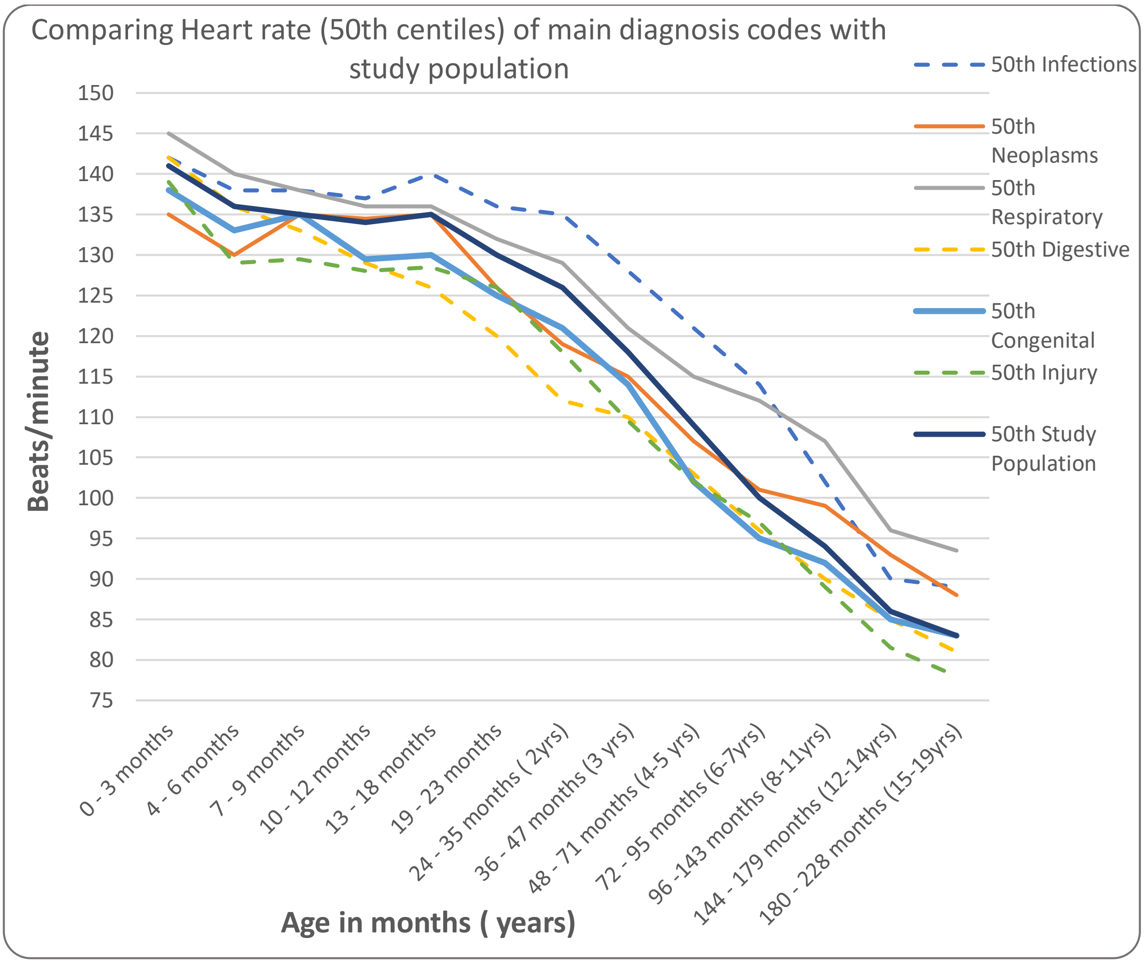


Figure 11. Comparing 50th Centile Heart Rates with the Six Most Prevalent Diagnosis Codes

Figure 11. shows the heart rate 50th percentile for each code alongside the 50th percentile for the study population. Respiratory disease and infection have higher median heart rates, apart from the neoplasm group were the median HR exceeds the study group from eight years onward. The difference between the centiles and the study population is 5 - 18 beats/minute. Between all groups there is greater variance between two and eleven years, where the difference can vary from 18 -23 beats/minute.

4.7 Comparing the observations of children in hospital to standard reference ranges

Using the discharge observations, age specific centile charts for the variables, respiratory rate, heart rate and systolic blood pressure were developed (appendix 4). The data has been plotted to visually compare the study observations to the following standard reference ranges:

- Advanced Paediatric Life Support Guidelines (ALSG 2016).
- Bonafide et al. (2013) Centile charts for children's heart rates and respiratory rates (USA).
- Fleming et al. (2011) Normal heart rates and respiratory rates in children (systematic review UK).
- O'Leary et al. (2015) Defining normal ranges and centiles for heart rate and respiratory rates in an Australian paediatric emergency department.

4.7.1 Comparing study group to Advanced Paediatric Life Support Guidelines (ALSG 2016)

The study groups 5th and 95th respiratory rate, heart rate and systolic blood pressure centiles were compared to the latest APLS observation reference ranges. These centiles were chosen as APLS describe their upper and lower limits using these two centiles. The study groups 50th centile is used to visualise the median of the distribution to assist in the comparison.

4.7.1.1 Respiratory rate and APLS

It is evident from the graph (figure 12.) that the study group's respiratory rates are generally higher than those from the APLS reference ranges, particularly in the 6months-3year age groups. Both the 5th and the 95th centiles for the study group are situated above those for APLS, with rates that are 5-10 breaths/minute higher. There is less variation with the zero to three month and over three-year age groups as the difference between the corresponding centiles is less than five breaths /minute.

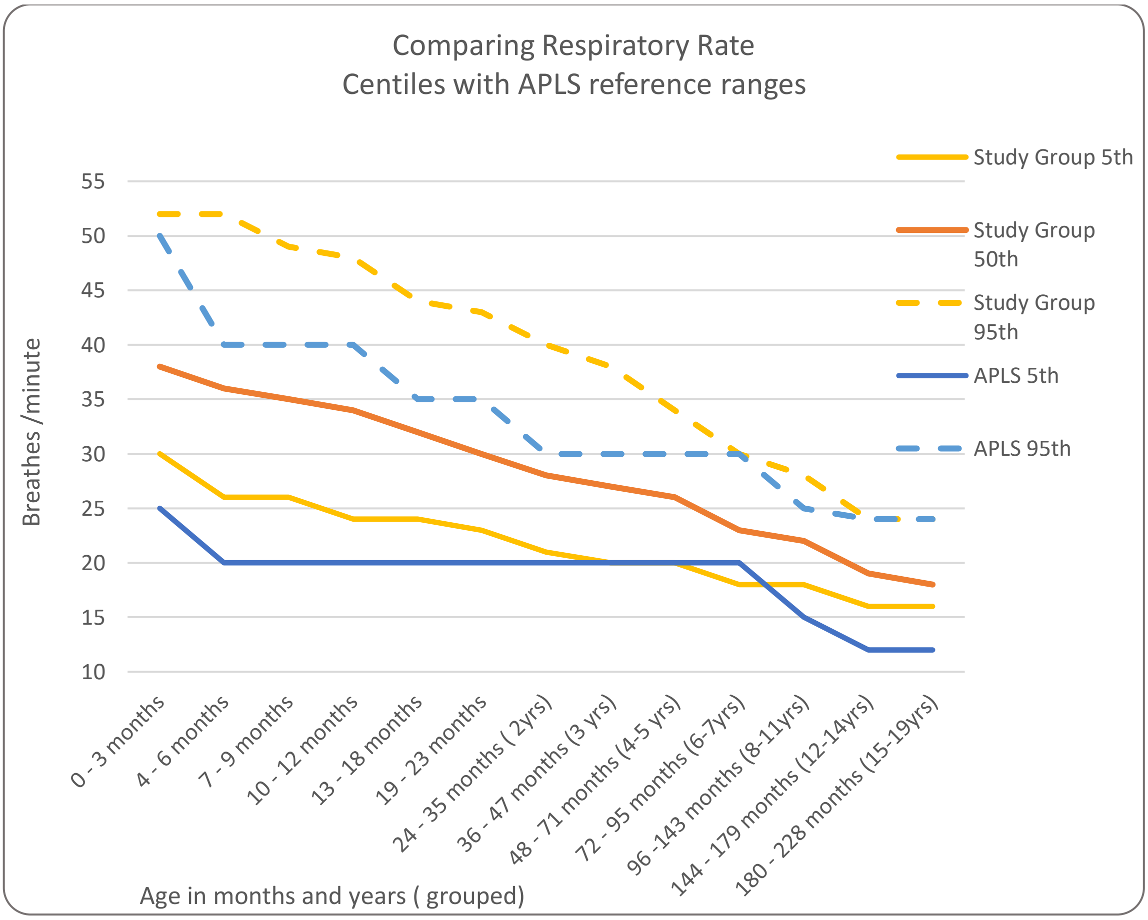


Figure 12: Comparison of Respiratory Rate Centiles with APLS Reference Range

4.7.1.2 Heart rate and APLS

The study group data appears comparable with APLS ranges for heart rate (figure 13.). There is little variation between the corresponding 5th and 95th centiles and the study group 50th centile sitting centrally between both sets of data. The study group heart rate is 2- 7 beats /minute higher on the 95th centile in all age group until 6-7 yrs., after which there is very little difference between the heart rates. Reviewing the 5th centile, for many of the age groups there is very little difference between the two, where there is a difference, the APLS range is 6 beats/minute greater that the study group (at 0-3mths, 13-18mths, 24-35mths, 6-7yrs).

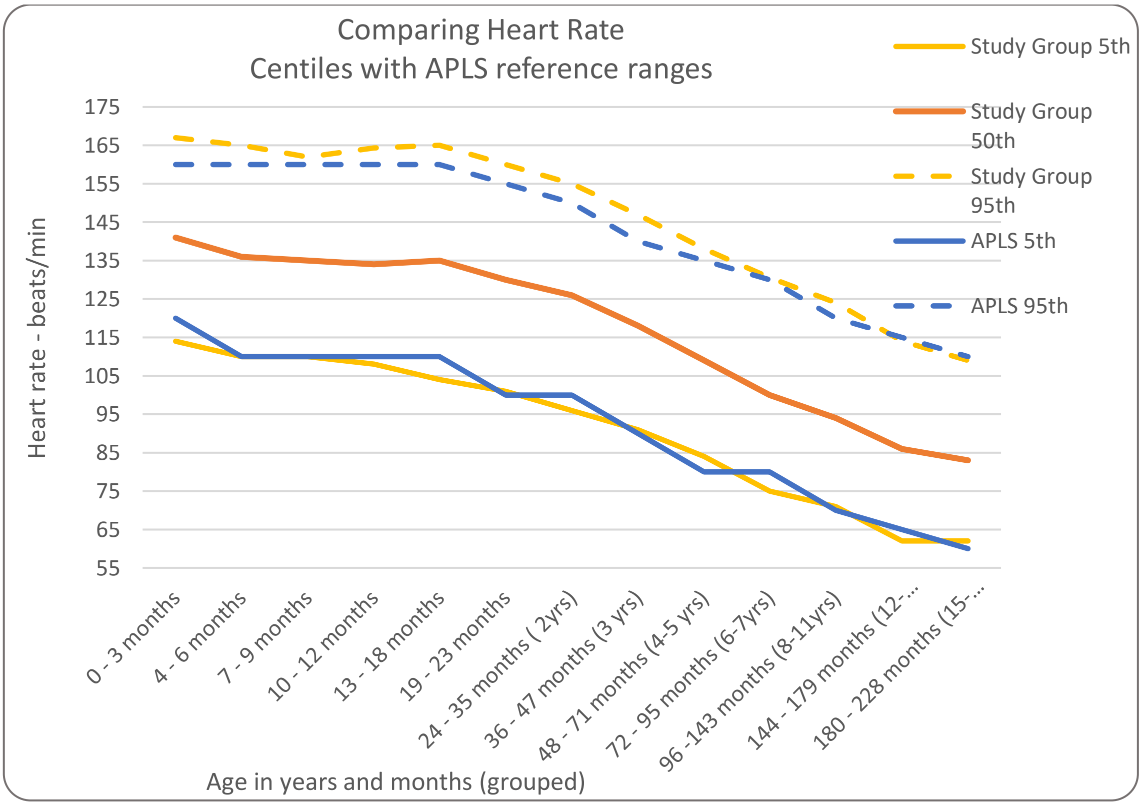


Figure 13: Comparison of Heart Rate Centiles with APLS Reference Range

4.7.1.3 Systolic blood pressure and APLS

For systolic blood pressure APLS has both an upper and lower range, both ranges use 5th, 50th and 95th centiles (figures 14 and 15). The study group systolic blood pressures are situated above the corresponding centiles devised for the APLS lower ranges (figure 14.). This was more noticeable in the 50th and 95th centiles where the study group systolic blood pressure can be between 5- 21mmHg higher than the corresponding APLS centile. There was less variance in the younger (≤ six months) and older age groups (≥12yrs). The 5th centiles appear to correspond more closely to each other, however between 12 months- 4 years of age the blood pressures do vary with a maximum difference of 15mmHg.

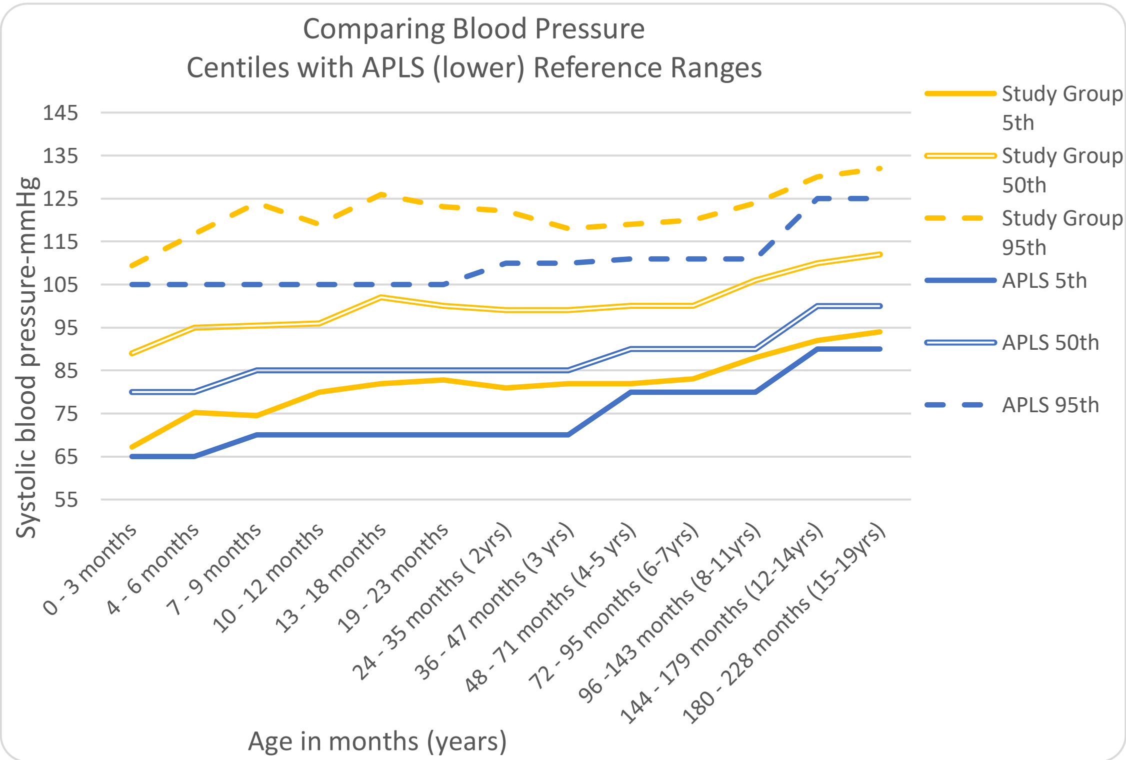


Figure 14: Comparing Blood Pressure Centiles with APLS (Lower) Reference Ranges

The study group varies significantly from the APLS reference ranges, indicating that the participants in this study have higher blood pressures than the reference ranges indicate.

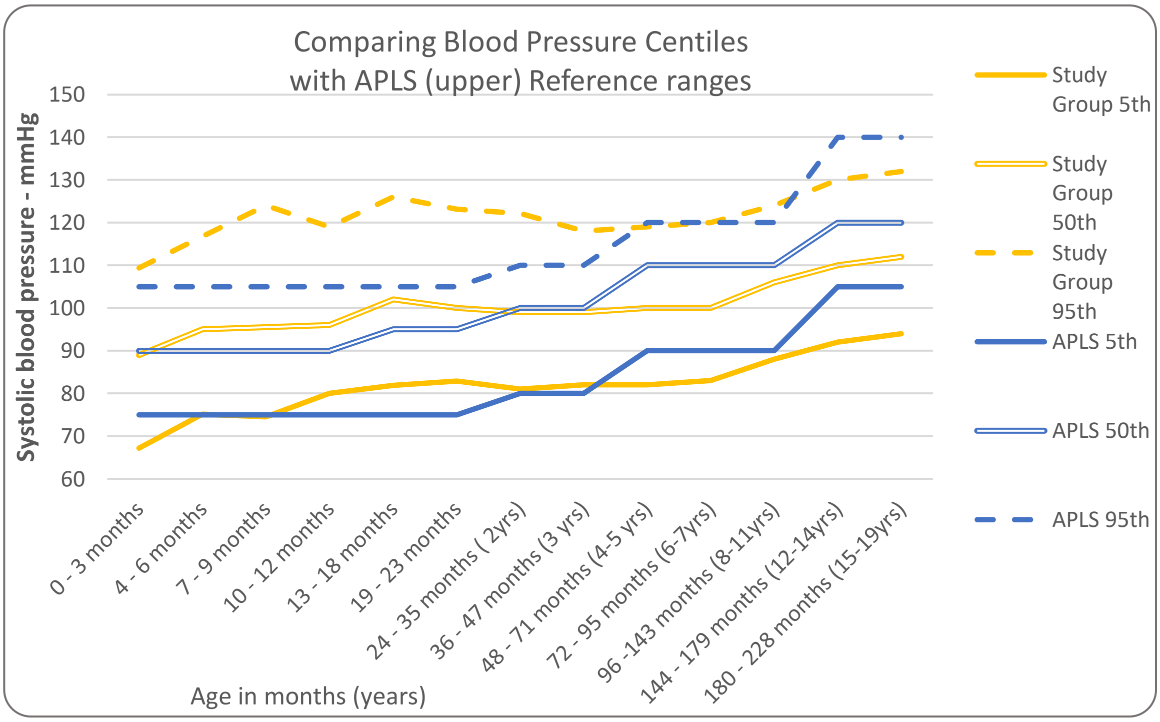


Figure 15: Comparing Blood Pressure Centiles with APLS (Upper) Reference Ranges

In contrast, the systolic blood pressure upper reference ranges (figure15) indicate that the data series traverse. Although in the younger age groups the study group blood pressures are generally higher, between the two – five year age groups this switches, and the APLS ranges are then higher. The 95th centiles show the greatest variance, particularly in the younger age groups were the blood pressures can vary by up to 21 mmHg higher in the study group (i.e. 13-18month group). The range between the 5th

and the 95th centile in the study group is also much larger (up to 49mmHg) when compared to APLS (up to 30mmg).

4.8 Comparing the study group to key clinical papers

The data was interrogated to compare the study group respiratory and heart rate centiles, with the reference ranges from three leading clinical papers (Bonafide et al. 2013, O'Leary et al. 2015 and Fleming et al. 2011).

The 5th, 50th and 95th centiles were used for the comparison and were chosen to ensure consistency in reporting. Unfortunately, Fleming et al. (2011) did not produce 5th and 95th centiles and therefore will be compared using the 25th, 50th and 75th centiles.

4.8.1 Comparison of respiratory rates from study group with leading clinical papers

Irrespective of the data series, figures 16,17 and 18 demonstrates that as expected they all have a similar monotonic relationship with age. The study group and the Bonafide et al. (2013) data series are most closely aligned, but there is variance across all groups. The 5th centile shows the least variance with the maximum range between any age group of three breaths/minute. The O'Leary et al. (2015) data series (figure18,) slightly changes its trajectory from the 18-24month age group, where unlike the other two series it plateaus until the three to five-year age groups, then follows the same course as the other two data series.

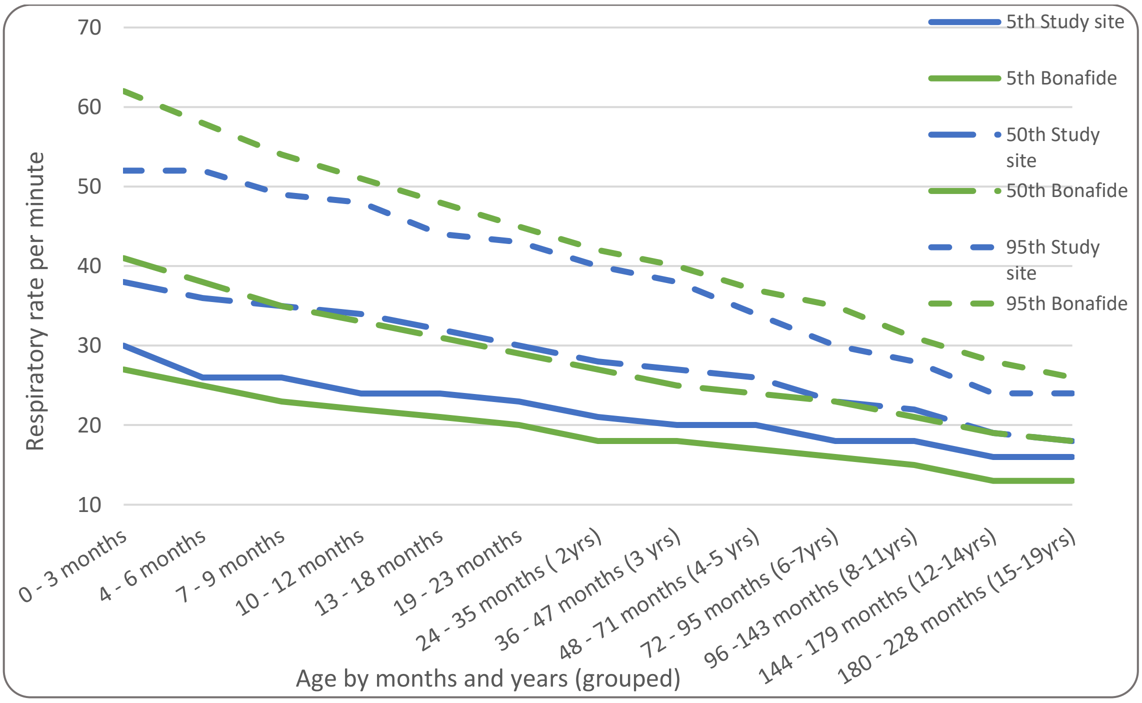


Figure 16: Comparison of Respiratory Rates - Study Group With Bonafide et al. (2013) Centiles

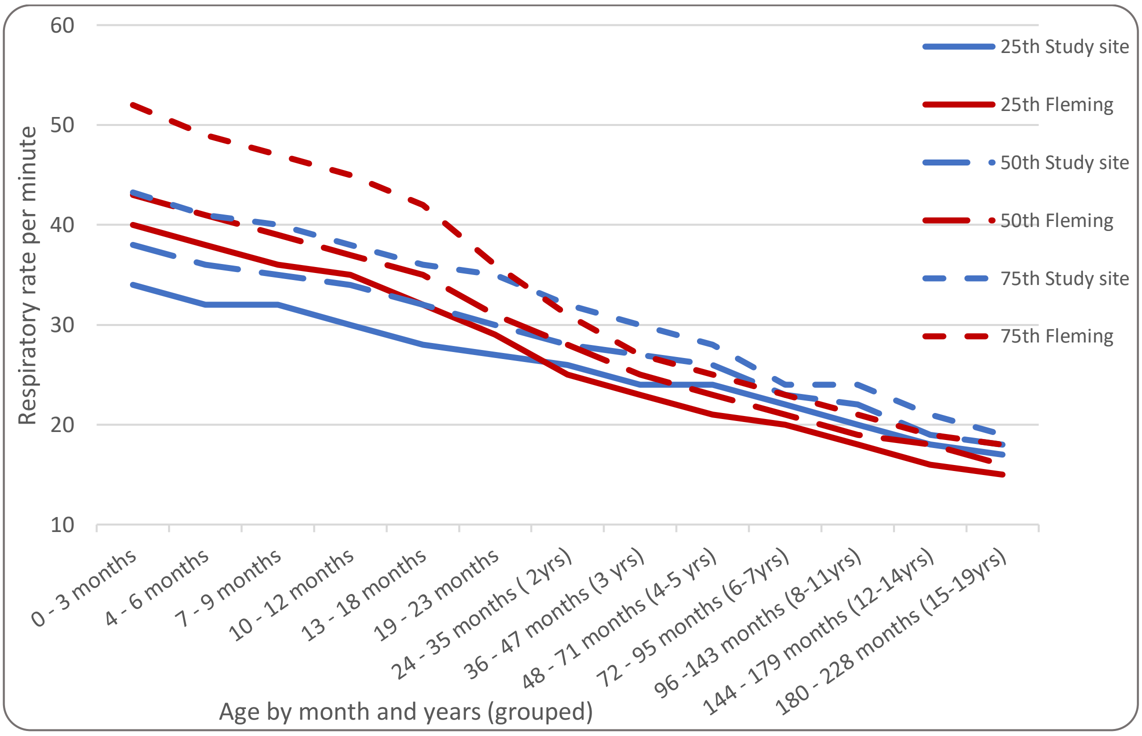


Figure 17: Comparison of Respiratory Rates - Study Group With Fleming et al. (2011) Centiles

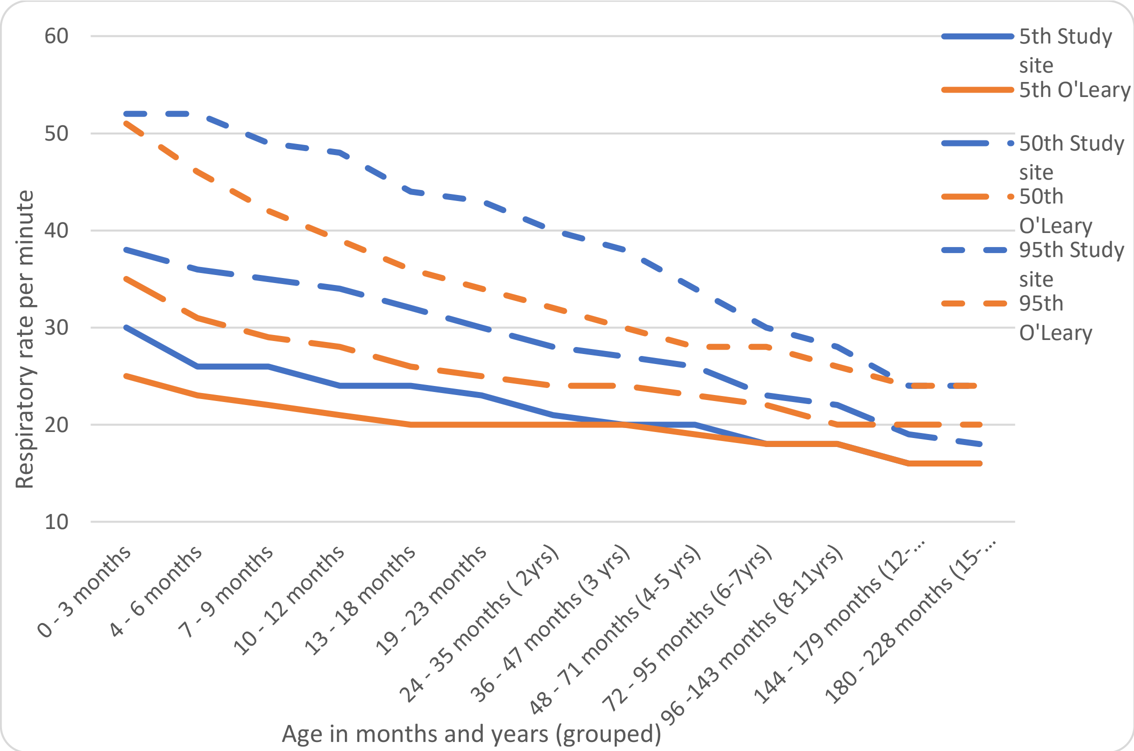


Figure 18: Comparison of Respiratory Rates - Study Group With O'Leary et al. (2015) Centiles

When exploring the 50th centile, the Fleming et al. (2011) data series (figure17) shows the greatest variance. A maximum difference in range being 10 breaths/minute, compared to seven breaths/minute between the other three data series. The younger age groups show the greatest variance, but from the two years' age groups the difference across all the data is minimal (≤ four breaths /minute).

The 95th centile has the greatest variance across the trajectory of the data series. The Bonafide et al. (2013) and O'Leary et al. (2015) data consistently show a nine (n=9) -12 breaths/minute difference between their data points, but from the six to seven-year age group this tails off to ≤ five (n=5) breaths/minute. The study group and the Bonafide et al. (2013) data (figure 16.) have the most closely aligned 95th centiles. The maximum difference between their data points is ≤5 breaths/minute across the trajectory, apart from the zero to three-month age group, were the study group is 10 breaths/minute lower and is more aligned to the O'Leary et al. (2015) data series.

4.8.2 Comparison of heart rates - study group with leading clinical papers

The data was interrogated to compare the study group heart rate centiles, figure 19, 20 and 21 depicts the data series to enable comparison. These graphs indicates that irrespective of the data series, they all have a similar monotonic relationship with age. There is much less variance when comparing the heart rate data series for the clinical papers.

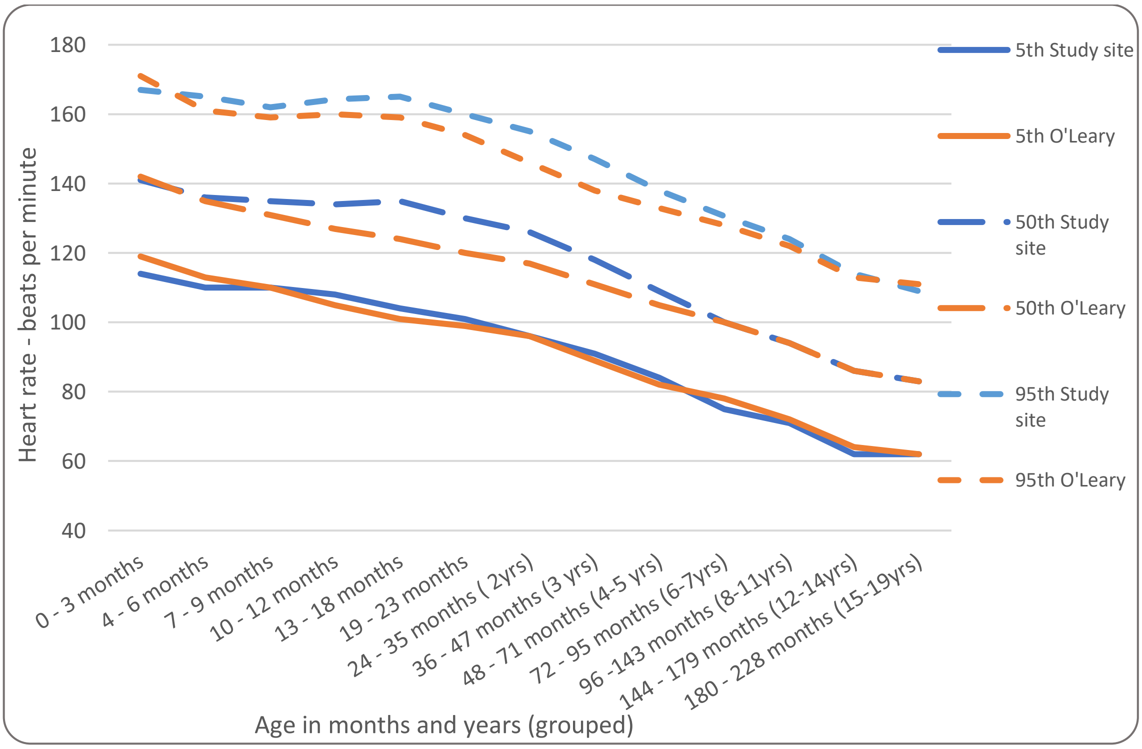


Figure 19 : Comparison of Heart Rates - Study Group With O'Leary et al. (2015) Centiles

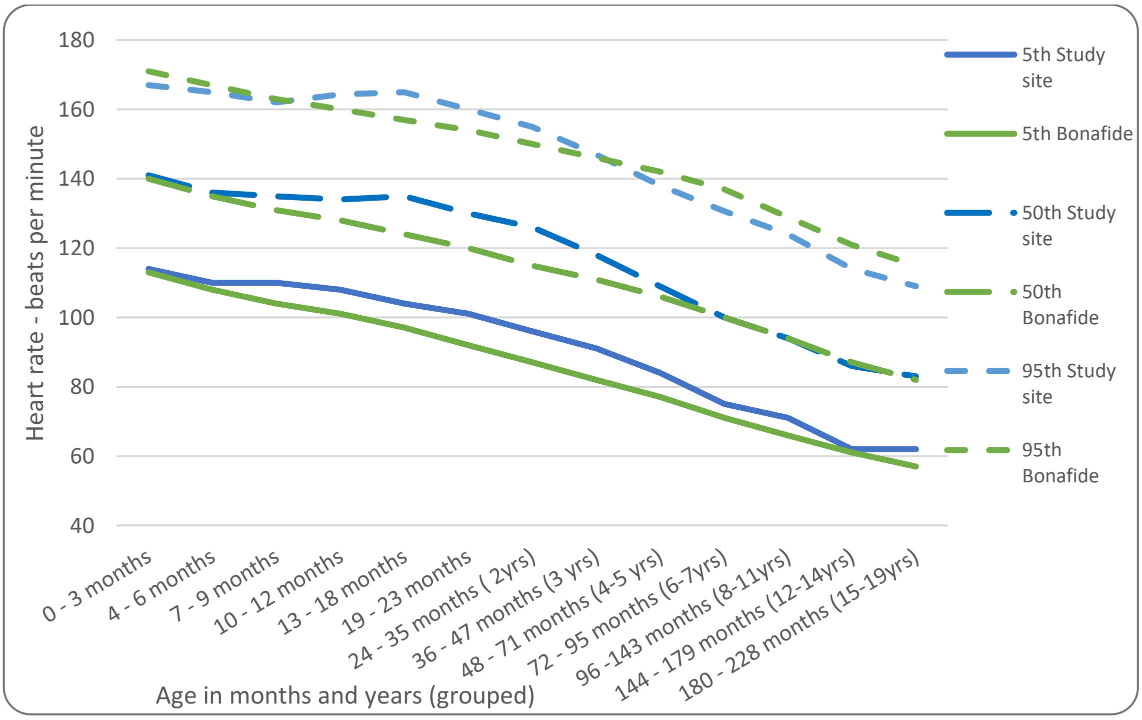


Figure 20 : Comparison of Heart Rates - Study Group With Bonafide et al. (2013) Centiles

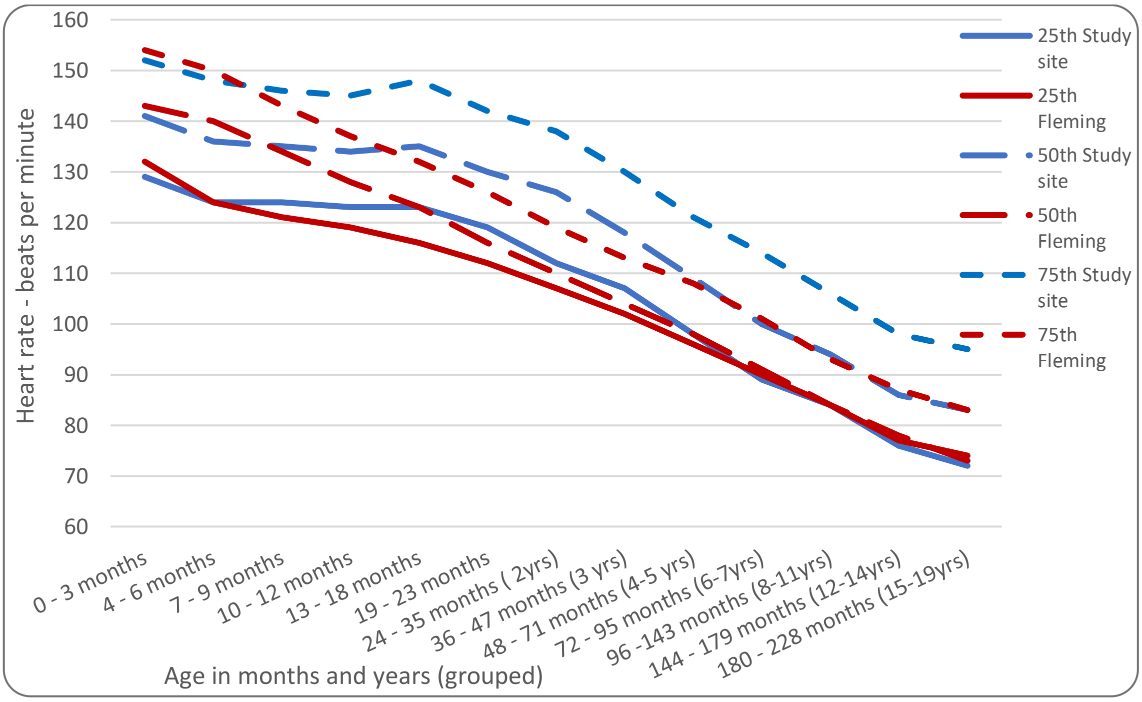


Figure 21: Comparison of Respiratory Rates - Study Group With Fleming et al. (2011) Centiles

The 5th centiles shows that the O'Leary et al. (2015) data (figure 19) and study group data series are particularly closely aligned, however across all the data groups there is only a difference of between 3-9 beats/minute. The Bonafide et al. (2013) data series (figure 20) from 13-18mth age group starts to be situated below the other data series and is up to 9 beats/min lower than the other groups.

When reviewing the 50th centile, the study group standout as the least aligned across the trajectory, particularly between the 13-18months and four to five-year age groups. Here the study group's heart rate is 10- 16 beats/minute higher than the other two groups.

The 95th centile also shows alignment across all three data series. The maximum variation between these groups at this centile is nine beats/minute. The O'Leary et al. (2015) data series generally has the lowest data points, although the maximum difference is eight to nine beats/min between the three year and six to seven-year age groups. The Bonafide et al. (2013) data points show the smoothest trajectory throughout the 5th, 50th and 95th data series.

4.9 Summary

This chapter has described the analysis and findings from the exploration of 40,802 admission episodes. The demographics of 22,584 participants have been explored. There are two peaks in age distribution, infants (>12mth) and at 15years, there are also slightly more males in this population sample. It has been noted that the four predominant diagnoses for this study population are infection, respiratory disease, neoplasm and injury, accounting for approximately 54% of the admissions. More CYP are admitted via an emergency rather than planned pathway, but survival to discharge across the study population is high at 99.9%. Approximately 80% of CYP stay in hospital for ≤ 2days and 41% for >24hrs.

Centiles were developed for respiratory rate, heart rate and systolic blood pressure. The greatest variation in these observations across the hospital stay can be seen in the younger age groups, this difference reduces sequentially with age. When these centiles were compared to APLS ranges, the study's respiratory rates were higher and did not compare well to APLS reference ranges, whereas heart rates were more aligned. When comparing APLS upper heart rate range to the study's 95th centile, the study was consistently two-seven beats per minute higher. SBP was also consistently higher in the study group and on the 95th centile is up to 21mmHg higher than the APLS upper range. The study centiles were also compared to centiles described in three leading clinical papers. There was variation in all the comparison groups, respiratory rate had most variance and similar to APLS, heart rate centiles aligned better. There was most agreement between the lower (5th) centiles and least between the upper (95th) centiles. The study group was the outlier in the 50th centile, and between one-three years had significantly higher heart rates (10-16 beats per minute). The following chapter will further discuss these findings in context of existing literature.

CHAPTER FIVE

5. Discussion

5.1 Introduction

This chapter will critically draw together the results in relation to the existing literature, highlighting the unique insights provided, and their implications for clinical practice. The study limitations will be examined and recommendations for future research will be formulated.

5.2 Characteristics and distribution of the physiological observations of CYP in hospital

5.2.1 Age

The population distribution in the study appears comparable to CYP emergency hospital admission rates across the UK (Keeble & Kossarova 2017:16), thereby supporting the generalisability of the findings. This study, as well as the literature (Fleming et al. 2011) show that age is an important determinant when creating observation reference ranges. Age bandings vary in many of the studies, which makes interpreting and comparing the ranges difficult (Fleming et al. 2011 and Van-Kuiken, Huth 2016). In this study, age was measured in both months and age groups. The age groups were chosen to ensure that the data could be compared to previous studies, but whether these are the most appropriate bandings for reference ranges remains unclear. Fleming et al. (2011), devised age bandings based on incremental increases in heart and respiratory rates[6]. Fleming's study is the only study reviewed that describes how they addressed this issue but makes no reference to how the increments were chosen. Therefore, this indicates they were derived from clinical experience and intuition, which is a consistent theme throughout the literature (Bonafide et al. 2013 and O'Leary et al. 2015). As demonstrated in the Findings chapter (pages 64 and 69), the vital signs of CYP have a monotonically inverse relationship with age. This suggests that continuous age adjusted centiles rather than age-group reference ranges would be beneficial.

5.2.2 Diagnosis

The findings showed that the four predominant diagnosis groups for the study population were respiratory disease, infection, neoplasm, and injury/poisoning. This data is comparable to UK emergency admissions data for 0-24-year olds (Keeble and Kossaroval 2017, Health Foundation 2018). However, the diagnosis of neoplasm is not identified in the Health foundation data, as these CYP are often admitted through a referral, transfer or clinic pathway rather than an emergency admission route.

[6] Five beats/minute for heart rate and two breaths for /minute for respiratory rate.

5.3 Outcome

As highlighted in Chapter one, the number of CYP with complex and long-term health needs has increased, which is also reflected by fewer children dying from acute illness and more from long-term chronic or complex disability. This study reports a mortality rate 0.39/1000 admissions for CYP admitted to the wards, comparable to national mortality rate for 0-24year olds which is 0.5 /1000 admissions (Health Foundation 2018). As the ability to intervene successfully has substantially increased, the long-term survival of CYP has improved (Nuffield Trust 2017). Consequently, inpatient care has become more complex as patient acuity rises (Keeble and Kossaroval 2017, Larcher et al.2015). In contrast, Wynne and Hull (1977), in the same Children's hospital as this study, found that after examining 399 consecutive admissions, 20% were admitted primarily for social the reason, described as failure to thrive or failure to rear, with disease symptoms an 'excuse rather than the reason for admission' (Wynne and Hull 1977 :1124).

The results of this study demonstrate the length of stay (LOS) for CYP on the wards was one day (IQR= 0-2, range 358). Heys et al (2017) in their cohort study regarding length of paediatric inpatient stay, socio-economic status and hospital configuration found similar findings when comparing two children's hospitals in the UK. They reported a median LOS of 1 (IQR=1-2). Similarly, Keeble and Kossaroval (2017) report that the average length of stay following emergency admission declined by 17 per cent between 2006/07 and 2015/16, from 1.99 days to 1.64 days which further supports the generalisability of this study's findings (Bryman 2016).

5.4 Physiological Observations

There is overwhelming evidence that although multiple reference ranges exist for vital signs, many are not supported by robust evidence (Fleming et al. 2011 Bonafide et al. 2013, O'Leary et al. 2015 and Van-Kuiken, Huth 2016). Exemptions are reference ranges that are symptom specific, such as those for high blood pressure (Van Kuiken and Huth 2016). Yet reference ranges such as APLS are prominent throughout healthcare practice, whether in primary or secondary care (Fleming et al. 2011).

5.4.1 Respiratory rate

Regarding respiratory rate, the results from this study concur with previous studies (Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015) that as age increases respiratory rate decreases with a monotonically inverse, rather than linear, relationship. As future reference ranges are developed, this needs to be accounted for to ensure that 'age banding' appropriately reflects the incremental changes in respiratory rates.

In this study the younger age groups (0-3 years), have greatest variance in their respiratory rates, with all outliers sitting above the upper quartiles. These results could be attributed to their predisposition to acute respiratory disease due to the relative immaturity of their immune system, (Schaad et al 2015, Tregoning and Schwarze 2010). High respiratory rates, coupled with an increased effort of breathing, are indicative of respiratory disease (ALSG 2016). Respiratory disease is common in young children, affecting up to 25% of children under one year and 18% of children one to four years

(Schaad et al. 2016). This study also demonstrates a high prevalence of respiratory disease in CYP, finding that 15.6% (n=6354) of the study population fell into this category.

When further reviewing the data for respiratory rates, other patterns also emerged. There is less variation in rates from four years of age (IQR 2-4, compared to 4-6 in younger age groups). Outliers in all age groups sit predominately above the upper quartiles, suggesting that extremely low respiratory rates are particularly abnormal in all CYP. These insights have implications for clinical practice and developing effective reference ranges/PEWS, that can account for variability in high respiratory rates and also set appropriate lower limits to ensure both sensitivity and specificity.

5.4.2 Work of breathing

In this study WOB was predominately recorded as normal or mildly increased. Therefore, when considering reference ranges and EWS triggers, scores above mild should be considered as significantly abnormal. The subjective nature of this assessment and its reliability to predictive deterioration has been questioned . Sinitsky and Reece (2013) suggest that WOB does not play a significant role in PEWS demonstrating that the predictive power of the NHS Institute PEWS did not change when WOB was excluded (AUC 0.86 with WOB and 0.85 without). In contrast, an observational study to determine the interrater reliability in the Paediatric Observation Priority Score (Langton et al 2018) demonstrated good observer agreement (Kappa 0.833) in the assessment of WOB. It is important to note that the sample size was small in this study (n=12) potentially limiting the reliability of the findings.

Seven percent (7% n=2726) of CYP had poor, moderate or severe respiratory effort recorded during their hospital stay, compared to <0.5% (n=126) on discharge. In young CYP the thoracic cage is not as stable and is more pliable, and the diaphragm is also less efficient, therefore an increased WOB is easily observed (ALSG 2016). It is therefore not surprising that this study found increased WOB, to be more prevalent in the younger age groups (< four years).

5.4.3 Heart rate

Regarding heart rate, the findings from this study concurs with previous studies (Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015) that as age increases rate decreases with a monotonically inverse, rather than linear relationship. Taking this into consideration, the large stepped approach used in APLS reference ranges seems somewhat simplistic and counterintuitive. Either side of the transition points (where the range value changes), the reference point will either be too high or too low, causing false positive and false negative escalation of the parameter. This is particularly significant for the younger age groups where variation in physiology and development change rapidly, this pace of change decreases with age (Smyth 2011). Just as with respiratory rates, future reference ranges need to account for these issues when devising both the age bandings and incremental changes in the heart rates.

When viewing heart rate across the trajectory of the admission episode the IQ ranges stays fairly static across all age bandings (IQR 22-23) and outliers sit either side of the median, meaning that in the clinical setting it will be more common to see these extremes in heart rate. However, an anomaly in the data set appears at the 13-18mth age banding. Here, the median heart rate rises slightly (from 96 to 102 bpm), rather than following the downward trend of the median as age increases. Similarly, the data shows a steep rise in SBP at 13-18mths, which then drops back to a more normal incremental step at 19-23months. This may be a chance finding, although at this age, infants begin to mobilise and are more upright (Gerber et al. 2010). This could have an impact on the infant's cardiovascular status until the infant becomes more stable and confident in sitting and walking. The physical energy required to sit, and pull to stand, elicits a cardiac autonomic response, which in turn increases heart rate (Finley and Nugent 1995, Porges and Furman 2011). When considering the related physiology this appears a plausible theory, however there is a paucity of empirical evidence to substantiate this. There is also several other possible cofounds; crying, increased body temperature, movement artefact from vital signs monitors that could affect these measurements (Massin and Bernuth 1997, Thompson et al.2009, RCN 2017). The findings therefore need to be interpreted with caution and further exploratory research is required to ascertain whether the anomaly is purely a chance finding or is reflective of this age group.

5.4.4 Systolic blood pressure

Hypertension occurs in 3-5% of the paediatric population (Flynn and Urbina 2012), which maybe a contributing factor to the number of outliers seen above the upper quartiles in this study. The measurement of blood pressure in children though can be challenging, and erroneous recordings of high blood pressure in particular can often occur if the CYP is crying, anxious or in pain (Rao 2016). White Coat Hypertension may also be a causative factor and is said to account for 30-40% of high blood pressure recordings (Flynn and Urbina 2012). Here the CYP's SBP sits above the 95th centile when recorded in a clinical setting (even when they are settled and comfortable) but they are normotensive outside a clinical setting (Rao 2016 and Flynn and Urbina 2012). Poor measurement validity is also well recognised. This may be due to staff choosing the wrong cuff size, poor placement of cuff or inappropriate inflation pressure settings - all potentially causing erroneous readings (Burchell and Michie 2005).

Conversely, few outliers sit below the lower quartiles, therefore it appears uncommon for CYP to have low SBP. Hypotension therefore should be considered a significantly abnormal result.

5.5 Comparing vital signs in relation to specific disease

In this study, data was extracted to compare respiratory and heart rates with the six most prevalent diagnosis codes, these codes accounted for 65% of all admissions.

Infection and respiratory disease had the highest median respiratory rates (one-four breaths/minute higher). This was not surprising given the physiological impact both have on respiratory rate (APLS 2016) or example approximately one-third of infants with a viral respiratory infection will present with increased respiratory rate (Tregoning and Schwarze 2010).

Contrary to expectations, the median respiratory rate for digestive illness and injury sit below the study group's centile, with the highest rates being between six months and two years of age. It is difficult to draw conclusions from these finding regarding pathophysiology. Increased respiratory rate is often the bodies attempt to correct hypoxaemia (low oxygen) and hypercarbia (high carbon dioxide - CO_2). Cretikos et al. 2008 in a discussion paper describe how conditions that cause metabolic derangements, including digestive illness and injury, often see a precipitous increase in respiratory rate. One potential explanation is that these two groups are often subjected to surgery/investigations that require an anaesthetic and/or opiate pain relief, both of which could be contributing factors to lower respiratory rates (Cretikos et al. 2008). These two groups may have more participants that are normally fit and well, without any underlying chronic illness, therefore on discharge their respiratory rates may be reflective of respiratory rates of well CYP. When comparing this study's findings to those of Fleming et al. (2011), their 50th centile for the respiratory rates of well CYP sits above this study's corresponding centile, therefore not supporting the theory.

When comparing heart rate with each of the diagnosis codes, similar to respiratory rate, respiratory disease and infection have the highest median heart rates and the digestive disease and injury groups have the lowest heart rates amongst all the diagnosis groups. There are clear pathophysiological explanations that link high heart rates to both respiratory disease and infection (ALSG 2016). Fever is viewed as a normal physiological response to an infection. Thompson et al. (2009) in a cross-sectional study of 1933 CYP presenting in primary care devised centiles for heart rate that were both age and temperature adjusted. Their findings support those of Davies and Maconochie 2009 who demonstrated that for every one-degree Celsius rise in body temperature, heart rate increases by approximately ten beats per minute. These findings have now been replicated in primary, emergency and in hospital settings (Davies and Maconochie 2009, Thompson et al. 2009, Daymont et al. 2015). However, further studies are required to comprehensively investigate the impact diagnosis has on vital signs.

5.6 Comparison to APLS UK reference ranges

APLS is a nationally recognised and respected training and educational resource for advanced resuscitation (O'Leary et al. 2015). The vital signs centiles developed in this study, do not compare favourably to the ranges set by APLS. The study groups respiratory rates on the 95th centile are up to seven breaths per minute higher than the APLS upper limit. Therefore, if these ranges were used for the study CYP a significant number would be classified as having abnormally high respiratory rates, even though they sit on, or below, the study groups 95th centile.

Conversely the 5th centile for APLS appears to sit too low and would therefore potentially not pick up CYP from the study group who have significantly low respiratory rates. These findings contradict those of O'Leary et al. (2015), who in an earlier study found that the respiratory rates of 'well' CYP in a children's emergency department, were lower than the APLS 5th centile, suggesting CYP with normal respiratory rates would be classified as having abnormally low rates (O'Leary et al. 2015). It is worth noting that the O'Leary et al. (2015) study used ranges from the 5th Edition APLS.

Interestingly, when comparing heart rate, the APLS 95th centile appears slightly low (the study groups heart rates two-seven beats per minute higher), and the 5th centile too high (ALSG lower range up to six beats per minute higher). The differences are relatively small, and therefore difficult to determine if this would have an impact clinically.

APLS provide, 5th, 50th and 95th centiles as their reference range for SBP. The study data demonstrate that generally CYP in hospital have SBP's that sit above the APLS reference range. There is little difference between the 5th centiles, but when comparing the 50th and 95th centiles, the study groups SBP sits five -21mmHg above the corresponding APLS centiles. Therefore, the APLS reference range would be sensitive too low SBP readings but a significant number of CYP would fall outside the APLS upper limit and therefore be considered abnormally high. These findings are consistent with those of Chan et al. (2011) who found that approximately 50% of patients had higher SBP compared to APLS ranges. It is important to note, that in study by Chan et al. (2011), APLS 5th ED reference ranges were used, the APLS ranges have been amended since this time.

5.7 Comparison to previous studies

The meta-analysis by Fleming et al. (2011) provides evidence for the normal vital signs of well children outside the context of the health care setting. When compared to the study group the data is interesting. Fleming et al. (2011) 50th centile for respiratory rate sit's above that of the study group, and in the younger age groups (< three years) is up to ten breaths per minute higher. Deciding whether this is a clinically significant difference is problematic, as there is no empirical evidence on which to base the decision. Chan et al. (2011) used five breaths, five beats and five mmHg as their cut off points to detect a clinically relevant change when comparing their data to APLS. If this scale was used it would indicate that the difference between the study group and APLS range is therefore clinically relevant.

O'Leary et al. (2015) had the lowest centiles for respiratory rate, these centiles were devised using data from 'well' children presenting in a children's emergency department. Bonafide et al. (2013) developed centiles for CYP in tertiary children's hospitals in the USA. Although the study's population is drawn from the USA, other sample and setting characteristics are similar, with both developing centiles for CYP in hospital. As both used the vital signs data collected in tertiary children's hospitals, there will have a similar patient cohort, including CYP with complex health care needs. The Bonafide centiles align well to those of the study group at both the 5^{th} and 50^{th} centiles but are slightly higher on the 95^{th}, which is indicative of the similarities between the study population, sample and setting.

When comparing the centiles for heart rate, similar to the APLS findings, there is much less variation between the data. The study group, on the 50^{th} centile stood out as having the least conforming data with heart rates 10-16 beats per minute higher than the centiles from the other studies in the one – five-year age groups. This difference could be accounted for as CYP with high temperatures were included in this study, whereas both the O'Leary et al. (2015) and Bonafide et al. (2013) studies excluded CYP with temperatures >38°C. When reviewing the temperatures of the study group the highest median temperatures are between this age group. However, caution is required when extrapolating these finding into clinical practice as the difference in the median temperatures is minimal (<0.2°C)

5.8 Study Limitations

This study has several limitations. Firstly, the centiles for this study were derived from age adjusted frequency distribution charts for the vital signs, without any specific statistical modelling being applied. O'Leary et al. (2015) used quantile regression, an alternative to the Box-Cox power exponential (BCPE) in the generalised additive models for location, scale and shape (GAMLSS) used by Bonafide et al. (2013). Both of these methods have been previously described with growth chart centile development and are seen as appropriate statistical methods as they are more readily able to identify the monotonic relationships in the distribution of the dependent variables. The physiological data was shown to be both non-parametric and have multiple outliers and therefore this type of statistical modelling would have been beneficial. Within the constraints of the thesis this was not achievable but is a future consideration.

Ethnicity in relation to physiological observations was not explored despite evidence from the literature suggesting that ethnicity may impact on physiological observations of CYP (Chan et al. 2011). This is recognised as a limitation of this study as the ethnicity data at the study site was not reliably captured on the EHR and therefore discounted from the analysis.

As the study used previously collected data, the researcher had no control over the quality of the observations being recorded or the method in which they were captured. Measurement errors are a potential study limitation. Local measures were in place to maintain standards of practice regarding the measuring and recording of vital signs (as described in Chapter three).

When the centile charts were generated sensitivity analysis was not undertaken, this would have given further insight into the impact that either disease/diagnosis or deranged parameters, such as temperature, has on heart and respiratory rate. O'Leary et al. (2015) and Bonafide et al. (2013) excluded CYP with a temperature >38°C. therefore, by not removing this group from the study data the researcher added further level of heterogeneity to comparing the centiles. The decision to not remove these sub groups from this initial analysis was driven by the literature review. Bonafide et al. (2013) found that in their sub group analysis of patients with respiratory illness (including those who were febrile) the impact was only seen on the upper centiles and very little difference was seen on the 50% centile or below. The researcher therefore wanted to compare the observations initially without removing this group of potential outliers in the first instance to see how the data compared. It is anticipated that subgroup analysis, along with improved statistical modelling of the centiles will be undertaken following this initial comprehensive descriptive analysis of the data.

CHAPTER SIX

6.Conclusion

6.1 Introduction

This study is the first in the UK to describe the physiological observations of CYP in hospital. Understanding the characteristics of vital signs across the trajectory of the patient pathway will have a positive impact not only on the development of future reference ranges but also on day to day clinical decision making.

6.1 Future Research Recommendations

The author recognises that although this study has contributed to the understanding of the physiological observations of CYP in hospital; there remains scope for further research.

6.1.1 Statistical modelling

The researcher recognises the limitations of the centiles developed for this study. These will need to be refined using appropriate statistical modelling such as quantile regression, with support and guidance from a statistician.

The impact that heterogeneity of the study population, setting, ethnicity and diagnosis has on the physiological observations of CYP requires further research. This will provide useful additional insights that will further support the development of evidenced based centiles for vital signs, and their utility in clinical practice.

6.1.2 Vital signs across the trajectory of the admission

Studies have explored vital signs at either a single point in time or merged all the observations, not specifying when in the patient journey they were taken. This is an important issue for future research if the nuances of these observations are to be understood.

With electronic capture of observations, it would be possible to track all in-patient vital signs across the trajectory of the admission episode. This would develop a more comprehensive insight into the changes that occur, the characteristics of these changes; whether gradual or quick and how long are they sustained for. This learning will help inform education regarding the deteriorating CYP and EWS development. Analysis of several PEWS demonstrates that although they have a positive predictive value, their specificity is low, producing significant false positive triggers (Mason et al. 2016). In practice this may lead to trigger fatigue and lack of confidence in the EWS tool (Cheung, Lachmann 2017). Understanding the characteristics of vital signs across the trajectory of the patient pathway could have a positive impact on the development and therefore the effectiveness EWS.

6.1.3 Age bandings

The monotonic relationship age has with both respiratory rate and heart rate age has provided an important insight for future research that is relevant not only to reference ranges but also EWS trigger thresholds.

6.1.4 Subjective assessments

WOB - With the growing ability to capture observations electronically, there is a greater opportunity to make assessment such as WOB less subjective. Incorporating an objective element into a digitalised assessment could produce a more quantifiable measure. Although outside the scope of this study, it should be a future consideration for EWS researchers.

6.1.5 Sub group analysis

Further subgroup analysis is required to investigate the impact the leading diagnosis and temperature have on vital signs.

6.2 Summary

There is a paucity of evidence available to allow health care professionals to determine what constitutes normal observations for CYP in hospital (Fleming et al. 2011, Bonafide et al. 2013 and O'Leary et al. 2015). This research study has helped to bridge this gap in knowledge by generating a contemporary understanding of the characteristics and distribution of the vital signs of CYP.

Developing reference ranges with high sensitivity and low specificity for CYP in hospital will be challenging and although there are now four studies where percentile for vital signs have been developed, there is still such a degree of heterogeneity within the samples, settings and methods that caution must be taken when interpreting the findings. This study has produced valuable insights into the physiological observations of CYP in hospital whilst also highlighting areas where there are gaps in knowledge.

Understanding the characteristics of vital signs across the trajectory of the patient pathway will have a positive impact not only on the development of future reference ranges but also on day to day clinical decision making.

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Appendix 1.

Critical Appraisal Checklists - for the seven studies included in the Literature Review

Fleming S, Thompson M, Stevens R, Henegan C, Pluddermann A, Maconochie I, Mant D (2013) Normal ranges for heart rate and respiratory rate in children from birth to 18 years old: A systematic review of observational studies

JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

Question	Y/N	Outcome
1. Is the review question clearly and explicitly stated?	Y	Age specific centile charts for heart rates and respiratory rate for HEALTHY children
2. Were the inclusion criteria appropriate for the review question?	Y	Well documented for the reader. Study types, age., minimum numbers, objective measures
3. Was the search strategy appropriate?	Y	Comprehensive 1950-2009, appropriate databases and comment on reference lists
4. Were the sources and resources used to search for studies adequate?	Y	Well documented sources Research team – specific roles, appeared well resourced (wasn't discussed in limitations)
5. Were the criteria for appraising studies appropriate?	?	No specific criteria discussed other than inclusion / exclusion or appraising studies
6. Was critical appraisal conducted by two or more reviewers independently?	Y	2 researchers assessed eligibility with a 3rd for and disagreements
7. Were there methods to minimize errors in data extraction?	Y	Data extracted by one researcher and checked by another and two identified sources for existing reference ranges. Guideline for data extraction documented.
8. Were the methods used to combine studies appropriate?	Y	Centile for each study calculated. If studies did not provide summary statistics, mean and SD estimated from the data. Tested for skewness – reported normal distribution … note – this is different from other studies. Kernel regression for centile chart development and compared visually to reference ranges. This is a non-parametric technique used to estimate the conditional value of a random variable I aims to find a non- linear relationship between variables X and Y.
9. Was the likelihood of publication bias assessed?	N	Not explicitly addressed
10. Were recommendations for policy and/or practice supported by the reported data?	Y	Adaptations to the standard ref ranges should be considered. New centile charts require 'testing'
11. Were the specific directives for new research appropriate?	Y	Testing of centile charts in different settings Further studies to review generalisability to the in -patient setting and designing of tools with vital signs embedded – EWS, triage, resus guidelines

Van Kuiken D, Martz Huth M (2016) What is Normal? Evaluating Vital signs **JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses**		
Question	Y/N	Outcome comments
1. Is the review question clearly and explicitly stated?	Y?	Some discrepancy between in patient and healthy patient – purpose and question
2. Were the inclusion criteria appropriate for the review question?	Y?	Appears to be a critical review? Text excluded if not inclusive of 1-5 yrs. or had a specific disease focus
3. Was the search strategy appropriate?	Y	Key search criteria and data bases
4. Were the sources and resources used to search for studies adequate?	Y	Quality search engines & data bases – appropriate to health research + additional manual searches – books and guidelines
5. Were the criteria for appraising studies appropriate?	Y?	Generalised grading system used - Melnyk and Fineout-Overholt No named frame work but nicely structured tables
6. Was critical appraisal conducted by two or more reviewers independently?	?	Not explicit – no description of how – only mention of author -as plural
7. Were there methods to minimize errors in data extraction?	N	narrative analysis not meta-analysis
8. Were the methods used to combine studies appropriate?	N	Studies not combined – described separately
9. Was the likelihood of publication bias assessed?	N	Not apparent
10. Were recommendations for policy and/or practice supported by the reported data?	Y?	Vital signs parameters not supported by strong evidence. Compare in the acute setting – i.e. Blood pressure parameters extrapolated from renal management guidelines.
11. Were the specific directives for new research appropriate?	Y	Questioned the value (psychological impact, nursing time and economic value) of 4 hourly vital signs Further research on defined age groups, gender, height, weight, BMI and health status and impact on Vital signs Explicit and consistent methodology in future studies

Paliwoda M, New K, Davies M, Bogossian F (2017) Physiological vital sign ranges in newborns from 34 weeks gestation

JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

Question	Y/N	Outcome
1. Is the review question clearly and explicitly stated?	Y	Good clarity and specific objective stated
2. Were the inclusion criteria appropriate for the review question?	?	All primary studies included 1946-2017. Observations ranges for new born, clarified from 34 week gestation. No discussion/ justification whether data from the earlier papers has contemporary relevance, impact of population demographics and ethnicity.
3. Was the search strategy appropriate?	?	Clear strategy – well documented. Only papers that could be electronically retrieved included, possible bias
4. Were the sources and resources used to search for studies adequate?	Y?	Appropriate data bases used No discussion about grey literature or un published work. Potentially impacted on why the review was limited to 10 studies
5. Were the criteria for appraising studies appropriate?	Y	Quality assessment tool for Quantitative studies - Effective Public Health Practice Project 1998
6. Was critical appraisal conducted by two or more reviewers independently?	Y	Two reviewers, plus strategy outlined for any discrepancies
7. Were there methods to minimize errors in data extraction?	Y	Data extraction spreadsheet. Reviewers extracted data and under took quality appraisal and grading of level of evidence independently
8. Were the methods used to combine studies appropriate?	N/A	Due to heterogeneity unable to use meta-analysis
9. Was the likelihood of publication bias assessed?	Y	National Health and Medical Research Councils Level of Evidence Hierarchy table (2009) utilised
10. Were recommendations for policy and/or practice supported by the reported data?	Y	Limited evidence therefore unable to derive reference ranges.
11. Were the specific directives for new research appropriate?	Y	Need for comprehensive research into what are the normal physiological ranges of vital sign in newborns. Suggested that future research takes into account gestational age

Bonafide C, Brady P, Keren K, Conway P, Marsolo K, Daymont C (2013) Development of Heart Rate and Respiratory Rate Percentile Curves for Hospitalized Children

JBI Critical Appraisal Checklist for Cross Sectional Studies

Question	Y/N	Outcome
1. Were the criteria for inclusion in the sample clearly defined?	**?**	Not explicit, although some criteria discussed in data source and data quality sections. Included - Age <18yrs and if HR and RR recorded simultaneously. Exclude, if implausible results ie RR exceeded HR
2. Were the study subjects and the setting described in detail?	**Y ?**	Age, sex and ethnicity. Setting not described – beds specialities etc possibly as set in an internationally known leading Children's hospital
3. Was the exposure measured in a valid and reliable way?	**Y**	Data taken from clinical practice where observations were routinely measured. No deviation from standard practice
4. Were objective, standard criteria used for measurement of the condition?	**Y ?**	No matching of groups required. All patients who had observations routinely recorded were included – data captured electronically as the observation were measured. The researchers extracted data retrospectively Intra observer reliability discussed as observations recorded as part of routine care – no control over who and how observations recorded
5. Were confounding factors identified?	**Y**	Impact of respiratory illness particularly on the observations – sub group analysis to look at the impact of this undertaken
6. Were strategies to deal with confounding factors stated?	**Y**	As above
7. Were the outcomes measured in a valid and reliable way?	**?**	The observation 'measures' were recorded as part of routine care – therefore no control over the measurement could bee made. HR and RR rate are objective measures, but quality of measurement may impact. Manual v's machine, duration of recording, setting etc
8. Was appropriate statistical analysis used?	Y	Data integrity measures adopted. Dealt will skewed data, digit preference issues and ascertainment bias. Described clearly statistical modelling (GAMLESS) that was used to develop centiles. 2/3rd data of development and1/3 for validation.

Chan S.S.W, Cattermole G.N, Leung P.Y.M, Mak P.S.K, Graham C.A, Rainer T.H (2011) Validation of the APLS age-based vital signs reference ranges in a Chinese population

JBI Critical Appraisal Checklist for Cross Sectional Studies

Question	Y/N	Outcome
1. Were the criteria for inclusion in the sample clearly defined?	Y	Inclusion – Chinese ethnicity, 12-143 months, with defined age groups Exclusion- current symptoms of illness, any chronic or congenital issues. Children that were uncooperative or distressed at the time of the assessment
2. Were the study subjects and the setting described in detail?	Y	Healthy children Defined age groups and ethnicity In schools Hong Kong – randomisation of schools
3. Was the exposure measured in a valid and reliable way?	Y	Trained team SOP for recording observations Standardised equipment
4. Were objective, standard criteria used for measurement of the condition?	N/A	No condition to measure No matching required
5. Were confounding factors identified?	?	Not discussed <u>but</u> ethnicity is a possible confounding factor and is captured and discussed. Also distressed children - theses were excluded at time of measurement
6. Were strategies to deal with confounding factors stated?	?	Although not explicitly discussed see above
7. Were the outcomes measured in a valid and reliable way?	N/A	As previous Q4
8. Was appropriate statistical analysis used?	Y	Positive aspect – clinical relevance of change in values considered. Sample size calculated. Centile curves show the distribution of a measurement as it changes according to covariate -age. The Lambda-Mu-Sigma method summarises the changing distribution by three curves representing the median, coefficient of variation and skewness, (skewness expressed as a Box-Cox power). The three curves can be fitted as cubic splines by non-linear regression, and the smoothing is expressed as smoothing parameters or degrees of freedom (Indrayan 2014)

O'Leary F, Hayden A, Lockie F, Peat J (2015) Defining normal ranges and centiles for heart rate and respiratory rate in infants and children: a cross-sectional study of patients attending an Australian tertiary hospital pediatric emergency department

JBI Critical Appraisal Checklist for Cross Sectional Studies

Question	Y/N	Outcome
1. Were the criteria for inclusion in the sample clearly defined?	?	Inclusion and exclusion criteria specific but not made explicit – found in methods, data and results sections.
2. Were the study subjects and the setting described in detail?	Y?	Setting, sample – no ethnicity or diagnosis Tertiary Children's Hospital – Emergency dept
3. Was the exposure measured in a valid and reliable way?	Y	Retrospective data collection from electronic patient records. No deviation from standard practice – observations used were all routinely recorded
4. Were objective, standard criteria used for measurement of the condition?	N/A	No condition measured No matching required
5. Were confounding factors identified?	Y	Temperature, digit preference and erroneous observations
6. Were strategies to deal with confounding factors stated?	Y	If a set of observations included a temperature <38 it was removed from study Others discussed as issues for the recording of observations generally
7. Were the outcomes measured in a valid and reliable way?	N/A	As previous Q.4
8. Was appropriate statistical analysis used?	Y	Quantile regression to develop centile charts and visual comparison with standard reference ranges and previously developed centiles. NB no discussion about data distribution in descriptive statistics BUT this maybe as choice of statistical modelling does not rely on parametric assumptions. Quantile regression methods are used to estimate upper and lower quantile reference curves as a function of age, sex, and other covariates without imposing parametric assumptions on the relationships among these curves (Koenker R & Hallock K 2001)

Wallis L, Healy M, Undy M, Maconochie I (2005) Age related reference ranges for respiratory rate and heart rate for 4 to 16 years **JBI Critical Appraisal Checklist for Cross Sectional Studies**		
Question	**Y/N**	**Outcome**
1. Were the criteria for inclusion in the sample clearly defined?	Y	All CYP invited to participate in participating schools Age -4-16
2. Were the study subjects and the setting described in detail?	Y?	UK schools Age/Height/Weight - no ethnicity
3. Was the exposure measured in a valid and reliable way?	Y	One researcher recorded all observations – continuity, reduced interrater reliability. Very clear SOP for how observation was recorded - consistency
4. Were objective, standard criteria used for measurement of the condition?	N/A	No condition to measure. But clear on what the observations were to be compared against, not able to have any control over the comparison reference ranges
5. Were confounding factors identified?	?	Impact of height and weight considered. Not ethnicity, impact of fever, any underlying illness, or comorbidities
6. Were strategies to deal with confounding factors stated?	Y	For the confounding factors identified were assessed for any correlation. Others discussed as potential bias in study
7. Were the outcomes measured in a valid and reliable way?	N/A	As above
8. Was appropriate statistical analysis used?	Y	Used a least squared regression – due to outliers Discussed sked data – how this was accounted for Little difference found in sexes therefore data analysed together – limiting factor in future generalisability

Appendix 2.
Data Preparation, Code Book & Coding Summary

Data preparation and cleaning

Ensuring the consistency and accuracy of the data prior to any analysis helps the reader have confidence in the reliability and validity of any findings (Kim and Mallory 2017:51, Baraldi and Enders 2010). In relation to this study data was exported from the e-obs system into an Excel spreadsheet by the hospital data team. The data was then prepared and cleaned prior to the analysis, this was carried out by the researcher and overseen by the supervisory team. The Excel files required some formatting adjustments prior to exporting, this ensured that the first case was on line one, and that each line represented just one case. This safeguarded against loss of cases when transferring data to Statistical Package for Social Sciences (SPSS) version 24 for windows (2016) for analysis to be undertaken. Once imported, the SPSS files were reviewed, variables were defined, and a codebook developed. The codebook summarises the characteristics of the variables and helped the researcher to expose any errors in the data entry and prior measurement decisions. The codebook includes variable label, variable name, variable type i.e. string or numeric, category for categorical variables and missing data strategy.

Data was then interrogated for both missing and erroneous entries using frequency distribution charts and ordering of each variable column. There were relatively low numbers of missing data (n=5), all of which were considered missing at random (MAR) data as it was scattered through the data base with no obvious pattern (Sterne et al. 2009). Two admission spells were found not to have either respiratory or heart rates recorded. As the sample is relatively large, they were deleted case-wise from the analysis in preference to being substituted with estimated values. Using estimated values can introduce bias into the analysis but may be preferential if sample size is small (Kim and Mallory 2017 p.172). One heart rate entry was considered erroneous (heart rate <20 bpm) and therefore the corresponding case was removed.

Two entries for sex were found to be missing, these two cases were not deleted as the corresponding entries for physiological observations and age were recorded and therefore these could be used for analysis and the development of the centiles. The MAR data may have been a result of data transfer as the numbers are small. When reviewing age, it became evident that the spreadsheet contained information for individuals over the inclusion age. The patients aged >19years old, although admitted to a children's day case area were classified as adults and therefore excluded from the study. This children's day case unit had been commissioned to provide specialist treatment not available in an equivalent adult area during the study period. Therefore, 185 admission episodes were removed to ensure only CYP aged 0-19years were included in the analysis.

Code Book – inclusion and exclusion criteria

Inclusion Criteria	
1. Patient index admissions	Admission to paediatric wards ('CSDC','EAMB','ECAU','E39D','ED33','ED34','ED35','EE37','EE39','EE40','WE17'); Patient admitted between 1 July 2014 and 31 December 2017; Patient has been discharged.
2. Observations	Only observations recorded on paediatric wards ('CSDC','EAMB','ECAU','E39D','ED33','ED34','ED35','EE37','EE39','EE40','WE17'). Observations recorded in ED or where the CHART_TYPE is 'NOT LIVE EOBS WARD%' or 'NUH ED %' are to be excluded; There must be at least one set of observations recorded for the patient between the admission and discharge date/times.

Exclusion Criteria	
1. Admissions to PCCU	Patients directly admitted to PCCU ('PICU','PHDU') are excluded.

Code book - Coding Summary

	Contents			
Item	**Data Item**	**Description**	**Units**	**Additional Comments**
1	RECORD_ID	Unique anonymous identification number assigned to each index admission.		
2	SEX	Sex of patient, recorded as Female or Male.		
3	AGE_YEARS	Age in years as at date of admission.		
4	AGE_MONTHS	Age in months as at date of admission.		

5	AGE_GROUP	Age group, e.g. 0-4 MONTHS; 5-8 MONTHS; 9-12 MONTHS; 1 YEAR etc.		
6	ADMISSION_METHOD	Indicates whether the admission was Elective or Non-elective.		
7	ADM_WARD_CODE	Admission ward code.		
8	DIS_WARD_CODE	Discharge ward code.		
9	LOS_DAYS	The length of stay in hospital (in whole days, 0 if less than 1 day).		
10	DISCHARGE_OUTCOME	Flag to indicate if the patient died during the index admission.		
11	TOTAL_OBS	Number of observations recorded in Nervecentre between the admission and discharge date/time.		
12	ADMISSION_ICD10_3	First 3 characters of the ICD10 code of the primary diagnosis recorded on the admission episode.		
13	ADMISSION_CCS	CCS number relating to the primary diagnosis on the admission episode (diagnostic group).		
14	ADMISSION_CCS_DESC	CCS description relating to the primary diagnosis on the admission episode (diagnostic group).		
15	DISCHARGE_ICD10_3	First 3 characters of the ICD10 code of the primary diagnosis recorded on the discharge episode.		
16	DISCHARGE_CCS	CCS number relating to the primary diagnosis on the discharge episode (diagnostic group).		
17	DISCHARGE_CCS_DESC	CCS description relating to the primary diagnosis on the discharge episode (diagnostic group).		
18	PEWS_ADMIT	PEWS recorded on the first set of observations as an inpatient (the admission observations).		
19	RESP_RATE_ADMIT	Respiratory rate recorded in the admission observations.	/min	
20	SATS_SPO2_ADMIT	Percentage of oxygen saturation recorded in the admission observations.	%	
21	INSPIRED_O2_PERCENT_ ADMIT	Percentage of Inspired Oxygen at admission (converted from litres,	%	

		Air or Wafting where not recorded as a percentage).		
22	TEMPERATURE_ADMIT	Temperature recorded in the admission observations.	°C	
23	BP_ADMIT	Blood pressure reading recorded in the admission observations.	mm Hg	
24	SYSTOLIC_BP_ADMIT	Systolic blood pressure reading recorded in the admission observations.	mm Hg	
25	DIASTOLIC_BP_ADMIT	Diastolic blood pressure reading recorded in the admission observations.	mm Hg	
26	HEART_RATE_ADMIT	Heart rate recorded in the admission observations.	/min	
27	PAIN_ADMIT	Pain recorded in the admission observations.		Includes No pain, Asleep, Mild, Moderate, Severe
28	WOB_ADMIT	Work of breathing recorded in the admission observations.		Includes Normal, Mild Effort, Moderate Effort, Severe Effort, Poor Effort
29	COLOUR_ADMIT	Colour recorded in the admission observations.		Includes Normal, Pallor, Grey, Cyanosed
30	BEHAVIOUR_ADMIT	Behaviour recorded in the admission observations.		Includes Asleep, Behaves Normally, Lethargy, Not Responding Normally, Unable to stay awake if roused, Unable to rouse
31	POSTURE_ADMIT	Posture recorded in the admission observations.		Includes Normal for patient, Abnormal for patient, Floppy

32	PEWS_DISCH	PEWS recorded on the final set of observations prior to discharge (the discharge observations).		
33	RESP_RATE_DISCH	Respiratory rate recorded in the discharge observations.	/min	
34	SATS_SPO2_DISCH	Percentage of oxygen saturation recorded in the discharge observations.	%	
35	INSPIRED_O2_PERCENT_ DISCH	Percentage of Inspired Oxygen at discharge (converted from litres, Air or Wafting where not recorded as a percentage).	%	
36	TEMPERATURE_DISCH	Temperature recorded in the discharge observations.	°C	
37	BP_DISCH	Blood pressure reading recorded in the discharge observations.	mm Hg	
38	SYSTOLIC_BP_DISCH	Systolic blood pressure reading recorded in the discharge observations.	mm Hg	
39	DIASTOLIC_BP_DISCH	Diastolic blood pressure reading recorded in the discharge observations.	mm Hg	
40	HEART_RATE_DISCH	Heart rate recorded in the discharge observations.	/min	
41	PAIN_DISCH	Pain recorded in the discharge observations.		Includes No pain, Asleep, Mild, Moderate, Severe
42	WOB_DISCH	Work of breathing recorded in the discharge observations.		Includes Normal, Mild Effort, Moderate Effort, Severe Effort, Poor Effort
43	COLOUR_DISCH	Colour recorded in the discharge observations.		Includes Normal, Pallor, Grey, Cyanosed
44	BEHAVIOUR_DISCH	Behaviour recorded in the discharge observations.		Includes Asleep, Behaves Normally, Lethargy, Not Responding Normally, Unable to

				stay awake if roused, Unable to rouse
45	POSTURE_DISCH	Posture recorded in the discharge observations.		Includes Normal for patient, Abnormal for patient, Floppy
46	PEWS_HIGH	Maximum PEWS recorded across all observations for this patient spell.		
47	RESP_RATE_HIGH	Maximum respiratory rate recorded across all observations for this patient spell.	/min	
48	SATS_SPO2_HIGH	Maximum percentage of oxygen saturation recorded across all observations for this patient spell.	%	
49	INSPIRED_O2_PERCENT_HIGH	Maximum percentage of inspired oxygen recorded across all observations for this patient spell.	%	
50	TEMPERATURE_HIGH	Maximum temperature recorded across all observations for this patient spell.	°C	
51	SYSTOLIC_BP_HIGH	Maximum systolic blood pressure reading recorded across all observations for this patient spell.	mm Hg	
52	HEART_RATE_HIGH	Maximum heart rate recorded across all observations for this patient spell.	/min	
53	PAIN_CAT_HIGH	Maximum pain recorded across all observations for this patient spell.		Includes No pain/Asleep, Mild, Moderate, Severe
54	WOB_CAT_HIGH	Maximum work of breathing recorded across all observations for this patient spell.		Includes Normal, Mild Effort, Moderate Effort, Severe Effort, Poor Effort
55	COLOUR_CAT_HIGH	Maximum colour recorded across all observations for this patient spell.		Includes Normal, Pallor,

				Grey/Cyanosed
56	BEHAVIOUR_CAT_HIGH	Maximum behaviour recorded across all observations for this patient spell.		Includes Behaves Normally/Asleep, Lethargy/Not Responding Normally, Unable to stay awake if roused, Unable to rouse
57	POSTURE_CAT_HIGH	Maximum posture recorded across all observations for this patient spell.		Includes Normal for patient, Abnormal for patient/Floppy
58	PEWS_LOW	Minimum PEWS recorded across all observations for this patient spell.		
59	RESP_RATE_LOW	Minimum respiratory rate recorded across all observations for this patient spell.	/min	
60	SATS_SPO2_LOW	Minimum percentage of oxygen saturation recorded across all observations for this patient spell.	%	
61	INSPIRED_O2_PERCENT_LOW	Minimum percentage of inspired oxygen recorded across all observations for this patient spell.	%	
62	TEMPERATURE_LOW	Minimum temperature recorded across all observations for this patient spell.	°C	
63	SYSTOLIC_BP_LOW	Minimum systolic blood pressure reading recorded across all observations for this patient spell.	mm Hg	
64	HEART_RATE_LOW	Minimum heart rate recorded across all observations for this patient spell.	/min	
65	PAIN_CAT_LOW	Minimum pain recorded across all observations for this patient spell.		Includes No pain/Asleep, Mild, Moderate, Severe

66	WOB_CAT_LOW	Minimum work of breathing recorded across all observations for this patient spell.		Includes Normal, Mild Effort, Moderate Effort, Severe Effort, Poor Effort
67	COLOUR_CAT_LOW	Minimum colour recorded across all observations for this patient spell.		Includes Normal, Pallor, Grey/Cyanosed
68	BEHAVIOUR_CAT_LOW	Minimum behaviour recorded across all observations for this patient spell.		Includes Behaves Normally/Asleep, Lethargy/Not Responding Normally, Unable to stay awake if roused, Unable to rouse
69	POSTURE_CAT_LOW	Minimum posture recorded across all observations for this patient spell.		Includes Normal for patient, Abnormal for patient/Floppy
70	UNPLANNED_PCCU_ADMISSION	Flag to indicate if the patient has an unplanned admission to PCCU during their spell.		
71	ADMISSION_METHOD_DESC	Description of Medway Admission Method		Includes GP Admission, Emergency Department, Other Emergency Admission, Planned, Waiting List and others
72	PCCU_WARD_STAY	Flag to indicate if the patient spent any time in PCCU during their spell.		
73	LOS_DAYS_ON_PCCU	The length of stay in PCCU (in whole days, 0 if less than 1 day) where the patient was in a PCCU		

		ward during the index admission (otherwise blank).		
74	BP_WITHIN_24HRS_ADMIT	Flag to indicate if the patient had a blood pressure reading recorded in Nervecentre within 24 hours of admission to the hospital as an inpatient.		

Appendix 3

Case summaries for respiratory rate, heart rate, systolic blood pressure and temperature

Respiratory Rate – Case Summary.

Case Processing Summary

	Age by month defined groups	Cases Valid N	Percent	Missing N	Percent	Total N	Percent
RESP_RATE_DISCH	0 - 3 months	3674	100.0%	0	0.0%	3674	100.0%
	4 - 6 months	1598	100.0%	0	0.0%	1598	100.0%
	7 - 9 months	1372	100.0%	0	0.0%	1372	100.0%
	10 - 12 months	1313	100.0%	0	0.0%	1313	100.0%
	13 - 18 months	2563	100.0%	0	0.0%	2563	100.0%
	19 - 23 months	1742	100.0%	0	0.0%	1742	100.0%
	24 - 35 months (2yrs)	3410	100.0%	0	0.0%	3410	100.0%
	36 - 47 months (3 yrs.)	2963	100.0%	0	0.0%	2963	100.0%
	48 - 71 months (4-5 yrs.)	4484	100.0%	0	0.0%	4484	100.0%
	72 - 95 months (6-7yrs)	2787	100.0%	0	0.0%	2787	100.0%
	96 -143 months (8-11yrs)	5545	100.0%	0	0.0%	5545	100.0%
	144 - 179 months (12-14yrs)	4487	100.0%	0	0.0%	4487	100.0%
	180 - 228 months (15-19yrs)	4864	100.0%	0	0.0%	4864	100.0%

Heart Rate – Case summary

Case Processing Summary

	Age by month defined groups	Cases Valid N	Valid Percent	Missing N	Missing Percent	Total N	Total Percent
HEART_RATE_DISCH	0 - 3 months	3674	100.0%	0	0.0%	3674	100.0%
	4 - 6 months	1598	100.0%	0	0.0%	1598	100.0%
	7 - 9 months	1372	100.0%	0	0.0%	1372	100.0%
	10 - 12 months	1313	100.0%	0	0.0%	1313	100.0%
	13 - 18 months	2563	100.0%	0	0.0%	2563	100.0%
	19 - 23 months	1742	100.0%	0	0.0%	1742	100.0%
	24 - 35 months (2yrs)	3410	100.0%	0	0.0%	3410	100.0%
	36 - 47 months (3 yrs.)	2963	100.0%	0	0.0%	2963	100.0%
	48 - 71 months (4-5 yrs.)	4484	100.0%	0	0.0%	4484	100.0%
	72 - 95 months (6-7yrs)	2787	100.0%	0	0.0%	2787	100.0%
	96 -143 months (8-11yrs)	5545	100.0%	0	0.0%	5545	100.0%
	144 - 179 months (12-14yrs)	4487	100.0%	0	0.0%	4487	100.0%
	180 - 228 months (15-19yrs)	4864	100.0%	0	0.0%	4864	100.0%

Systolic Blood Pressure - Case Summary

Case Processing Summary

	Age by month defined groups	Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
SYSTOLIC_BP_DISCH	0 - 3 months	211	5.7%	3463	94.3%	3674	100.0%
	4 - 6 months	121	7.6%	1477	92.4%	1598	100.0%
	7 - 9 months	124	9.0%	1248	91.0%	1372	100.0%
	10 - 12 months	118	9.0%	1195	91.0%	1313	100.0%
	13 - 18 months	237	9.2%	2326	90.8%	2563	100.0%
	19 - 23 months	256	14.7%	1486	85.3%	1742	100.0%
	24 - 35 months (2yrs)	596	17.5%	2814	82.5%	3410	100.0%
	36 - 47 months (3yrs)	779	26.3%	2184	73.7%	2963	100.0%
	48 - 71 months (4-5yrs)	1637	36.5%	2847	63.5%	4484	100.0%
	72 - 95 months (6-7yrs)	936	33.6%	1851	66.4%	2787	100.0%
	96 -143 months (8-11yrs)	2511	45.3%	3034	54.7%	5545	100.0%
	144 - 179 months (12-14yrs)	1883	42.0%	2604	58.0%	4487	100.0%
	180 - 228 months (15-19yrs)	2657	54.6%	2207	45.4%	4864	100.0%

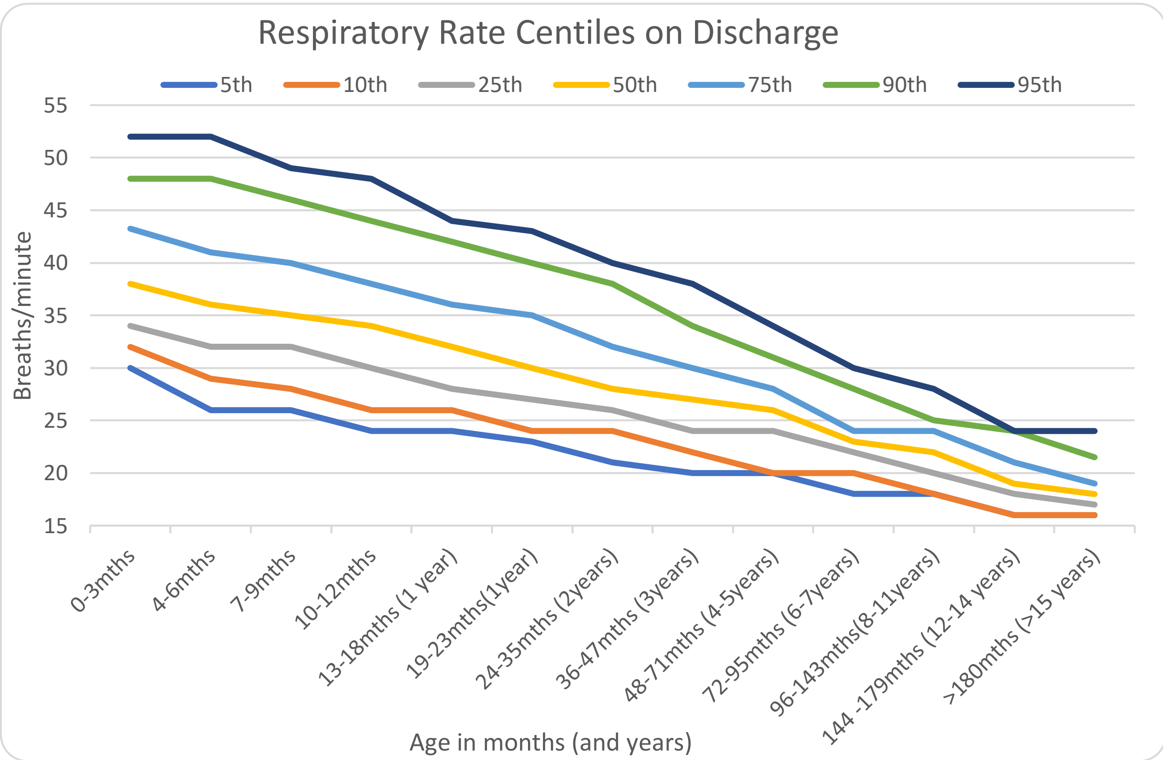
Temperature – Case Summary

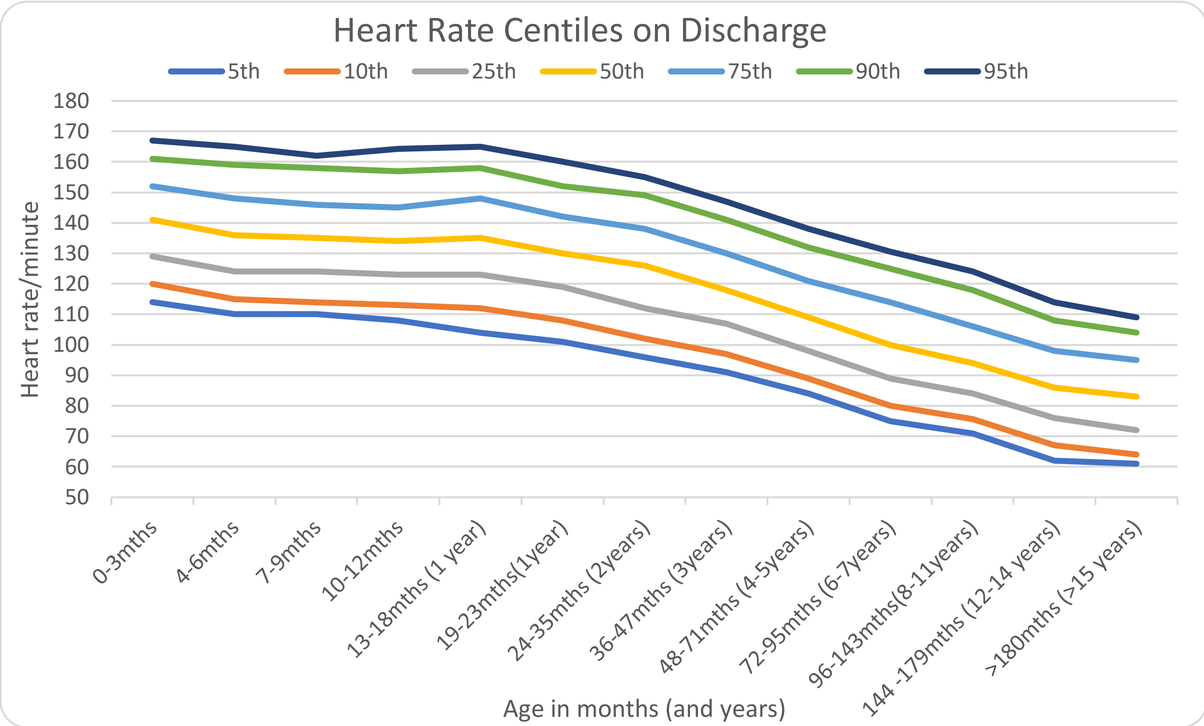
Case Processing Summary

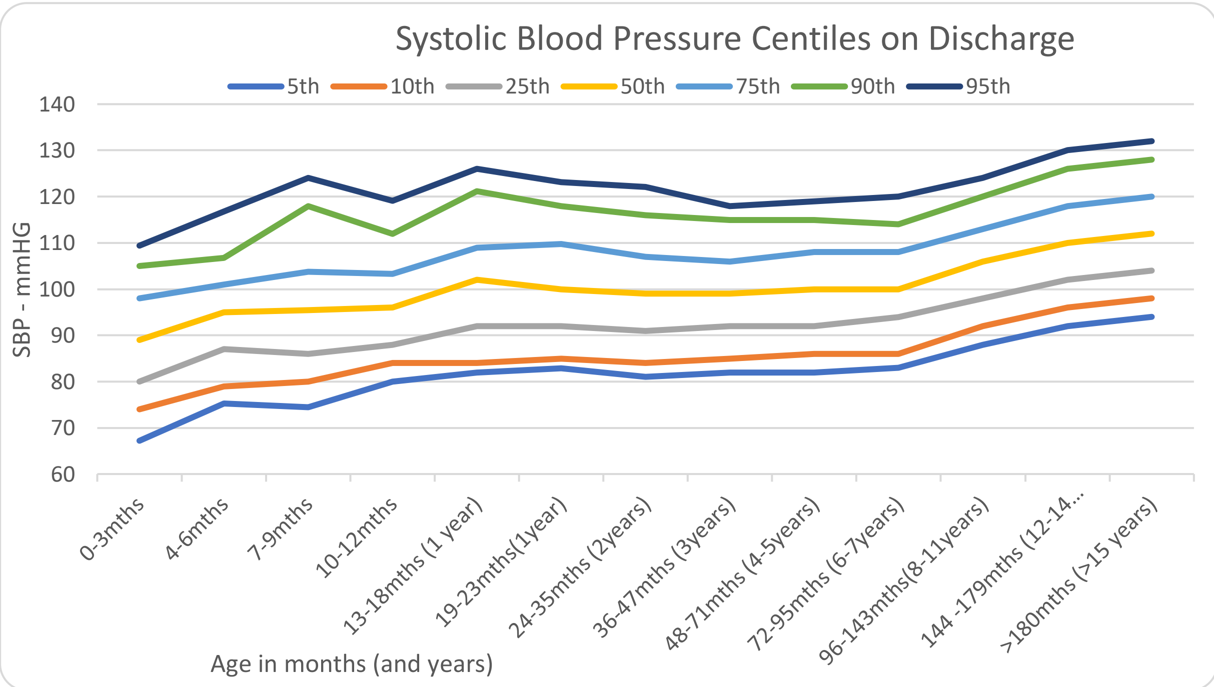
	Age by month defined groups	Cases Valid N	Percent	Missing N	Percent	Total N	Percent
TEMPERATURE_DISCH	0 - 3 months	2889	78.6%	785	21.4%	3674	100.0%
	4 - 6 months	1219	76.3%	379	23.7%	1598	100.0%
	7 - 9 months	1038	75.7%	334	24.3%	1372	100.0%
	10 - 12 months	985	75.0%	328	25.0%	1313	100.0%
	13 - 18 months	1900	74.1%	663	25.9%	2563	100.0%
	19 - 23 months	1356	77.8%	386	22.2%	1742	100.0%
	24 - 35 months (2yrs)	2677	78.5%	733	21.5%	3410	100.0%
	36 - 47 months (3 yrs.)	2293	77.4%	670	22.6%	2963	100.0%
	48 - 71 months (4-5 yrs.)	3626	80.9%	858	19.1%	4484	100.0%
	72 - 95 months (6-7yrs)	2215	79.5%	572	20.5%	2787	100.0%
	96 -143 months (8-11yrs)	4569	82.4%	976	17.6%	5545	100.0%
	144 - 179 months (12-14yrs)	3581	79.8%	906	20.2%	4487	100.0%
	180 - 228 months (15-19yrs)	3844	79.0%	1020	21.0%	4864	100.0%

Appendix Four

Respiratory Rate, Heart Rate and Systolic Blood Pressure Centiles on Discharge.

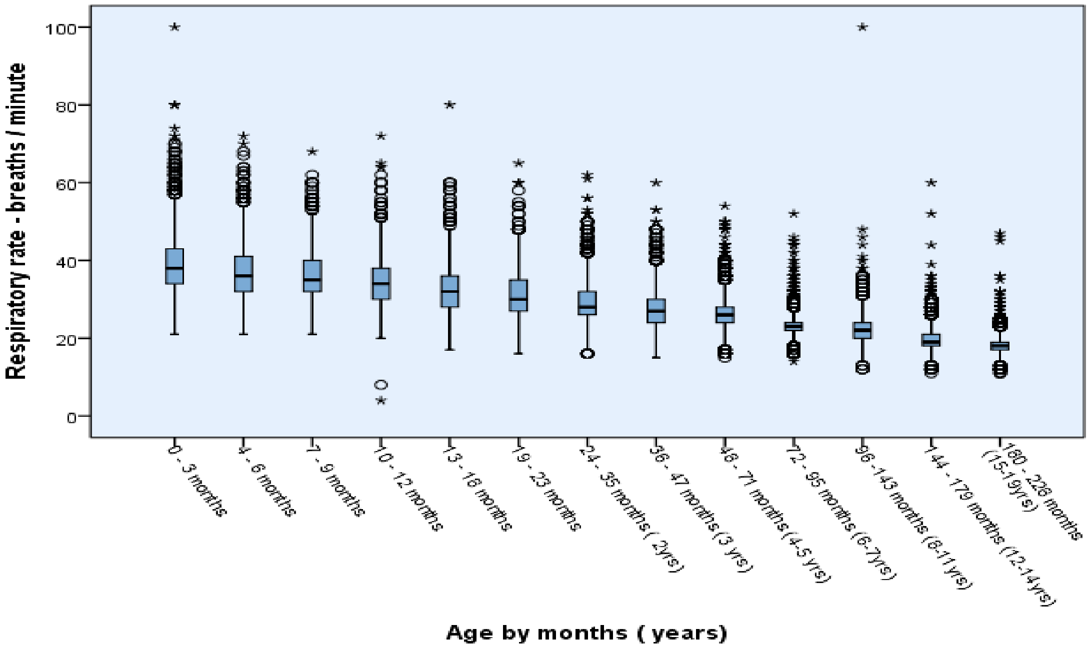



Heart Rate Centiles on Discharge
5th
10th
25th
50th
75th
90th
95th
Heart rate/minute
180
170
160
150
140
130
120
110
100
90
80
70
60
50
0-3mths
4-6mths
7-9mths
10-12mths
13-18mths (1 year)
19-23mths(1year)
24-35mths (2years)
36-47mths (3years)
48-71mths (4-5years)
72-95mths (6-7years)
96-143mths(8-11years)
144 -179mths (12-14 years)
>180mths (>15 years)
Age in months (and years)

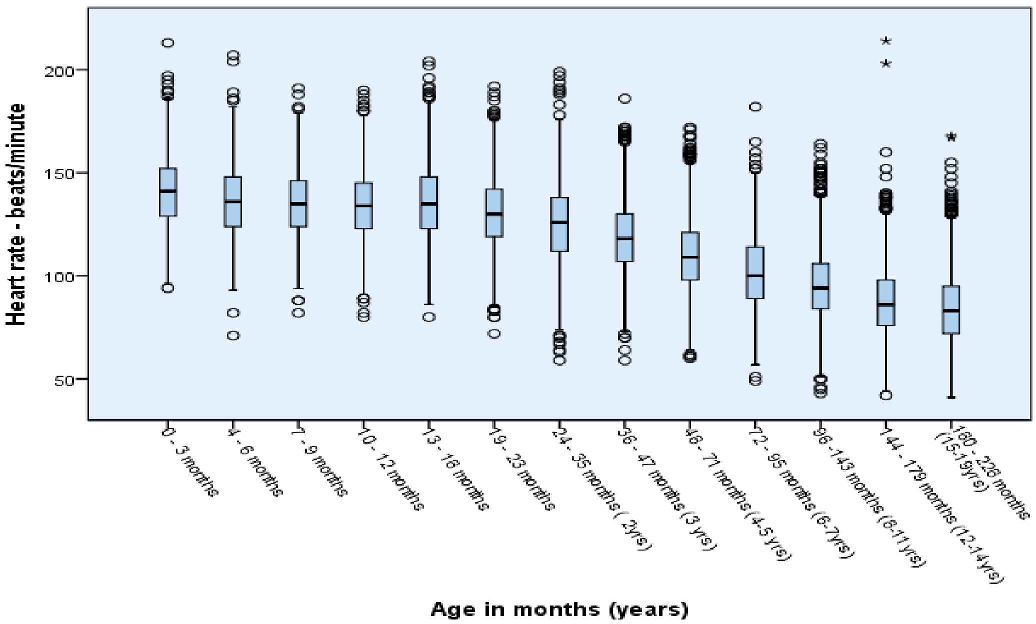

Systolic Blood Pressure Centiles on Discharge
5th
10th
25th
50th
75th
90th
95th
SBP - mmHG
140
130
120
110
100
90
80
70
60
0-3mths
4-6mths
7-9mths
10-12mths
13-18mths (1 year)
19-23mths(1year)
24-35mths (2years)
36-47mths (3years)
48-71mths (4-5years)
72-95mths (6-7years)
96-143mths(8-11years)
144 -179mths (12-14...
>180mths (>15 years)
Age in months (and years)

Appendix Five

BOXPLOTS SHOWING DISTRIBUTION, QUARTILES AND OUTLIERS FOR RESPIRATORY RATE and HEART RATE BY AGE



BOXPLOTS SHOWING DISTRIBUTION, QUARTILES AND OUTLIERS FOR RESPIRATORY RATE BY AGE

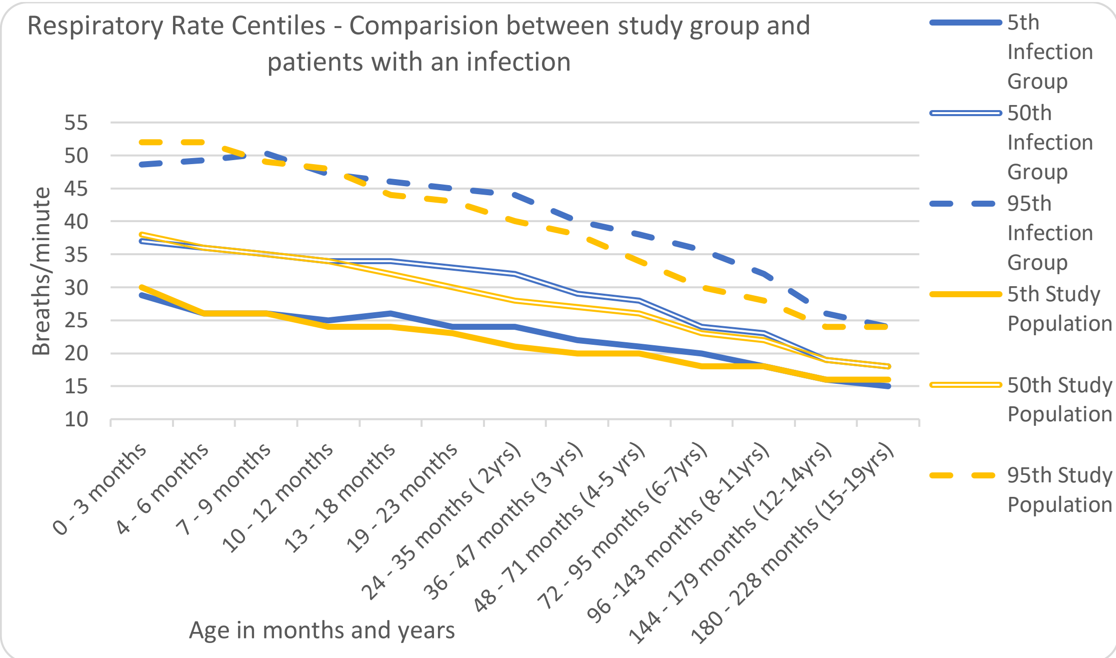


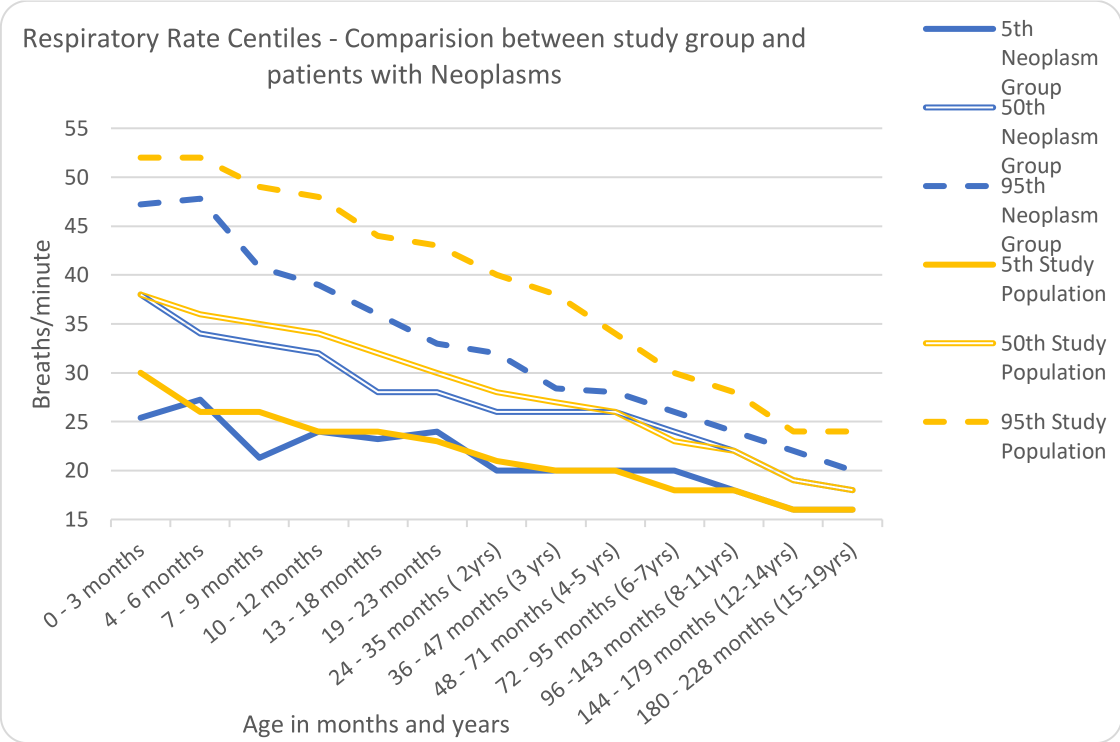
BOXPLOTS SHOWING DISTRIBUTION, QUARTILES AND OUTLIERS FOR HEART RATE BY AGE

Appendix Six

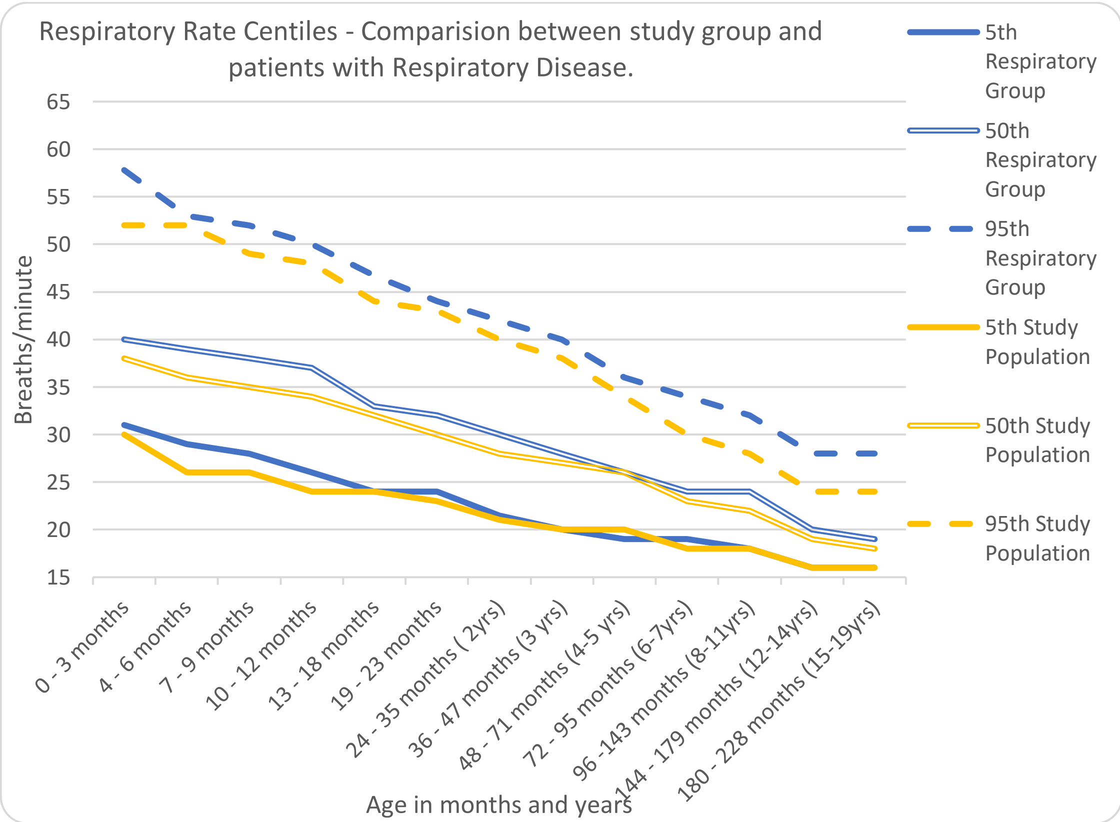
Respiratory Rate and Heart Rate Centiles:

Comparison with Key Diagnosis Groups

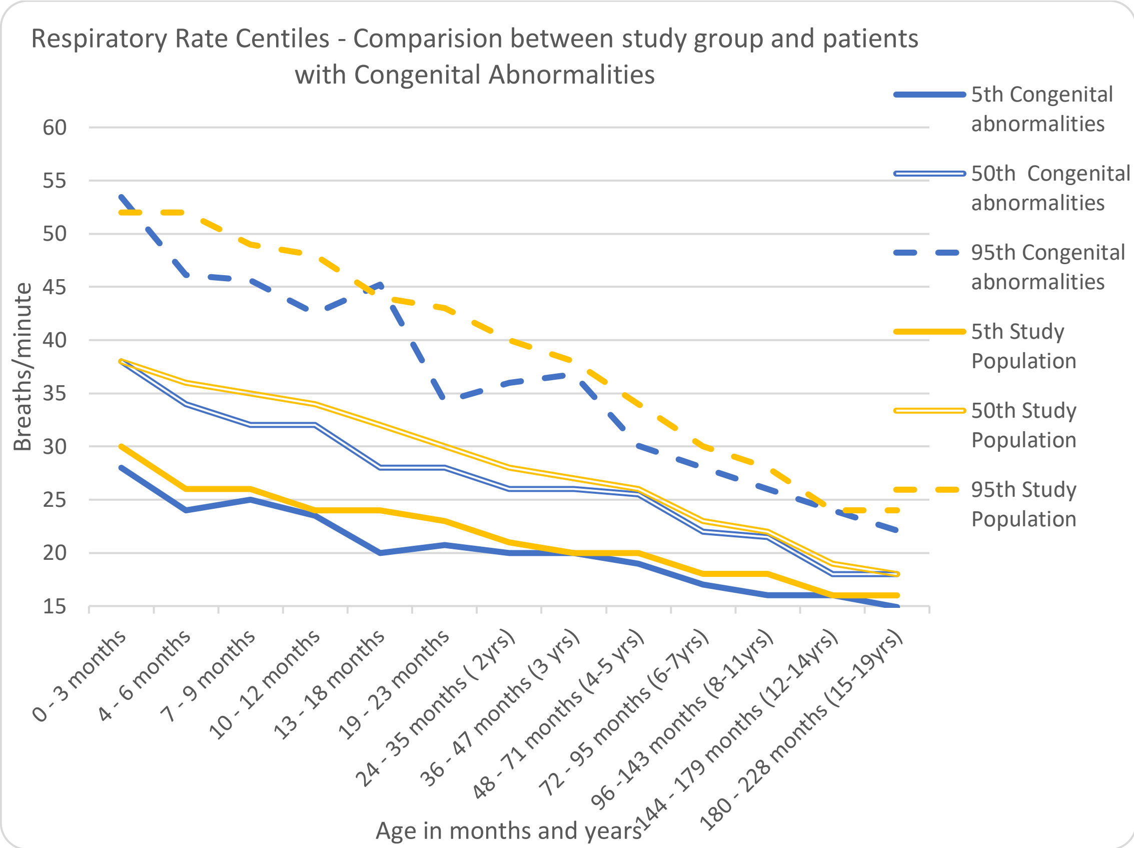




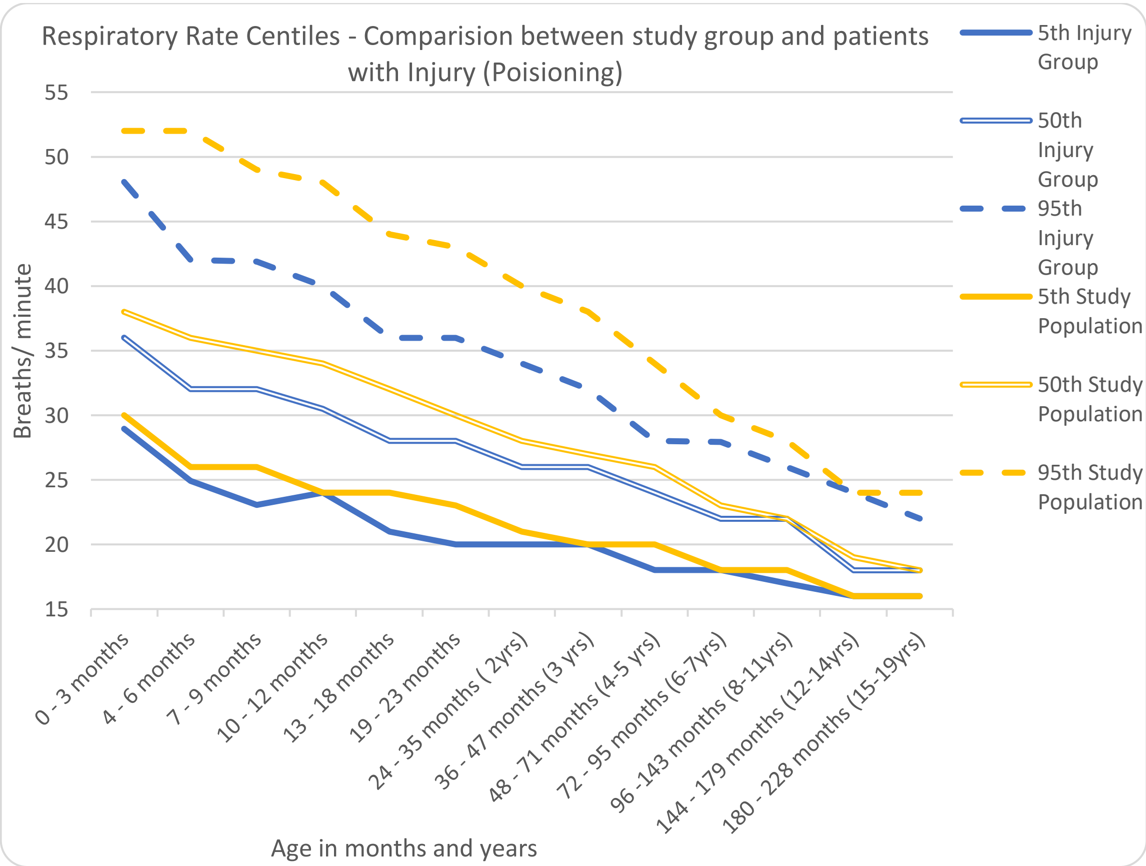
Respiratory Rate Centiles - Comparision between study group and patients with Neoplasms
Breaths/minute
55
50
45
40
35
30
25
20
15
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in months and years
5th Neoplasm Group
50th Neoplasm Group
95th Neoplasm Group
5th Study Population
50th Study Population
95th Study Population



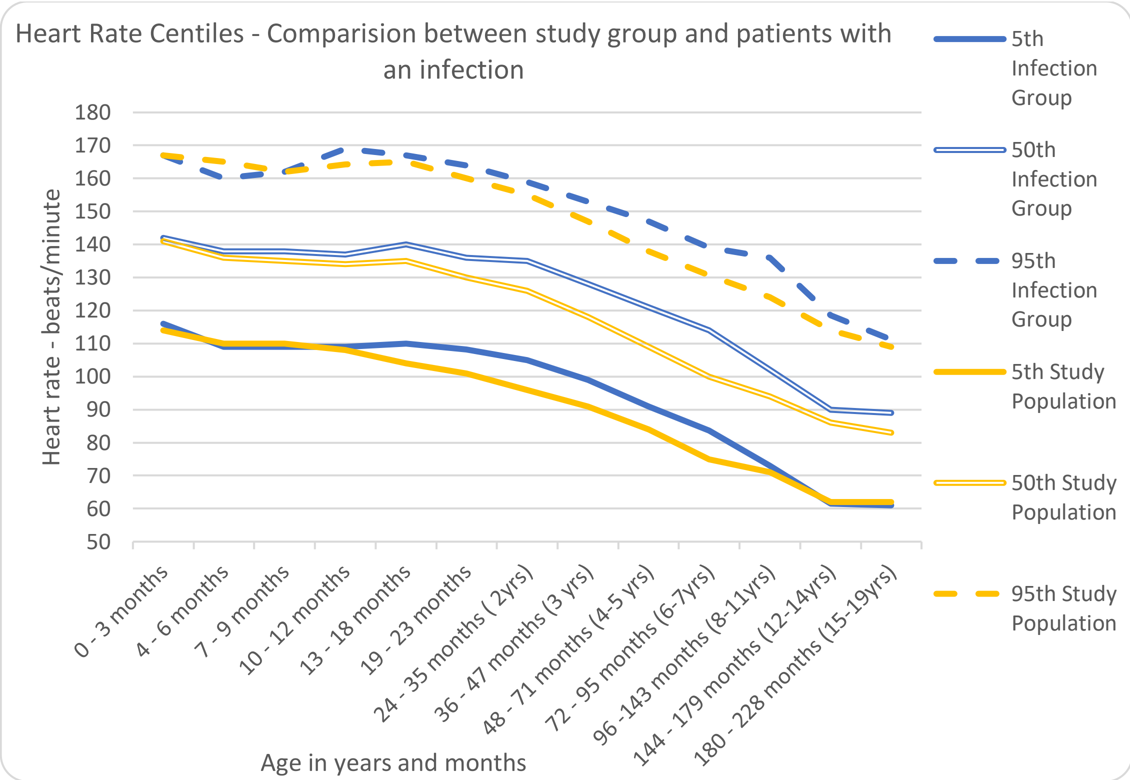
Respiratory Rate Centiles - Comparision between study group and patients with Respiratory Disease.
Breaths/minute
65
60
55
50
45
40
35
30
25
20
15
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in months and years
5th Respiratory Group
50th Respiratory Group
95th Respiratory Group
5th Study Population
50th Study Population
95th Study Population

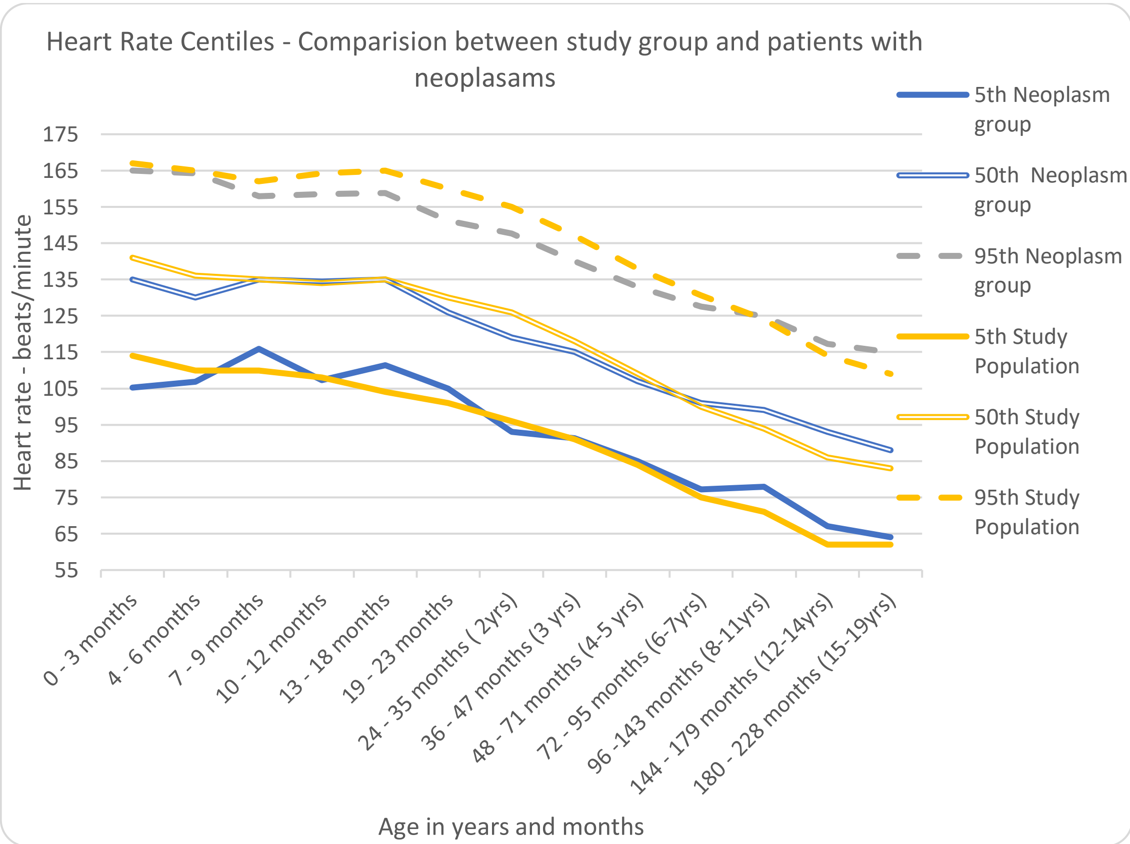


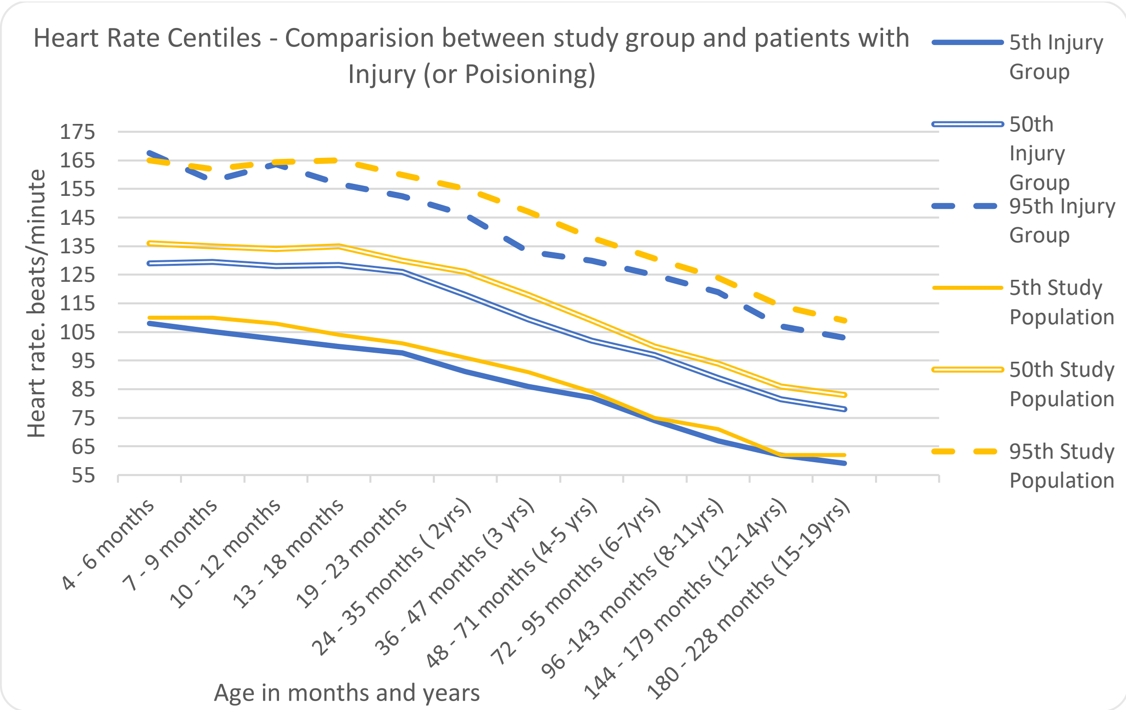
Respiratory Rate Centiles - Comparision between study group and patients with Congenital Abnormalities
5th Congenital abnormalities
50th Congenital abnormalities
95th Congenital abnormalities
5th Study Population
50th Study Population
95th Study Population
Breaths/minute
60
55
50
45
40
35
30
25
20
15
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in months and years



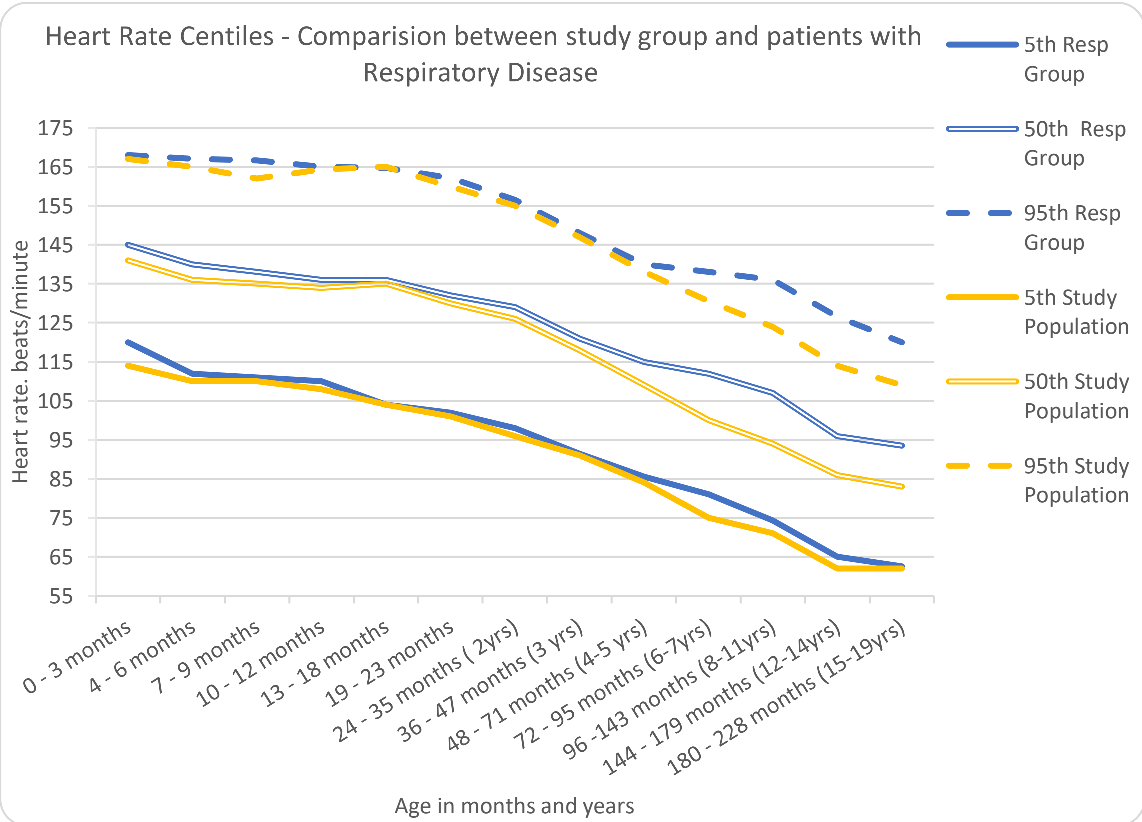
Respiratory Rate Centiles - Comparision between study group and patients with Injury (Poisioning)
5th Injury Group
50th Injury Group
95th Injury Group
5th Study Population
50th Study Population
95th Study Population
Breaths/ minute
55
50
45
40
35
30
25
20
15
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in months and years


Heart Rate Centiles - Comparision between study group and patients with an infection
Heart rate - beats/minute
180
170
160
150
140
130
120
110
100
90
80
70
60
50
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in years and months
5th Infection Group
50th Infection Group
95th Infection Group
5th Study Population
50th Study Population
95th Study Population


Heart Rate Centiles - Comparision between study group and patients with neoplasams
Heart rate - beats/minute
175
165
155
145
135
125
115
105
95
85
75
65
55
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in years and months
5th Neoplasm group
50th Neoplasm group
95th Neoplasm group
5th Study Population
50th Study Population
95th Study Population



Heart Rate Centiles - Comparision between study group and patients with Injury (or Poisioning)
175
165
155
145
135
125
115
105
95
85
75
65
55
Heart rate. beats/minute
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in months and years
5th Injury Group
50th Injury Group
95th Injury Group
5th Study Population
50th Study Population
95th Study Population



Heart Rate Centiles - Comparision between study group and patients with Respiratory Disease
175
165
155
145
135
125
115
105
95
85
75
65
55
Heart rate. beats/minute
0 - 3 months
4 - 6 months
7 - 9 months
10 - 12 months
13 - 18 months
19 - 23 months
24 - 35 months (2yrs)
36 - 47 months (3 yrs)
48 - 71 months (4-5 yrs)
72 - 95 months (6-7yrs)
96 -143 months (8-11yrs)
144 - 179 months (12-14yrs)
180 - 228 months (15-19yrs)
Age in months and years
5th Resp Group
50th Resp Group
95th Resp Group
5th Study Population
50th Study Population
95th Study Population

Appendix Seven

Supporting NHS Trust emails (x3)

1. Information Governance agreement from NHS Trust (Email trail).

From: "[redacted]

Date: 30 January 2018 at 14:24:06 GMT

To: "Taylor Nicola (Children's Services)" <nicola.taylor@[redacted]nhs.uk>

Cc: "[redacted]

Subject: RE: eobs research

Hi Nicky

The data can be used for your study, as it will be suitably anonymised.

Cheers

[redacted] Trust IG Lead

2. Support for Research Project from NUH Recognise and Rescue committee.

Hi Nicky,

Great to hear all about your MRes research proposal. As promised, I said I would get back to you by end of today.

I've spoken to [redacted] (R&R Clinical Lead) and [redacted] (Patient Safety Improvement Lead) and both are confident that your Masters project aligns with the Trust's Recognise & Rescue of the Deteriorating Patient Terms of Reference. One of the objectives is to 'reduce harm from Failure to Rescue' which includes the Early Warning Scores and improvements in care. Your exploration of the Trust's population data to identify more meaningful metrics to improve the Failure to Rescue rate for children would definitely be of benefit to the Trust's improvements in quality of care.

Recognise & Rescue's support of your project is only provided if you:

- Continue with the processes which you outlined with regards to Information Governance and ethical approval to ensure the protection of data moving outside the Trust; and
- Liaise with [redacted] to register your service evaluation with the Trust; and
- Have [redacted] as NUH Sponsor in relation to the above.

Recognise & Rescue very much look forward to reading your dissertation with your findings.

Kind regards and good luck with your project.

[redacted] Recognise & Rescue Project Lead [redacted] University Hospitals NHS Trust

3. Study support agreement from Nottingham Children's Hospital

From: [redacted]

Date: 19 February 2018 at 12:02:48 GMT

To: "Taylor Nicola (Children's Services)"

Subject: RE: observations research

For the attention of whom it may concern.

I fully support the research being completed by Nicola Taylor with regard to our electronic observations.

Kind Regards

[redacted]

Dr [redacted] (Children's Services)
Consultant Paediatrician