



**Identifying and understanding Risk factors for  
instability and adverse Events Associated with CHest  
physiotherapy in ventilated children**

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## **Declaration of content**

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

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## **Abstract**

### **Background**

Chest physiotherapy is a treatment option for ventilated children. Evidence supporting treatment effectiveness is limited and the safety profile is unknown. This study aimed to identify and understand risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children.

### **Methods**

This was a convergent mixed methods study.

*Work package 1:* Explanatory sequential study to describe current physiotherapy practice and explore decision making, utilising an anonymous questionnaire, semi-structured interviews, focus groups, and document analysis.

*Work package 2:* Retrospective single-centre study, using high-resolution data and electronic patient records. Mechanically ventilated children, aged 0-4 years, receiving chest physiotherapy were included. The primary outcome was oxygen saturation index (OSI). Incidence of adverse events (change  $\geq 0.3$ ) in the 60 minutes post-physiotherapy was investigated.

### **Results**

The questionnaire was sent to 26/27 (96%) UK paediatric intensive care units, with a response rate of 61% (72/118). Sixteen physiotherapist interviews and two focus groups (n=7) were completed. Twenty-nine organisational documents were analysed. The most frequently used techniques were position changes, saline instillation, manual hyperinflations and chest wall vibrations. Variation in practice included the personnel involved in treatments. Clinical decision making was described as complex, iterative, and collaborative, with experience and expertise important factors.

OSI data were available for 247 patients. OSI adverse event rates were between 7.4%-9.3%. The highest rate was recorded in the 5 minutes immediately post-



physiotherapy. A higher proportion of patients with an adverse event were emergency admissions ( $p < 0.001$ ). There was no association between occurrence of an OSI adverse event post-physiotherapy and length of ventilation or mortality.

## **Conclusion**

This is the first study to explore the safety of chest physiotherapy in ventilated children and the wider contextual factors. It has provided novel data regarding a popular treatment used in a vulnerable patient group. Further research is required to understand the risks and benefits of chest physiotherapy.

## Impact statement

Approximately 20000 children are admitted to UK paediatric intensive care units (PICUs) each year, with 60% requiring mechanical ventilation. Respiratory infection, and PICU therapies, including ventilation and anaesthesia, can impair airway clearance and cause secretion retention, atelectasis, and pneumonia. Chest physiotherapy aims to facilitate airway clearance and minimise these complications. Despite the role of physiotherapy being widely acknowledged, evidence to support safety and effectiveness remains inconclusive. The work presented in this thesis explores the delivery of chest physiotherapy and decision making processes, and provides novel findings related to risk factors for instability and adverse events associated with chest physiotherapy.

The findings confirm the popularity of chest physiotherapy in mechanically ventilated children within the UK. Variations in practice were apparent and predominantly related to individual and organisational factors. The complexity of physiotherapists' decision making on PICU was demonstrated and a conceptual model developed, highlighting the iterative and collaborative nature of the process. Challenges to decision making were described as experience, professional hierarchies and institutional constraints. This study combined high-resolution monitor and ventilator data with electronic patient records to provide the first detailed exploration of the safety of chest physiotherapy in ventilated children. Adverse events in the 60 minutes post-physiotherapy varied depending on the physiological outcome studied. Potential risk factors for adverse events were emergency admission, a respiratory diagnosis and ex-prematurity. Preliminary data regarding the impact of adverse events post-physiotherapy on longer-term outcomes were reassuring. These findings have important implications for clinical practice, future research, professional development, and training.

This study identified additional risk factors for instability and adverse events. Awareness and consideration of these in the clinical setting has the potential to impact patient care. Furthermore, the results of this exploratory study have provided data to support hypothesis generation for future trials which will directly

improve the safety and quality of patient care. Within this thesis areas for skills and knowledge development have been identified. Recommendations for educational topics have been provided, including the supervision of junior physiotherapists, and communication skills with families. Addressing these key areas is likely to improve physiotherapists' confidence and decision making. This study is the first to describe the psychological burden on physiotherapists working in paediatric intensive care. These findings have important implications for the health and wellbeing of the workforce.

The qualitative approaches used in this study required engagement of PICU physiotherapists across the UK. This has resulted in the development of a physiotherapy network, which provides valuable peer support, and is vital for future multi-site trials. Collaborative and respectful multidisciplinary team working were raised as essential components of shared decision making and management of instability. This thesis provides important recommendations related to education of the wider team and understanding of the role of physiotherapy, which can be used to improve interprofessional relationships and team working. This study has generated methodological experience and expertise combining high-resolution monitor and ventilator data with electronic patient records, which have important implications for future research within the fields of paediatric intensive care medicine and physiotherapy.

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## Abbreviations

ARDS	Acute respiratory distress syndrome
ASL	Airway surface liquid
BD	Twice daily
CAQDAS	Computer assisted qualitative data analysis software
CF	Cystic Fibrosis
CICU	Cardiac intensive care unit
CO <sub>2</sub>	Carbon dioxide
COPD	Chronic obstructive pulmonary disease
COVID19	Severe acute respiratory syndrome coronavirus 2 2019 pandemic
CPB	Cardiopulmonary bypass
CPT	Chest physiotherapy
CS	Closed suction
CVVH	Continuous veno-venous haemofiltration
CWV	Chest wall vibrations
CXR	Chest x-ray
DNase	Dornase alpha
DRE	Digital research environment
DRIVE	GOSH Digital Research, Innovation, and Virtual Environment
ECMO	Extracorporeal membrane oxygenation
EELV	End expiratory lung impedance view
EFIT	Expiratory flow increase technique
EIT	Electrical impedance tomography
EPR	Electronic patient records
ERCC	Expiratory rib cage compression
EtCO <sub>2</sub>	End tidal carbon dioxide
ETT	Endotracheal tube
EU	European Union
FiO <sub>2</sub>	Fraction of inspired oxygen
FLACC	Face, legs, activity, cry, consolability behavioural pain score
GDPR	General data protection regulation
GOS ICH	Great Ormond Street Institute of Child Health

GOSH	Great Ormond Street Hospital for Children NHS Foundation Trust
HFCWO	High frequency chest wall oscillation
HFOV	High frequency oscillatory ventilation
HR	Heart rate
HRA	Health Research Authority
ICP	Intracranial pressure
ICU	Intensive care unit
iNO	Inhaled nitric oxide
IPA	Interpretive phenomenological analysis
IPV	Intrapulmonary percussive ventilation
IQR	Inter quartile range
IRAS	Integrated research application system
IRT	Inspiratory rise time
ISQ	In-status-quo
LOS	Length of stay
LOV	Length of ventilation
LRTI	Lower respiratory tract infection
MAP	Mean airway pressure
MBP	Mean blood pressure
MDT	Multidisciplinary team
MHI	Manual hyperinflations
MI-E	Manual insufflation/exsufflation
NAC	N-acetylcysteine
NaCl	Sodium chloride
NBBAL	Non-bronchoscopic bronchioalveolar lavage
NHS	National Health Service
NICU	Neonatal intensive care unit
NIHR	National Institute of Health Research
O <sub>2</sub>	Oxygen
OI	Oxygenation index
OS	Open suction
OSI	Oxygen saturation index
P(A-a)O <sub>2</sub>	Arterial-alveolar oxygen tension difference
PaCO <sub>2</sub>	Partial pressure of arterial carbon dioxide



PaO <sub>2</sub>	Partial pressure of arterial oxygen
PCL	Periciliary layer
PC-SIMV	Pressure controlled – synchronised intermittent mandatory ventilation
PEEP	Positive end expiratory pressure
PEF	Peak expiratory flow
PELOD	Pediatric Logistic Organ Dysfunction
PICANet	Paediatric Intensive Care Audit Network
PICUs	Paediatric intensive care units
PIF	Peak inspiratory flow
PIM3	Paediatric Index of Mortality version 3
PIP	Peak inspiratory pressure
PMH	Past medical history
PO <sub>2</sub>	Partial pressure of oxygen
PPIE	Patient and public involvement and engagement
PSV	Pressure support ventilation
RCT	Randomised controlled trial
RSV	Respiratory syncytial virus
SaO <sub>2</sub>	Oxygen saturation of arterial blood
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SMA	Spinal muscular atrophy
SOP	Standard operating procedure
SpO <sub>2</sub>	Peripheral oxygen saturation
UCL	University College London
UK	United Kingdom
VAD	Ventricular assist device
VAP	Ventilator acquired pneumonia
VC-SIMV	Volume controlled synchronised intermittent mandatory ventilation
VD <sub>phys</sub>	Physiological dead space
VD <sub>alv</sub>	Alveolar dead space
VHI	Ventilator hyperinflations
VILI	Ventilator induced lung injury

## **Thesis overview**

Paediatric intensive care units (PICUs) support the complex medical needs of children with life threatening conditions. There are around 20000 admissions to PICUs each year in the United Kingdom (UK) and approximately 60% require invasive mechanical ventilation (PICANet, 2022). Chest physiotherapy is a treatment option for these patients. This intervention, which aims to facilitate airway clearance and improve ventilation, was first described in the early 1900s. I have been involved in providing chest physiotherapy to children in paediatric intensive care, across several institutions, for the last 16 years. In this time, I have seen only subtle refinement and advances in practice. Meanwhile I have observed significant progress in the technology and drug therapies available on PICU, which have supported the successful recovery of increasingly complex patients. These factors, coupled with the drive for evidence-based practice, provided the motivation for this thesis.

Given the limited evidence base and anecdotal reports of variation in practice it was necessary to take a step back and consider the fundamentals of cardiorespiratory physiotherapy. Patient safety is a key component in the provision of any intervention on ICU. Therefore, the focus of this study was based on the safety of chest physiotherapy. It aimed to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children. A mixed methods approach allowed exploration of the wider contextual factors. This thesis includes nine chapters, which are outlined below.

Chapter 1 introduces the key concepts related to the project and includes a comprehensive literature review. Specific gaps in the literature are identified and the overall aim and research questions presented.

Chapter 2 describes the methodology which guided the development and implementation of the study. The rationale for the choice of mixed methods is discussed and the philosophical perspectives underpinning the study considered.

Chapter 3 explores current physiotherapy practice within UK PICUs. This component uses a bespoke questionnaire sent to PICU physiotherapists. Both quantitative and qualitative data were collected, and the analysis is presented. The findings from this chapter guided the development of subsequent phases.

Chapter 4 provides an in-depth understanding of clinical decision making and management of instability and adverse events, through semi-structured interviews with physiotherapists. Data are presented in framework form with illustrative quotations and diagrams.

Chapter 5 presents the focus group component of the study. This explores current practice, together with clinical decision making and management of instability and adverse events from a more practical perspective. In line with chapter 4, framework tables are used to present data, with quotations and visual representations.

Chapter 6 includes analysis of organisational documents related to chest physiotherapy in ventilated children. Content and purpose are explored in relation to practice and decision making.

Chapter 7 presents the final study component which is of quantitative design. It explores the incidence of adverse events post-physiotherapy, identifies potential risk factors, and investigates impact on long-term outcomes.

Chapter 8 integrates and merges the relevant findings from the individual study components. Results are compared for similarities and differences and presented as narrative and through visual methods

Chapter 9 summarises the study's main findings and provides an overview of the strengths and limitations. Recommendations for clinical practice and future research directions are discussed.

## **1. Introduction and Literature Review**

This chapter introduces the key concepts related to the project, including airway clearance, chest physiotherapy, adverse events and clinical decision making. The literature related to the effectiveness and safety of chest physiotherapy in ventilated children is presented and critiqued. Gaps in the literature are identified and study rationale discussed, before presenting the aim and research questions under investigation.

### **1.1 Airway Clearance**

The respiratory system is a dichotomous branching structure of up to 23 generations, divided into the conducting zone (trachea to bronchioles) and the respiratory zone (alveolar duct to alveoli) (Ganesan et al., 2013, Patwa and Shah, 2015, Tilley et al., 2015). The size of the airway tract progressively decreases and is lined by a continuous layer of pseudostratified epithelium. The lungs are in direct contact with the environment and are constantly exposed to inhaled particles, toxins, and microbial pathogens, which must be cleared to maintain homeostasis and prevent inflammation and infection. Natural airway clearance depends on normal mucociliary function, appropriate production and composition of mucus, adequate cough strength and unobstructed airways (Volsko, 2013).

Within cardiorespiratory physiotherapy it is important to understand the principles of airway clearance, given that the interventions provided by physiotherapists aim to manipulate or affect these. Three key components, which will be discussed in more detail, are mucociliary clearance, two phase gas liquid flow and cough.

#### **1.1.1 Mucociliary function**

Mucociliary clearance is characterised by mucus secretion and its transport by ciliary action. Effective mucociliary clearance is dependent upon appropriate interaction between the mucus gel layer, the periciliary layer (PCL) and the ciliated epithelium (Figure 1.1). A balance between rheology and quantity of the mucus, adequate PCL, and normal cilia function is required (Voynow and Rubin, 2009).

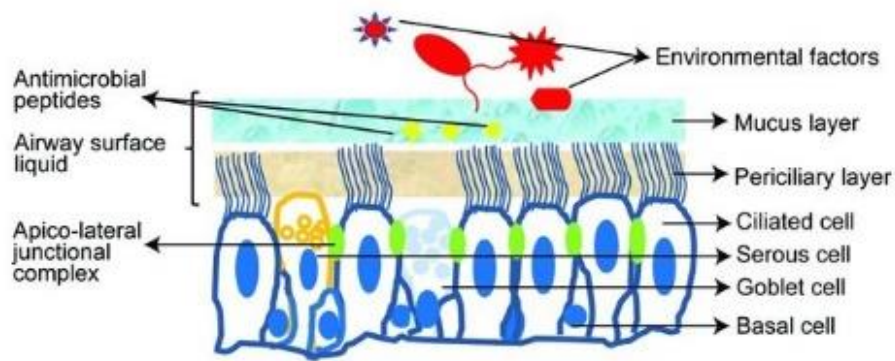


Figure 1.1 Components of airway tract epithelium  
(Reproduced from Ganesan et al., 2013)

The mucus gel layer provides a physical barrier trapping inhaled pathogens and particles. Mucus is a viscoelastic material which, in normal circumstances, consists of 97% water and 3% solids. The main solid component is mucin, a high molecular weight glycoprotein (Ganesan et al., 2013, Munkholm and Mortensen, 2014). The rheological properties of mucus are regulated through hydration, via control of the transepithelial movement of water, ions and soluble proteins. The balance of hydration can also be disrupted by mucus hypersecretion (Munkholm and Mortensen, 2014). Mucus exhibits shear thinning following exposure to high shear forces, allowing viscosity to be either permanently or temporarily reduced (King, 1998).

The PCL, a poly-anionic gel, extends from the cell surface to the height of the extended cilia and lubricates the airway surface providing an optimal environment for ciliary beating (Mall, 2008). The thickness of the periciliary layer is critical for effective propulsion of mucus (Houtmeyers et al., 1999). Dehydration of the PCL results in compression of the PCL brush and cilia, slowing down and eventually stopping mucociliary clearance (Button et al., 2012).

The main function of ciliated airway cells is to moderate the propulsion of the mucus layer in a cephalad direction. This is achieved by highly synchronised in-plane cilia beating, creating a wave like movement. In healthy lungs the cilia beat frequency is between 12-15hz which can propel the mucus gel layer at a rate of 4 to 20mm/min (Tilley et al., 2015). The beat pattern of cilia is asymmetric. The cilia tips only contact the mucus layer on the forward stroke, bending on the recovery stroke to pass under the mucus layer. This ensures unidirectional

movement of mucus (Braiman and Priel, 2008). Teff et al. (2008) report that mucus transport velocity increases linearly with cilia beat frequency. Normal function of the cilia can be impaired by cilia dysfunction directly, increased viscosity/volume of the mucus layer or PCL dehydration.

### **1.1.2 Two phase gas liquid flow**

A secondary clearance mechanism, known as two phase gas liquid flow, plays an important role in clearing excessive mucus from the lungs (Kim et al., 1986a, Kim et al., 1987). When air flows through an airway lined with a thick mucus layer a shear force is created on the surface of the mucus layer. The mucus layer can be propelled in the direction of airflow if velocity is sufficient to produce a shear force that can overcome viscous or gravitational resistance (Kim et al., 1986a, Kim et al., 1987, Kim et al., 1986b).

An early in-vitro study demonstrated increased mucus transport speed with increasing airflow in a continuous airflow model (Kim et al., 1986a). However, airflow within the lungs is not continuous, it is periodic and reversible, acting in an unpredictable manner particularly in relation to an uneven mucus layer. Hence the authors subsequently investigated mucus transport by periodic airflow (Kim et al., 1987). Increasing the peak expiratory to inspiratory flow rate increased the mucus transport speed. Transport speed was predominantly governed by the absolute value of the higher airflow and an expiratory flow bias of 10% was necessary for cephalad mucus transport (Peak inspiratory flow:peak expiratory flow <0.9). The results also demonstrated that a critical thickness of mucus was required for clearance via two phase gas liquid flow. This was reported as 10-15% of the diameter of the large airways.

Factors favouring two phase gas liquid flow transport in-vivo include: the inclined orientation of airway branches which may reduce the influence of gravity, and the presence of the PCL which will aid movement of the mucus layer (Kim et al., 1987, Kim et al., 1986b). Animal studies have demonstrated cephalad movement of mucus in situations with an expiratory flow bias (Benjamin et al., 1989, King et al., 1990)

### 1.1.3 Cough

Cough is a fundamental defence mechanism, with two key functions. It protects the respiratory system from foreign particles and clears airway secretions (Fernández-Carmona et al., 2018). Cough clearance is vital for excessive mucus or when mucociliary clearance mechanisms are injured or insufficient (King, 1998).

A cough occurs through the stimulation of a complex reflex arc, which includes cough receptors, an afferent pathway, a central pathway or cough centre and an efferent pathway (Polverino et al., 2012). Cough is initiated by the activation of receptors found in the larynx, trachea, carina, and large intrapulmonary bronchi. These receptors respond to both mechanical and chemical stimuli. There are additional mechanical airway receptors within the external auditory canals, eardrums, paranasal sinuses, pharynx, diaphragm, pleura, pericardium, and stomach. Afferent neural subtypes include C-fibres, rapidly adapting receptors, and slowly adapting stretch receptors. These vagal afferent sensory nerves project the signal centrally to the upper brain stem and pons, where it undergoes modulation. This results in the generation of an appropriate efferent motor response, via the vagal, phrenic, and/or spinal motor nerves (Canning et al., 2014, Polverino et al., 2012).

In adults, a cough is characterised by an initial inspiration of approximately 2.5l of air. The glottis is then closed and a sudden increase in intrathoracic pressure of approximately 100cmH<sub>2</sub>O is generated through contraction of the abdominal and respiratory muscles. The glottis immediately reopens and a turbulent blast of air, composed of a 30–50ms rapid peak with high flow rates and flow accelerations (12 l/s and 300 l/s<sup>2</sup>, respectively) followed by a 200–500ms relaxation phase with low flow rates (3–4 l/s), passes through the partially collapsed trachea and other airways (Naire, 2008). The high velocity airflow generated during the expiratory phase results in large shear forces being applied to the mucus layer, propelling it into the large airways towards the larynx (Button et al., 2018, King et al., 1985).

In vitro studies using a simulated cough machine displayed increased mucus clearance with repetitive coughing, versus a single cough or period of quiet sitting

(Bennett et al., 1990, Zahm et al., 1991). Effective cough was associated with increasing expiratory flow and the initial high flow phase of cough was found to contribute most to cough clearance (King et al., 1985). An inverse relationship was reported between mucus viscoelasticity and particle displacement. Mucus with high shear-thinning properties and high thixotropic properties was better transported by the cough mechanism (Tambascio et al., 2013).

## **1.2 Paediatric intensive care and airway clearance**

The natural defence mechanisms which contribute to effective airway clearance are essential to ensure the removal of foreign particles and pathogens, prevent infection, and optimise respiratory function and ventilation. Whilst these mechanisms are sufficient in healthy individuals they are disrupted during critical illness, particularly in patients with respiratory disease or those undergoing mechanical ventilation or anaesthesia. This section explores the impact of critical illness and the paediatric intensive care unit on airway clearance.

### **1.2.1 Respiratory disease and airway clearance**

Respiratory admissions to paediatric intensive care units (PICU) in the UK account for 30% of patients (PICANet, 2022). Children may present with respiratory distress due to an acute infection or an exacerbation of an inherited or acquired lung disease such as asthma.

Bronchiolitis is a common cause of hospitalisation in children. An acute viral illness results in inflammation of the lining of the epithelial cells. The most common infecting agent is respiratory syncytial virus (RSV) (Florin et al., 2017). An in vitro study, using high speed video microscopy, found a significant increase in ciliary dyskinesia in human epithelium within 24 hours of infection with RSV (Smith et al., 2014). In the same study electron microscopy revealed an increase in cilia loss and mitochondrial damage associated with RSV. In severe bronchiolitis exudate, cell debris and peribronchial lymphoid infiltration can cause plugging of the airways (De Boeck et al., 2008). Significantly increased ciliary dyskinesia has also been reported in healthy individuals infected with human coronavirus (Chilvers et al., 2001). Mucus hypersecretion and inflammation, as a result of infection, can limit airflow and impair mucociliary clearance (Tilley et al.,



2015). Abnormal airway mucus composition has also been attributed to several viral infections, often identified in patients in paediatric intensive care. RSV, influenza and severe acute respiratory syndrome coronavirus 2 are reported to result increased mucus viscosity (Li and Tang, 2021).

Mucociliary clearance is impaired in children with asthma. Shahana et al. (2005) have reported extensive epithelial damage in asthmatic patients. Cilia beat frequency was significantly decreased in moderate and severe asthma compared to controls (Thomas et al., 2010a). In children with severe asthma cilia dyskinesia and immotility were higher and abnormalities in the ultrastructure of the epithelium reported (Thomas et al., 2010a). Munkholm and Mortensen (2014) highlight the increased viscosity of mucus in patients with asthma, attributed to goblet cell metaplasia leading to hypersecretion of mucin. In children with cystic fibrosis (CF), mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) disrupt chloride secretion, sodium reabsorption, and water transport, leading to mucus hyperconcentration. This is characterised by excess mucus adhesiveness (stickiness) and cohesiveness (stringiness), resulting in impaired mucociliary clearance (Rubin, 2007, Turcios, 2020). In addition chronic infection and colonization with bacteria are predominant features of respiratory disease, which can lead to mucus gland hypertrophy and epithelial damage, further impacting mucociliary clearance (Munkholm and Mortensen, 2014).

### **1.2.2 Intubation, mechanical ventilation, and airway clearance**

Approximately 60% of children admitted to PICU within the UK require mechanical ventilation (PICANet, 2022). Although intubation and mechanical ventilation provide lifesaving therapy, prolonged ventilation with an endotracheal tube or tracheostomy is associated with numerous risks and complications (Principi et al., 2011).

Repeated delivery of tidal mechanical energy has the potential to cause ventilator-induced lung injury (VILI) when stress and strain exceed the limits of tissue tolerance (Kneyber et al., 2020). Ventilation strategies causing volutrauma and atelectrauma can lead to VILI. Injury mechanisms, which include disturbance of the surfactant layer, formation of hyaline membranes, stimulation of pulmonary

inflammatory cytokines and elevated alveolar protease activity, can impair mucociliary clearance (MacIntyre, 2005, Yamashita and Veldhuizen, 2011).

The impact of mechanical ventilation on mucociliary clearance has been investigated in a series of in-vivo rabbit studies (Piccin et al., 2011). Three ventilation strategies were investigated: low volume, high volume and high pressure. There was a significant decrease in cilia beat frequency post-mechanical ventilation, when compared to before, in the high pressure group: 13.51Hz (11.62–14.49) to 11.69Hz (10.12–14.18) ( $p=0.047$ ). Electron microscopy revealed signals of injury on the epithelial cells in the high volume and pressure groups. These findings are in contrast to those of Konrad et al. (1995) who concluded that impaired mucociliary transport in intubated patients was associated with loss of cilia rather than ultrastructural abnormalities. Patients with markedly depressed mucus transport velocity (group 2) demonstrated a significantly reduced number of cilia on the laminar surface compared to patients with normal/slightly reduced transport velocity (group 1). Eleven patients in group 1 compared to four in group 2 displayed a ciliated area  $> 75\%$  ( $p=0.013$ ) (Konrad et al., 1995).

Mechanical ventilator flow patterns have been found to influence airway secretion movement. Volpe et al. (2008) reported that flow bias obtained with ventilator settings may embed mucus during ventilation. The authors identified a threshold difference above which mucus was displaced. Mucus moved towards the mouth if the expiratory-inspiratory flow difference was greater than 17L/min or towards the lungs if inspiratory-expiratory flow difference was greater than 17L/min. These deleterious effects of mechanical ventilation on secretion clearance were also discussed by Ntoumenopoulos et al. (2011). Measurements of peak inspiratory and expiratory flows were taken during quiet ventilation in 20 intubated and ventilated adults. In eight patients inspiratory flow bias was greater than 17L/min potentially promoting secretion retention. The remaining 12 patients had flow bias values that, theoretically, would result in no net movement of secretions.

After endotracheal intubation the upper airway loses its capacity to heat and humidify inhaled gas. Early studies investigating the effects of dry air inhalation in intubated dogs reported reduced clearance velocity and excessive cooling and

drying of the cilia (Burton, 1962, Tsuda et al., 1977). More recently inadequate humidification has been reported to increase mucus viscosity, depress ciliary function, and cause tracheal inflammation (Gross and Park, 2012). Despite humidification during mechanical ventilation now being an accepted standard of care, there is a risk of insufficient humidification when compared to native mechanisms (Branson, 2007).

Intubation with an endotracheal tube (ETT) has a significant impact on mucociliary clearance and the cough mechanism. The presence of an ETT was found to alter the normal timing of cough pressure and flow when assessed in intubated, healthy, adult men completing spontaneous coughs (Gal, 1980). The flows achieved with an ETT at maximum cough pressure decreased significantly to 59% of the flows achieved during normal cough. Additionally, flow occurred earlier and did not return to baseline in between individual bursts of cough. This is attributed to the prevention of glottic closure by the presence of the ETT (Volpe et al., 2008). The non-compliant nature of the ETT, together with the fact that it splints the trachea open preventing it from collapsing as seen in normal cough, increases the resistance to airflow. This leads to accumulation of secretions at the end of the ETT and the need for higher flow to effectively clear these (Gal, 1980).

Cuffed ETT are frequently used in PICU. Cuff inflation has been demonstrated to damage the tracheal mucosa, which persists up to 96 hours after extubation (Li Bassi et al., 2015). In an early study, Sackner et al. (1975) compared tracheal mucus velocity in dogs intubated with either an un-cuffed, a low compliance cuffed or a high compliance cuffed ETT. The un-cuffed ETT demonstrated no significant changes in mucus velocity over time. The low compliance cuff significantly reduced transport velocity by 26% at one hour ( $p < 0.02$ ) and 74% at four hours ( $p < 0.001$ ). The ETT with a high compliance cuff also reduced velocity; 37% at one hour ( $p < 0.01$ ) and 52% at four hours ( $p < 0.01$ ). Supporting results have been reported by Li Bassi et al. (2015). Normal mucociliary clearance rates in pigs are reported as 5-7mm/min. However the fastest rate of mucociliary clearance, in pigs intubated and ventilated with cuffed ETT, was 1.1+/- 2.1 mm/min (Li Bassi et al., 2015).

The position of the intubated trachea in relation to gravity has also been shown to influence mucociliary transport. Intubated and ventilated sheep positioned 40° trachea up displayed abnormal mucociliary clearance. Secretions were initially transferred by the cilia towards the glottis, however once in the proximal trachea movement reversed and mucus was transported towards the lungs (Li Bassi et al., 2008). This is in contrast to sheep positioned 5° below horizontal, where mucus only moved towards the glottis. The authors reported that this was highly associated with bacterial colonization of the airways and lungs. This is clinically relevant to PICU where standard practice is to elevate the head of the bed (>30°) to minimize risks of gastroesophageal reflux and protect against intracranial haemorrhage.

The ETT is rapidly colonized by microorganisms that form a biofilm on its surface (Diaconu et al., 2018, Gil-Perotin et al., 2012). This biofilm acts as a reservoir for highly infective microorganisms which can be aerosolized and aspirated into the lungs as a result of gas flow during ventilation or dislodgement (Mietto et al., 2013). Biofilm was present in 95% of ETTs when investigated in a prospective, observational study of ventilated adults (Gil-Perotin et al., 2012). Development of the biofilm was noted as early as 24 hours after intubation. The presence of an ETT is the principal determinant of ventilator acquired pneumonia (VAP), due to the impact on mucociliary clearance, cough and biofilm development (Mietto et al., 2013). VAP is the most common infectious complication in critically ill patients. The infective process results in mucus hypersecretion, which further impairs mucociliary function.

Maintaining the patency of the ETT is vital to ensure effective ventilation. Endotracheal suctioning is necessary to remove secretions and prevent obstruction. The negative pressure applied during suctioning has been associated with tracheobronchial trauma. Damage including oedema, loss of cilia and stripped epithelium was observed with suction using both 100mmHg and 200mmHg in intubated dogs (Kuzenski, 1978). Injury related to the depth of suctioning has been investigated in rabbits (Bailey et al., 1988). Oedema, vascular congestion and infiltrates were found after shallow and deep suction techniques. Necrosis, loss of cilia and amount of mucus were significantly greater

following deep suction (Bailey et al., 1988). A more recent study has reported suction related damage including sub epithelial inflammation and loss of cilia. Following repeated subglottic secretion aspiration in intubated pigs, Li Bassi et al. (2015) reported tracheal injury rates of 12.2% on bronchoscopy and 25% on autopsy.

### **1.2.3 Other PICU interventions and airway clearance**

Other interventions in PICU can also have a detrimental impact on airway clearance. Children on PICU are frequently exposed to anaesthetic agents, either in surgery prior to admission or during their stay when used as sedative agents. Approximately 34% of all PICU admissions in the UK are following a surgical intervention (PICANet, 2019). A loss of respiratory muscle tone during anaesthesia results in a fall in functional residual capacity, leading to airway closure and reabsorption atelectasis (Hedenstierna and Edmark, 2015). Persistent atelectasis can act as a locus for infection (Hedenstierna and Edmark, 2005). Respiratory infection can result in mucus hypersecretion, altering the depth and rheology of the mucus gel layer and impairing the mucociliary escalator. There are conflicting data around the effects of morphine on mucociliary clearance. Wang et al. (2003) reported decreased mucociliary clearance due to an opioid induced reduction in cilia beat frequency. However no significant change in cilia beat frequency was reported after exposure to morphine in an in-vitro study using human nasal epithelium (Selwyn et al., 1996). In ventilated adults remifentanil, when used in conjunction with propofol, was found to significantly reduce bronchial mucus transport velocity when compared to morphine and propofol (morphine mean  $9.2\text{mm}/\text{min}^{-1}$  vs remifentanil  $4.2\text{mm}\cdot\text{min}^{-1}$ ,  $p=0.028$ ) (Ledowski et al., 2006). The cough reflex is suppressed with the use of anaesthesia and muscle relaxants, eliminating a vital component of airway clearance.

Children admitted to PICU following cardiothoracic surgery may have been subject to cardiopulmonary bypass (CPB). CPB is associated with postoperative lung dysfunction. The deleterious effects of CPB on the respiratory system are due to a series of inflammatory events involving the endothelium, leukocytes, platelets, coagulation cascade, and the release of cytokines (Beer et al., 2014,

Durukan et al., 2013). Despite advances in strategies to attenuate this inflammatory process, including low tidal volume ventilation, ultrafiltration, technical modifications and pharmacological agents, respiratory dysfunction is still prevalent (Apostolakis et al., 2010, Chi et al., 2017, Fiorentino et al., 2019, Mahmoud et al., 2005). Endothelial and interstitial oedema, together with alveolar collapse and surfactant loss, impact the equilibrium of the ASL required for effective mucociliary clearance (Bhatia et al., 2018).

Intravenous furosemide, a commonly used diuretic, has been shown to significantly decrease mucociliary transport after administration in mechanically ventilated adults (Kondo et al., 2002). Nasal mucociliary clearance was impaired in healthy adults following oral furosemide (Goto et al., 2010). The effects of prednisolone on mucociliary clearance have been studied in rats. High dose prednisolone significantly reduced mucociliary transport velocity when compared to controls ( $0.51 \pm 0.19$  mm/min vs  $0.61 \pm 0.08$  mm/min,  $p=0.07$ ) (Oliveira-Braga et al., 2012). Prado e Silva et al. (2013) investigated mucociliary clearance following the use of triple immunosuppression therapy, including prednisolone, compared to a control group. The results demonstrated a significant decrease in ciliary beat frequency and mucociliary transport velocity, together with overproduction of mucus, in the treatment group.

This section has highlighted the deleterious effects respiratory infection, intubation and mechanical ventilation, anaesthesia and medications can have on airway clearance. Critically ill children are a vulnerable population hence it is important to ensure the risks and complications of the PICU are minimised, whilst recovery and long-term outcomes are enhanced.

### **1.3 Chest physiotherapy**

Chest or respiratory physiotherapy is an accepted treatment option for mechanically ventilated children (Morrow, 2015, Pathmanathan et al., 2015). It aims to facilitate the removal of obstructive tracheobronchial secretions, improving mucociliary clearance and ventilation, helping to address or alleviate the negative sequelae of PICU on the respiratory system. An overview of the goals of chest physiotherapy are displayed in Table 1.1.

Table 1.1 Goals of chest physiotherapy in PICU

Goals of chest physiotherapy
Facilitate mucociliary clearance
Maintain or recruit lung volume
Improve regional/global ventilation and compliance
Improve ventilation/perfusion mismatch
Reduce airway resistance and work of breathing
Optimize oxygenation and ventilation
Improve respiratory muscle strength
Minimise risk of infection

(Adapted from Pathmanathan et al. (2015), Pryor and Prasad (2008))

Chest physiotherapy was first described in the early 1900s and included postural drainage and deep breathing exercises (Macmahon, 1915, Nelson, 1934). In current practice chest physiotherapy is an umbrella term encompassing several therapeutic modalities, which can be used in combination for optimal effectiveness. Treatment modalities include manual and ventilator hyperinflations, manual techniques such as percussion, chest wall vibrations and assisted cough, and positioning. Mechanical adjuncts include manual insufflation/exsufflation, the metaneb and intermittent positive pressure breathing. The physiotherapy techniques relevant to this study will now be described individually and literature for their theoretical basis for use discussed.

### **1.3.1 Chest physiotherapy techniques in mechanically ventilated patients**

#### *1.3.1.1 Manual hyperinflations*

Manual hyperinflations (MHI), also referred to as ‘bagging’ or ‘bag squeezing’, are provided via a manual resuscitation bag. They are characterised by a series of large volume breaths at a low inspiratory flow, a brief inspiratory hold, followed by a quick release with a high expiratory flow (Morrow, 2015, Paulus et al., 2012). The rationale behind MHI is based around the capacity to create an expiratory flow bias, moving secretions towards central airways through the two-phase gas liquid transport mechanism (Volpe et al., 2018b). As discussed previously the critical thresholds for cephalad movement of secretions are reported as PIF:PEF

<0.9 or a PEF-PIF difference greater than 17 L/min (Benjamin et al., 1989, Kim et al., 1987, Volpe et al., 2008). In a simulated lung model physiotherapists were able to use MHI to create an expiratory flow bias and fulfil the criteria for secretion movement (Jones et al., 2009). Two MHI circuits were trialled, and both created PIF:PEF <0.9; Mapleson-C circuit 0.52 (+/-0.21) and Magil circuit 0.75 (+/- 0.26).

In a test lung Volpe et al. (2018b) investigated the influence of the individual components of MHI on mucus stimulant movement, PIF:PEF and PEF-PIF difference. MHI were completed prior to, and following, expert instruction. The initial MHI technique was characterised by fast breaths with no inspiratory hold. Following expert instruction small breaths with a longer inspiratory time were completed. Mean centre of mucus displacement differed significantly. The pre-instruction MHI technique moved mucus towards the test lung -2.35cm (+/-0.63). The second technique resulted in cephalad movement of secretions 0.52cm (+/-0.33) ( $p < 0.001$ ). The PIF:PEF and PEF-PIF differences were also advantageous following MHI with lower inspiratory volume and longer inspiratory time: 0.58 (+/-0.16) and 27.5L/min (+/-11.0) respectively. Further in-vitro work has investigated the flow profiles generated by physiotherapists. Different circuits, manual techniques including 'rapid release', and lung volumes were compared (Maxwell and Ellis, 2003). The 'rapid release' technique produced faster expiratory flow rates irrespective of the circuit type or lung volume used. The effect of positive end expiratory pressure (PEEP) on peak expiratory flow during MHI was investigated by Savian et al. (2005). As PEEP increased PEF was found to decrease; at PEEP 5cmH<sub>2</sub>O mean PEF was 41.04L/min (+/- 5.98) versus a mean PEF of 32.03L/min (+/-6.59) at a PEEP of 15cmH<sub>2</sub>O. This indicates potential for secretion clearance to be impaired at higher PEEP.

Historically, MHI has also been used by physiotherapists as a recruitment manoeuvre to recruit collapsed or atelectatic lung (Maa et al., 2005, Ntoumenopoulos, 2005). This is based on inflating collapsed alveoli by promoting airflow through collateral ventilation channels and the phenomenon of interdependence. However there are concerns regarding the risk of over distension of normal alveoli, given that the increased volume delivered with MHI predominantly reaches the most compliant parts of the lungs (Stiller, 2000).



Morrow (2015) highlights this as a particular concern for critically ill children given their propensity for baro- and volutrauma.

### *1.3.1.2 Ventilator hyperinflations*

Ventilator hyperinflations (VHI) are an alternative technique to MHI, defined as the use of the ventilator to deliver increased tidal volume aimed at facilitating secretion removal (Volpe et al., 2020). VHI have been postulated as a safer method as they avoid disconnection from the ventilator, thus preventing loss of PEEP, hypoxemia, and shear stress caused by cyclic opening and closing of small airways (Volpe et al., 2020). Studies of VHI have used a variety of criteria to determine the inspiratory volume used: 50% above the current tidal volume, 130% of the set tidal volume, 15 mL/kg, and volume corresponding to a peak inspiratory pressure of 40 cmH<sub>2</sub>O (Volpe et al., 2020).

A bench-top study reported that volume controlled synchronised intermittent mandatory ventilation (VC-SIMV) more frequently achieved the flow patterns required for secretion movement, when compared to pressure support ventilation (PSV) and pressure controlled synchronised intermittent mandatory ventilation (PC-SIMV) (Thomas, 2015). The ability to control peak inspiratory flow rate in VC-SIMV mode was offered as a rationale. Similar results have been reported in an in-vivo study by Ribeiro et al. (2019), where VC-SIMV and PSV displayed the highest effectiveness scores for VHI. Despite the superiority of VC-SIMV and PSV the authors highlighted that all ventilator modes used demonstrated improvements in peak expiratory flow, PIF:PEF and PEF-PIF difference. The effects of different VHI inspiratory rise time (IRT) percentages on mucus displacement, PIF:PEF and PEF-PIF have been investigated (Chapman et al., 2019). Significant cephalad mucus movement of 2.42cm (1.59 to 3.94) occurred with IRT between 5% and 20%, compared with caudad movement of 0.53cm (0.31 to 1.53) at 0% IRT (median mucus movement difference 3.7cm, 95%CI 2.2 to 4.8,  $p < 0.001$ ). Inspiratory rise time is an important component of VHI when aiming to achieve effective mucus clearance. Increases in IRT percentage produced linear enhancements in PIF:PEF and net PEF. However, once the critical threshold for PIF:PEF was achieved sputum movement remained

consistent for all IRT values <5%. These findings challenge the linear relationship model proposed in early work by Kim et al. (1986a).

Mixed results have been reported in studies comparing MHI and VHI. In 14 intubated and ventilated adult patients VHI was found to increase PIF:PEF when compared to MHI (Savian et al., 2006), although neither hyperinflation technique generated a PIF:PEF that reached the critical threshold for cephalad secretion movement; VHI 1.01 (+/-0.21) and MHI 1.27 (+/-0.24). Li Bassi et al. (2019) reported marginal effects of MHI and VHI on mucus clearance, in an animal model with severe pneumonia. Both hyperinflation techniques improved PEF by approximately 44L/min, however a reduction in mucociliary clearance rate was observed when compared to pre-intervention. The median (IQR) mucus clearance rate was 1.31 (0.84–2.30) prior to the interventions, and 0.70 (0.00–2.58) and 0.65 (0.45–1.47) during MHI and VHI, respectively (p=0.09) (Li Bassi et al., 2019).

#### *1.3.1.3 Chest wall vibrations*

Expiratory chest wall vibrations (CWV) are a manual technique employed by physiotherapists, either in isolation or in combination with hyperinflations. The terminology used lacks consistency and it is also referred to as expiratory rib cage compression (ERCC). For the purposes of this thesis the term CWV will be used. During CWV physiotherapists apply a compressive force with a superimposed oscillatory force to the patient's chest wall (McCarren et al., 2003). It is thought that CWV facilitate secretion clearance through increasing peak expiratory flow and hence the two phase gas liquid flow mechanism, and via the transmission of mechanical energy into the airways reducing mucus viscosity (Stiller, 2000, Volpe et al., 2020).

In early studies the use of a mechanical cuff to deliver CWV demonstrated an increase in peripheral mucus clearance index in mechanically ventilated dogs and a 2.4 times improvement in tracheal mucus clearance rate in a lung model (Gross et al., 1985, King et al., 1990). However in practice CWV are a manual 'hands-on' therapy. Shannon et al. (2010) explored the effect of timing of CWV on peak expiratory flow (PEF) and peak inspiratory pressure (PIP) in a ventilated

lung model. Thirty experienced physiotherapists delivered vibrations applied at mid to late inspiration (early), at the start of expiration (optimal), and early to mid expiration (late). During optimal and early vibrations, PEF increased significantly compared with baseline (mean difference optimal vibrations 8.8L/m, 95%CI 6.0 to 11.6; mean difference early vibrations 7L/min, 95%CI 4.3 to 9.9). PIP was significantly higher during early vibrations compared with baseline (mean difference 5.6cmH<sub>2</sub>O, 95%CI 2.9 to 8.2). The authors concluded that CWV applied at the beginning of expiration were the most effective and demonstrated the best safety profile. Marti et al. (2013) described similar findings in an animal study. Two types of CWV were completed by an experienced respiratory physiotherapist. CWV were described as either hard and brief synchronized with the early expiratory phase, or soft and gradual applied during the late expiratory phase. PEF increased to 60.1L/min +/-7.1 with hard CWV, in comparison to 51.2L/min ± 4.6 without treatment (p<0.0015) and 48.7L/min ± 4.3 with soft vibrations (p=0.0002). Mucus movement towards the glottis was observed with hard CWV (1.01mm/min ± 2.37) compared to mucus movement towards the lungs with no treatment (-0.28mm/min ± 0.61) and soft CWV (-0.15mm/min ± 0.95).

In a recent study the mean peak expiratory flow during CWV increased to 44L/min +/-7 compared to 31L/min +/-7 without treatment (p<0.001) (Ouchi et al., 2020). CWV combined with endotracheal suctioning increased mucus clearance compared with suctioning alone (mucus weight, 5.5g (3.4–9.4) vs 0.7g (0.5–2.0), p=0.004). CWV did not affect dynamic compliance when investigated in mechanically ventilated rabbits (Unoki et al., 2003). The effects of CWV on peak expiratory flow has been studied in a single healthy human subject (McCarren et al., 2006). CWV applied by a group of cardiopulmonary physiotherapists increased peak expiratory flow by 50% compared to flow during deep breathing. The peak expiratory flow generated by CWV was at least 15% faster than occurred during chest wall oscillation and compression when applied separately.

Gregson and colleagues investigated the impact of MHI and CWV exclusively in mechanically ventilated children (Gregson et al., 2012, Gregson et al., 2007). A purpose designed force-sensing mat together with a respiratory monitor enabled

the authors to conduct trials in critically ill children on PICU. An initial study included 55 children with a range of clinical diagnoses (Gregson et al., 2007). Chest physiotherapy was delivered by specialist respiratory physiotherapists. PEF doubled from 19L/min during baseline ventilation to 40L/min during MHI and CWV ( $p<0.05$ ). When describing the force profile of CWV, the maximum force applied ranged from 15 to 172N and correlated with age ( $r=0.76$ ). A follow-up study investigated percentage change in PEF and PEF:PIF ratio between baseline, and MHI with and without CWV (Gregson et al., 2012). One hundred and five sedated and fully ventilated children were included. The mean percentage change in PEF compared to baseline was 22% when MHI was used alone ( $p<0.01$ ). However, PEF increased on average by 76% during MHI and CWV ( $p<0.001$ ). The increase in PEF was significantly related to the increase in inflation volume, peak inspiratory pressure and the force applied. PEF increased by, on average, 4% for every 10% increase in volume and 5% for every 10% increase in peak inspiratory pressure, with an additional increase of 3% for each 10N of force. A 29% increase in PEF:PIF was observed with MHI and CWV when compared to baseline, versus -11% for MHI (NB: the authors presented the inverse ratio compared to other studies). The improvement in ratio was only related to the force applied; 4% increase for each 10N of force. These results provide evidence of the unique contribution of CWV to increasing peak expiratory flow bias and cephalad mucus clearance.

The expiratory flow increase technique (EFIT) is used with infants predominantly in France. EFIT consists of a prolonged slow manual chest and abdomen compression throughout an entire expiration phase (Freyne et al., 2016). It aims to clear airway obstruction. There is minimal description available within published literature. However, it can be postulated that its use is based on similar principles to that of CWV, including manipulation of airflow and creation of an expiratory bias.

#### *1.3.1.4 Percussion*

Percussion or chest clapping is another manual physiotherapy technique. It is performed with cupped hands on the thorax, during inspiration and expiration (van der Schans et al., 1999). Percussion is thought to loosen mucus from the

bronchial walls through transmission of mechanical energy, although there is minimal experimental evidence to support physiological theories (Wong et al., 2003). In a mixed group of patients with hypersecretion, the use of percussion with or without breathing exercises did not affect mucus transport (Sutton et al., 1985). In adults with chronic obstructive pulmonary disease clearance of a radio-aerosol tracer was greater, from both peripheral and central zones, in the period when percussion was applied than during quiet breathing (van der Schans et al., 1986). In an animal study abnormally low peak expiratory flow of 9.9L/min +/- 5.7 and expired tidal volume of 9.5L/min +/-1.1 were recorded during percussion on mechanically ventilated sheep (Wong et al., 2003). However, the authors report that these were likely to be artefacts and no conclusions were drawn.

#### *1.3.1.5 Positioning*

Body positioning can be used to enhance mucociliary clearance, reduce work of breathing and optimise ventilation/perfusion matching (Lupton-Smith et al., 2014). Historically, positioning was based on the hypothesis that alignment of a segmental bronchus with gravity would accelerate clearance from that segment. Several standardised positions for clearance of specific segments of the lung have been developed (Elkins et al., 2005, Foster-Carter, 1943). Some of the positions involve tipping the patient into an inverted, head-down position. This positioning is termed postural drainage and can be used in conjunction with other physiotherapy interventions such as MHI and CWV. Although positioning is frequently acknowledged as a treatment option within the literature there is a lack of support for its effectiveness as an isolated intervention. The effects of body position on maximal expiratory pressure and peak expiratory flow have been studied in spontaneously ventilating adults with cystic fibrosis (Elkins et al., 2005). Peak expiratory flow was significantly reduced in three quarters sitting, supine, side lying and head down positions when compared to standing and upright sitting. When postural drainage was used in combination with percussion and breathing exercises, rate of mucus clearance increased in adults with chronic obstructive pulmonary disease, when compared to percussion alone (van der Schans et al., 1986).

It is also worth noting that there are reports of harm arising from head-down positioning in children and infants. Risks include increased gastro-oesophageal reflux and raised intracranial pressure (Button and Button, 2013). Hence modified postural drainage is advocated within the paediatric community, where head down tipping is avoided. Electrical impedance tomography (EIT), end-expiratory to end-inspiratory relative impedance change, has been used to investigate the effects of position changes on ventilation distribution in infants and children (Lupton-Smith et al., 2014). Measurements were taken from 55 participants in supine and side lying. The distribution of ventilation varied between the children with no clear pattern. Nineteen (35%) children consistently showed greater ventilation in the non-dependent lung, eight (15%) displayed increased ventilation in the dependent lung and 28 (51%) showed a varied pattern between left and right side lying, indicating that the effect of positioning in children may not be as straightforward as in adults or as previously defined.

Prone positioning is widely used in mechanically ventilated adults with acute respiratory distress syndrome or respiratory failure. Studies have demonstrated improved oxygenation and mortality with the application of early and prolonged prone positioning (Guérin et al., 2013, Langer et al., 2021). A recent systematic review reported improvements in oxygenation index with prone positioning in hospitalised infants and children with acute respiratory distress (Bhandari et al., 2022). There are several physiological principles explaining how prone positioning impacts lung and chest mechanics, and alveolar ventilation/perfusion relationships. In supine, ventilation is distributed primarily to nondependent lung regions, whilst the dorsal regions of the lung are susceptible to profound lung derecruitment due to higher pleural pressure and increased parenchymal oedema (Kallet, 2015). The heart and abdominal contents result in compression of adjacent lung parenchyma. When placed prone the dorsal lung is no longer subject to high pleural pressure and dorsal lung atelectasis decreases. Prone also improves resting lung volume in the dorsocaudal regions by reducing the pressure of both the heart and the abdomen. In prone pulmonary perfusion remains preferentially distributed to the dorsal lung regions, thus improving overall alveolar ventilation/perfusion relationships (Henderson et al., 2014, Kallet, 2015).

#### *1.3.1.6 Saline instillation*

The instillation of isotonic saline (0.9% sodium chloride) via the ETT is used in combination with chest physiotherapy such as MHI and CWV, and ETT suction (Main et al., 2004, Morrow and Argent, 2008, Shannon et al., 2015a). However the American Association for Respiratory Care guidelines for artificial airway suctioning state that the use of normal saline should be avoided (Blakeman et al., 2022).

Historically it has been used under the assumption that saline facilitates the removal of secretions by lubricating the suction catheter, thinning and dislodging secretions, and eliciting a cough (Blackwood, 1999). However the ability of mucus and water to mix, even after vigorous shaking, has long been questioned (Demers and Saklad, 1973). Hence there is ongoing debate regarding the efficacy of saline instillation in mechanically ventilated patients. Early studies demonstrated a significant increase in the amount of secretions cleared following the use of 5ml saline in adult patients (Gray et al., 1990). Conversely a systematic review of intubated adult patients reported minimal evidence of benefit from the use of saline (Paratz and Stockton, 2009).

#### *1.3.1.7 Mechanical adjuncts*

A variety of adjuncts to chest physiotherapy are available for mechanically ventilated patients. Mechanical insufflation-exsufflation (MI-E) delivers a positive-pressure insufflation followed by a negative expulsive exsufflation, thereby simulating a cough. MI-E has been described as an efficient technique for cough augmentation in patients with reduced or no capacity to cough and expectorate (Siriwat et al., 2018, Volpe et al., 2020). It can be delivered noninvasively via a mask or mouthpiece, or invasively through a tracheostomy or endotracheal tube. In a lung model, simulating a mechanically ventilated patient, MI-E was optimized by applying slow lung insufflation (Volpe et al., 2018a). This reduced the peak inspiratory flow (37.5L/min (24.9–47.9) vs 101.8L/min (89.1–115.7),  $p < 0.001$ ), and consequently increased the expiratory flow bias (PEF:PIF 1.44 (1.30–1.56) vs 4.03 (2.32–5.90),  $p < 0.001$ ). The higher expiratory flow bias resulted in greater outward mucus displacement, with a difference of 2.6cm compared with the

standard MI-E settings. Striegl et al. (2011) reported that greater MI-E pressure differentials resulted in a higher peak expiratory flow when using an infant tracheostomy lung model. This also indicates that secretion clearance may be improved by using asymmetric MI-E pressure settings.

Intrapulmonary percussive ventilation (IPV) administered by the Percussionator IPV-1 ventilator is another airway clearance adjunct. The device provides internal thoracic percussion by delivering small bursts of high velocity air flow, generating airway pressures to oscillate between 5 and 35 cmH<sub>2</sub>O. Bursts of air at a frequency of 80–650 cycles per minute are created. This process causes the airway walls to vibrate in synchrony with these oscillations, creating a percussive effect with the aim of breaking up mucus and enhancing deep and homogeneous ventilation of the lungs (De Boeck et al., 2008, Deakins and Chatburn, 2002, Lauwers et al., 2018). High frequency chest wall oscillation provided at the mouth by a pistol pump did not improve tracheal mucus clearance rate in mechanically ventilated dogs (King et al., 1984). However in a follow up study mucus transport rates increased by 99% (+/-11) during high frequency oscillation with an expiratory flow bias compared to control (King et al., 1990). The Metaneb is a new generation IPV device, which provides a simultaneous combination of positive pressure, continuous high frequency oscillations and aerosol delivery (Ferguson and Wright, 2017). The Metaneb was found to be safe for use with an artificial airway in a study exploring the pressure attenuation across an ETT during continuous high frequency oscillation (Bullock and Smallwood, 2014).

High frequency chest wall oscillation (HFCWO) is another device that can be used in infants and children. Historically it has been used for the treatment of chronic conditions such as cystic fibrosis, bronchiectasis, and neuromuscular disorders. A specially designed inflatable vest, worn around the torso, is attached to an air blast generator which applies external chest wall oscillation (Hansen et al., 1994). This pulsatile mechanical energy increases the air-liquid shear forces during expiration resulting in secretion mobilisation (Lee et al., 2017).



### *1.3.1.8 Endotracheal suction*

Children with an artificial airway require endotracheal suctioning to remove respiratory secretions and maintain patency of the endotracheal tube (ETT) (Morrow and Argent, 2008). ETT suctioning is an important component of chest physiotherapy in mechanically ventilated patients, utilised after the airway clearance techniques discussed in this section (Pryor and Prasad, 2008). A soft catheter is passed through the ETT and negative pressure applied to clear secretions through the catheter. There are two methods of ETT suction. Open suction is performed by disconnecting the ventilator circuit from the ETT to insert the suction catheter, whereas closed suction uses an in-line catheter that is enclosed in a sheath and attached to the ETT, hence disconnection from the ventilator is not required (Evans et al., 2014).

In this section the individual treatments available for use with invasively ventilated children have been described, together with exploration of their physiological and theoretical bases. However, in a clinical setting chest physiotherapy is often delivered as a package involving several different components. Therefore, it is important to consider the evidence for chest physiotherapy in terms of the clinical effects and impact.

### **1.3.2 Clinical effects of chest physiotherapy in mechanically ventilated children**

This study focused on chest physiotherapy for mechanically ventilated children, who ranged from neonates (0-28 days of age) to adolescents aged up to 18 years. Only term neonates born at  $\geq 37$  weeks or those with a corrected gestational age of  $\geq 37$  weeks were under investigation. There are significant differences in anatomy and physiology, lung development, and the common medical and respiratory conditions between preterm infants ( $< 37$  weeks) and term neonates and children. Therefore, the physiotherapy techniques used in preterm infants differ to those previously described in Section 1.3.1. Airway clearance is often limited to positioning, ventilation optimisation and endotracheal suction, with the role of physiotherapy focusing on neurodevelopmental care (APCP, 2020). Due to the differences in physiotherapy approaches and separate

evidence base, literature related to preterm infants was not included in this review.

A systematic review investigating the effects of chest physiotherapy in mechanically ventilated children was completed as part of this PhD project. The protocol was registered in the PROSPERO database (CRD42019160813) and the review is available in its published format in Appendix 1. Five databases were searched from inception to 9<sup>th</sup> February 2021, these were Medline, Embase, Cinahl Plus, PEDro, and Web of Science. Medical subject headings included “physical therapy modalities” and “respiratory therapy” combined with “artificial ventilation.” Additional keywords included “chest physiotherapy,” “respiratory physiotherapy,” “mechanical ventilation,” and “invasive ventilation.” Studies investigating chest physiotherapy for mechanically ventilated children (0–18 years), in a paediatric intensive care unit only were included. Chest physiotherapy was defined as any intervention performed by a qualified physiotherapist. Exclusion criteria included preterm infants, children requiring non-invasive ventilation, and those in a nonacute setting. Measurements of effectiveness and safety were included. Thirteen studies met the inclusion criteria: two randomised controlled trials, three randomised crossover trials, and eight observational studies. The physiotherapy techniques investigated by the studies included MHI with CWV and postural drainage, EFIT, IPV and a recruitment manoeuvre. The Cochrane risk of bias and the Critical Appraisal Skills Program tools were used for quality assessment (CASP, 2018, Sterne et al., 2019). There were few high-quality studies, with heterogeneity in interventions and populations.

A broader review of the literature revealed variable definitions and terminology related to chest physiotherapy. The implementation of techniques aligned with physiotherapy were also used by a range of professionals and ventilated children were treated in a variety of settings. Therefore, the findings of the systematic review have been incorporated into the wider literature that is presented in this section.

This section will provide an up-to-date overview and critical appraisal of the current literature investigating the clinical effects of chest physiotherapy in ventilated children. A summary of the studies reviewed in this section is displayed

in Table 1.2. The narrative discussion is presented using subheadings based on the clinical outcome under investigation, these include oxygenation, ventilation, respiratory mechanics, the cardiovascular system and atelectasis.

Table 1.2 Summary of studies investigating clinical effects of chest physiotherapy in mechanically ventilated children

Authors	Study design	Sample (size, age, diagnosis)	Main outcomes	Intervention	Comparator	Main findings
<b>Luadsri et al., 2022</b>	Randomised cross over	n=12 3-43 months Pneumonia	Ventilation, Respiratory mechanics	MHI with suction. Physiotherapists	Suction (nursing led)	Statistically significant improvements in tidal volume and static compliance immediately after MHI with suction compared to suction. Differences not maintained at 15- or 30-minutes.
<b>McAlinden et al., 2020</b>	Secondary data analysis - RCT	n=60 mean age months (SD), CPT group 28.7 (49.3), control group 47.8 (55.8)	Ventilation distribution	MHI, manual techniques, suction. Physiotherapists	Suction	Changes to ventilation distribution (global end expiratory lung impedance view, global inhomogeneity) significantly greater in the CPT group.
<b>Martinez Herrada et al., 2020</b>	Retrospective	n=15 5-22 months Refractory atelectasis	Atelectasis	MHI, saline, chest wall compressions & vibrations, suction. Medical team	nil	Median atelectasis score improved significantly following treatment.
<b>Acosta et al., 2020</b>	RCT (Feasibility)	n=40 6 months – 5 years Atelectasis after anesthesia induction	Respiratory mechanics, Atelectasis	Postural recruitment maneuver	Recruitment maneuver	Significant decrease in lung ultrasound aeration score in the intervention group compared to control. Compliance significantly higher following intervention compared to baseline and controls. No differences in resistance.
<b>Mehrem et al., 2018</b>	RCT	n=60 1-6 days Term neonates, pneumonia	Other – Days of ventilation	Routine medical care plus postural drainage, percussion, vibrations. Physiotherapists	Routine medical care	Significantly shorter length of mechanical ventilation/oxygen and length of stay in intervention group compared to control.

<b>Tume et al., 2017</b>	Pilot randomized cross over trial	n=24 Median age 15 days (IQR 5-53) Infants post-cardiac surgery	Cardio-vascular system	Closed ETT suction	Open ETT suction	Statistically significant change in HR and MBP with open suction compared to closed. Although not clinically significant.
<b>Bidiwala et al., 2017</b>	Retrospective	n=8 1-22 years Long term ventilated with tracheostomy	Other – N° of respiratory illnesses and hospital admissions	HFCWO	IPV	Number of respiratory illnesses reduced from 32/year on HFCWO to 15/year with IPV. Improvements in number of lower respiratory tract infections requiring antibiotic and hospitalizations with IPV.
<b>Elizabeth et al., 2016</b>	RCT	n=40 1-204 months Patients with lung pathology on CXR	Oxygenation, Ventilation	MHI with CWV and suction	Suction	No differences between groups in tidal volume, mean PO <sub>2</sub> or median SpO <sub>2</sub> .
<b>Shannon et al., 2015</b>	Randomised cross over	n = 63 3 days – 16 years Mixed diagnoses	Ventilation, Respiratory mechanics	MHI, ETT saline instillation, CWV, positioning, suction. Physiotherapists	Specialist vs Non specialist	Statistically significant increase in respiratory compliance & tidal volume. Statistically significant reduction in respiratory resistance.
<b>Soundararajan et al., 2015</b>	Observational	n=18 mean 1.6years Cardiac surgery, upper lobe collapse	Oxygenation	MHI (with AMBU), CWV, saline, suction Physiotherapists	nil	Improved PaO <sub>2</sub> 30 minutes after physiotherapy. Improvements in chest x-ray.
<b>Lanza et al., 2011</b>	Observational	n = 10 3 – 20 months Mixed diagnoses	Oxygenation, Respiratory mechanics, Cardio-vascular system	MHI (with AMBU), CWV, suction. Physiotherapists	nil	No statistically significant changes Trend of lower SpO <sub>2</sub> and higher HR at 30 & 60 minutes after physiotherapy.
<b>Demont et al., 2007</b>	Retrospective	n = 124 Gestation 32-41 Acute or chronic lung disease	Atelectasis	Expiratory flow increase technique, suction. Physiotherapists	nil	Post-extubation atelectasis in 1/124. No severe brain lesions diagnosed after physiotherapy.

<b>Morrow et al., 2007</b>	RCT	n = 34 mean age intervention group 5.7 months & control 6.8 months Pulmonary disease	Oxygenation, Ventilation	ETT suction, followed by Recruitment maneuver. Physiotherapists	Suction	No difference between groups in respiratory compliance, resistance or SpO <sub>2</sub> .  Immediate reduction in mechanical expired tidal volume, an increase in respiratory rate and spontaneous expired tidal volume but not sustained at 25 minutes.
<b>Morrow et al., 2006</b>	Observational	n=54 0.3-25 months Mixed diagnoses	Respiratory mechanics	Pre-oxygenation and open ETT suction.	nil	Statistically significant decrease in dynamic lung compliance and expiratory tidal volume post-suction vs pre.
<b>Schultz et al., 2005</b>	Randomised cross over	n=35 8-96 months Mixed diagnoses	Oxygenation	Kinetic therapy bed – automatic turning and percussion.	Manual position changes and percussion.	Improvements in oxygenation, OI and P(A-a)O <sub>2</sub> , in both groups. Statistically significant changes only in intervention group.
<b>Almeida et al., 2005</b>	Observational	n = 22 28 days to 12 months Acute obstructive respiratory failure	Oxygenation, Ventilation, Respiratory mechanics	Expiratory flow increase technique, 40 times, suction. Physiotherapists	nil	Significant increase in respiratory rate & SpO <sub>2</sub> after physiotherapy.
<b>Main &amp; Stocks 2004</b>	Randomised cross over	n = 75 3 days to 16 years Mixed diagnoses	Respiratory mechanics	Pre-oxygenation, saline instillation, MHI, CWV, percussion, postural drainage, suction. Physiotherapists	Pre- oxygenation, saline instillation, MHI, suction (nursing led)	Significant increases in physiological & alveolar dead space post-physiotherapy. Significant differences between physiotherapy and suction in physiological and alveolar dead space, and tidal volume.
<b>Main et al., 2004</b>	Randomized cross over	n = 83 3 days to 16 years Mixed diagnoses	Oxygenation, Ventilation, Respiratory mechanics	Pre-oxygenation, saline, MHI, CWV, percussion, postural drainage, suction. Physiotherapists	Pre- oxygenation, saline, MHI, suction (nursing led)	No significant group changes in expired tidal volume or respiratory compliance after either treatment. Trend of reduced respiratory resistance after physiotherapy.

<b>Bernard-Narbonne et al., 2003</b>	Observational	n = 20 1 – 30 weeks Acute bronchiolitis	Oxygenation, Ventilation	K-R method – slow increase exhalatory flow, suction. Physiotherapists	nil	Statistically significant increase in tidal volume & SpO <sub>2</sub> maintained at 60 minutes.
<b>Ridling et al., 2003</b>	RCT	n=24 10 weeks – 14 years Mixed diagnoses	Oxygenation	ETT saline instillation and suction. Nurses	Suction	SpO <sub>2</sub> significantly reduced in the intervention group immediately post suction. Not sustained at 10 minutes.
<b>Deakins et al., 2002</b>	Retrospective & RCT	n = 46 1 month – 15 years  n = 12 7 weeks – 14 years	Atelectasis	IPV – with albuterol  IPV – with normal saline 10 minutes  Physiotherapists	nil  Postural drainage, percussion, CWV and suction	Significant improvement in atelectasis score.  No change in atelectasis score in comparator group. Statistically significant improvement in atelectasis score in IPV group. Duration of treatment to resolution of atelectasis significantly less in IPV group.
<b>Hussey et al., 1996</b>	Observational	n = 69 5 days to 47 months Post-operative cardiac surgery	Oxygenation, Cardio-vascular system	Percussion, CWV, position change, pre-oxygenation, MHI, suction. Physiotherapists	Different combinations of treatment 'treatment packages'	Statistically significant drop in SpO <sub>2</sub> during treatment in all groups. Statistically significant increase in MBP in 2 groups & HR in 6 groups during treatment.
<b>Galvis et al., 1994</b>	Retrospective	n=57 < 1 year Persistent lung collapse	Atelectasis	Pre-oxygenation, saline instillation, MHI with CWV, suction. Medical team	nil	48 (84%) of the 57 patients showed improvement in chest x-ray post-intervention.

(CPT – Chest physiotherapy, CWV – Chest wall vibrations, ETT – Endotracheal tube, HFCWO – High frequency chest wall oscillation, HR – Heart rate, IPV – Intrapulmonary percussive ventilation, MHI – Manual hyperinflations, MBP – Mean blood pressure, OI – Oxygenation index, PaO<sub>2</sub> – Partial pressure of oxygen in arterial blood, P(A-a)O<sub>2</sub> – Arterial-alveolar oxygen tension difference, PO<sub>2</sub> – Partial pressure of oxygen, RCT – Randomised controlled trial, SpO<sub>2</sub> – Peripheral oxygen saturations)

### 1.3.2.1 Oxygenation

Oxygen is fundamental to mitochondrial respiration and survival for all aerobic animals. Hence the impact of chest physiotherapy on oxygenation is important, particularly in vulnerable, critically ill children. Variable results have been reported regarding the effects of chest physiotherapy on oxygenation in ventilated children. A small observational study involving ventilated children with upper lobe collapse following cardiac surgery reported an improvement in arterial oxygenation 30-minutes post-physiotherapy (Soundararajan and Thankappan, 2015). Eighteen children received ETT saline instillation, MHI with CWV and suction. Mean PaO<sub>2</sub> improved from 56.78mmHg to 82.79mmHg (p<0.0001). During the treatment patients received FiO<sub>2</sub> 1.0, with the impact of this on the study findings not considered by the authors. Contrasting results have been reported by Hussey et al. (1996). Chest physiotherapy involving MHI and CWV resulted in a statistically significant decrease in peripheral oxygen saturations (SpO<sub>2</sub>) during treatment. This prospective, observational study included 69 children under four years of age who had undergone cardiac surgery. The sample was divided into eight treatment groups who received varying combinations of percussion, CWV, MHI, position change, pre-oxygenation and suction. A reduction in SpO<sub>2</sub> was observed in all groups during physiotherapy, the maximum median change was -5% (p<0.05). Only percentage change was reported hence the clinical relevance of these findings is unknown. A further limitation is the small sample size following allocation to treatment subgroups (maximum n=20).

In a randomised cross over trial, including 83 children with a range of diagnoses, a decrease in SpO<sub>2</sub> 15 minutes after MHI/CWV was reported (Main et al., 2004). Although this result was statistically significant it did not demonstrate a difference of clinical importance (mean change -0.8, 95%CI -1.47 to -0.16, p<0.05). Furthermore, there were no statistically significant differences in mean change of SpO<sub>2</sub> between chest physiotherapy and a control treatment. The patients were pharmacologically paralysed and any demonstrating instability were excluded. Current care no longer involves routinely paralysing patients for prolonged periods. Hence the generalisability of these findings to current chest physiotherapy practice is limited.



No differences in SpO<sub>2</sub> were reported pre- and post-chest physiotherapy in a small, observation study (Lanza et al., 2011). This study investigated a single intervention of MHI, CWV and suction in 10 children under two years old. Outcomes were recorded pre-treatment and at 15, 30 and 60 minutes afterwards. Patient level data were not provided and limitations included the small sample size. Similar findings have been reported by Elizabeth et al. (2016). This randomised, single blind study compared MHI with CWV and suction (n=24), to suction alone (n=16) in ventilated children. The authors reported no statistically significant differences 30 minutes post-treatment between the groups in mean PO<sub>2</sub> (136.6 vs 139.2mmHg, p=0.834) or median SpO<sub>2</sub> (98.5 vs 98.3%, p=0.967). These results should be interpreted with caution. Although there were no statistically significant differences in baseline characteristics or physiological variables the groups appeared clinically different, in terms of age and weight, and were unequal with regards to numbers. Additionally, the study procedure included 30 minutes of chest physiotherapy, which is longer than average treatment times reported in other studies (Main et al., 2004, Shannon et al., 2015b, Torreiro Diéguez et al., 2022).

Morrow et al. (2007) observed no differences in SpO<sub>2</sub> in ventilated children receiving a physiotherapy-led recruitment manoeuvre after ETT suction compared to suction alone. Due to participant withdrawals related to ETT leak after data collection, the study was underpowered to detect statistically significant differences. Intrapulmonary percussive ventilation was compared to percussion and CWV in ventilated children (Deakins and Chatburn, 2002). Oxygen saturations were a secondary outcome measure in this small (n=12) RCT. There were no within or between group differences in SpO<sub>2</sub> immediately following treatment.

In contrast, two studies investigating the expiratory flow increase technique (EFIT) reported improved oxygenation following chest physiotherapy. Almeida et al. (2005) reported a mean increase in SpO<sub>2</sub> from 97% to 98% 30 minutes post physiotherapy (p=0.04). Twenty-two children, < 12 months of age, with acute obstructive respiratory failure underwent a single intervention of EFIT repeated 40 times. In the second study (n=20) mean SpO<sub>2</sub> increased immediately after 10

minutes of EFIT (94.5% to 98%,  $p < 0.05$ ) which was sustained at one hour (94.5% to 97.5%,  $p < 0.05$ ) (Bernard-Narbonne et al., 2003). The change in  $SpO_2$  in both these studies represent minimal clinical importance. Each have several limitations including: no confidence intervals provided, small sample size, no description of confounders and unclear methodological processes.

An RCT, including 24 critically ill children, compared a group who received 0.25-2ml of saline prior to every suction and a group with no saline instillation (Ridling et al., 2003). No incidences of ETT occlusion were reported in either group. Oxygen saturations were significantly reduced in the saline group at one-minute post suction (% change 5.7% vs 1.5%,  $p = 0.013$ ) and at two minutes (4.8% vs 1%,  $p = 0.005$ ). However, these differences were not sustained at 10 minutes following the interventions. A recent review investigating the efficacy and safety of normal saline instillation during ETT suction in PICU included only three studies (Schults et al., 2018). Endotracheal suction with saline was associated with a transient decrease in oxygen saturations. The studies were not powered to detect differences in ETT occlusion or VAP. The authors concluded that in children with obstructive mucous, saline instillation may have a positive effect.

Manual position change and percussion were compared to a kinetic therapy bed, which provided automated turning and percussion (Schultz et al., 2005). This randomised cross over trial included 35 ventilated children and used oxygenation index (OI) and arterial-alveolar oxygen tension difference [ $P(A-a)O_2$ ] as outcomes. Improvements in OI and  $P(A-a)O_2$  were observed in both groups. However, the authors concluded that the kinetic therapy bed was more efficient than standard therapy at improving oxygenation. In patients who received the kinetic therapy bed first, median OI decreased from 7.4 to 6.19 ( $p = 0.015$ ) and the median  $P(A-a)O_2$  decreased from 165.2 to 126.4 ( $p = 0.023$ ). The improvements in the standard therapy group did not reach statistical significance. Ventilation parameters were not consistent during the 36-hour study period which may have influenced the results. A further limitation is the small sample size.

### 1.3.2.2 Ventilation

Ventilation is an important consideration for physiotherapists. Changes in ventilation parameters, such as tidal volume or peak inspiratory pressure (PIP) may influence gas exchange and the risk of ventilator induced lung injury, described previously in Section 1.2.2. In a recent study the impact of MHI, manual techniques and ETT suction on ventilation has been investigated using electrical impedance tomography (EIT). McAlinden et al. (2020) compared chest physiotherapy (n=17) to suction only (n=43), in ventilated children. Changes to ventilation distribution were significantly greater in the chest physiotherapy group: global end expiratory lung impedance view (EELV) (mean difference 0.084, 95%CI 0.047-0.078,  $p < 0.0001$ ) and global inhomogeneity (mean difference 0.043, 95%CI 0.008-0.078,  $p = 0.017$ ). The authors suggested changes observed in EELV were indicative of either recruitment of atelectatic alveoli or further distention of already ventilated alveoli. The higher inhomogeneity index reflects greater variation in ventilation distribution and regionally opening lung fields. The conclusions provided are predominantly based on the value of EIT as an outcome measure rather than the clinical significance of the results. Limitations include the small sample and non-randomised allocation to treatment groups.

Changes in tidal volume have also been used to measure the effect of physiotherapy on ventilation. Luadsri et al. (2022) completed a randomised cross over trial comparing MHI with suction to suction alone, in 12 intubated and ventilated children diagnosed with pneumonia. Tidal volumes were recorded from the ventilator immediately post-intervention and every 5 minutes up to 30 minutes, by a nurse blinded to the intervention. The authors reported statistically significant improvements in tidal volume immediately following MHI with suction when compared to suction alone, mean difference 1.4ml/kg (95% CI 0.8-2.1,  $p < 0.05$ ). The clinical relevance of these results is limited as the differences in tidal volume were not maintained at 15 or 30 minutes post-treatment. Elizabeth et al. (2016) reported no differences in tidal volume at 30 minutes post-treatment between MHI with CWV and suction, and suction alone (median tidal volume 60 vs 56.5ml,  $p = 0.838$ ). For individual group changes, tidal volume in the chest physiotherapy group appeared to decrease post-treatment (median tidal volume

62 vs 60ml), whereas the opposite occurred in the suction only group (median tidal volume 55 vs 56.5ml). The relevance of these findings is not discussed by the authors. Furthermore, the clinical importance of these results is unknown due to the use of absolute values, ml rather than ml/kg.

Several studies have used validated respiratory profile monitors (CO<sub>2</sub>SMO Plus and NICO<sub>2</sub>) to measure tidal volume. In the study by Main et al. (2004) no significant changes in expired tidal volume were reported post chest physiotherapy with MHI and CWV or suction alone. However individual responses demonstrated an improvement in tidal volume that exceeded the 95% limits of agreement (+/- 5.5%) in twice as many subjects post physiotherapy compared to control treatment (27:13, p=0.01). Statistically, but not clinically, significant improvements in tidal volume following treatment with MHI and CWV have been reported by Shannon et al. (2015a). The overall aim, in this randomised cross over trial, was to compare specialist and on-call physiotherapists' treatments (n = 52). Mean change in expired tidal volume 15 minutes post physiotherapy by specialist physiotherapists was 0.8ml/kg (95%CI 0.5 to 1.2, p<0.001) and 0.7ml/kg (95%CI 0.4 to 1.0, p<0.001) at 30 minutes. For treatments by non-specialists, mean change was 0.6ml/kg (95%CI 0.3 to 1.0, p<0.001) and 0.4ml/kg (95%CI 0.1 to 0.8, p<0.05) at 15 and 30 minutes respectively. A small proportion (n = 11, 17%) of participants in the Shannon et al. (2015a) study were ventilated using a volume-controlled setting and PIP was used as an alternative outcome. However, no significant changes in PIP were reported following chest physiotherapy. The main limitation of these studies is that all patients were paralysed or deeply sedated, which is not typically representative of current PICU practice.

The CO<sub>2</sub>SMO Plus respiratory monitor was also used by Morrow et al. (2007) to investigate expiratory tidal volume following a recruitment manoeuvre. There was a decrease in mechanical expiratory tidal volume immediately post recruitment manoeuvre, compared to the control group (-0.3ml/kg, 95%CI 0.1 to 0.6, p=0.03). Spontaneous expired tidal volume increased in the treatment group at the same time point (0.03ml/kg, 95%CI 0.00 to 0.06, p=0.04). However, these minor changes were not sustained at 25 minutes post treatment.

The two small observation studies investigating EFIT reported conflicting results regarding tidal volume. No statistically significant difference in mean expired tidal volume was reported by Almeida et al. (2005), (39.92ml +/-14.88 pre vs 39.02ml +/-17.37 post-physiotherapy,  $p=0.13$ ). Volumes were measured, using the validated CO<sub>2</sub>SMO, immediately before physiotherapy and 30 minutes after. In contrast statistically significant improvements in both inspired and expired tidal volume were found by Bernard-Narbonne et al. (2003). Five tidal volume measurements were taken from the patients' ventilator at each time point and an average calculated. Mean inspiratory tidal volume increased from 55.4ml to 66.3ml immediately post EFIT and to 63.6ml at one hour ( $p<0.05$ ). A similar change in mean expiratory tidal volume was seen; pre-EFIT 52.15ml versus 66.1ml immediately post-EFIT and 62.3ml at one hour ( $p<0.05$ ). Both authors provided absolute values of volume in ml, rather than the more clinically relevant measurement of ml/kg. No confidence intervals were provided, and a large standard deviation presented, limiting interpretation of the true effect size.

### *1.3.2.3 Respiratory mechanics*

Respiratory mechanics, including compliance and resistance, are important factors in ventilation and provide information regarding respiratory function. Compliance relates to the elasticity of the respiratory system, being a measure of volume change per unit of pressure applied (Shannon et al., 2015a). Dynamic compliance is measured during breathing whilst static compliance is measured in the absence of flow. Improvements in compliance may represent lung recruitment following secretion removal. Respiratory resistance is a combination of resistance to gas flow in the airways and resistance to deformation of tissues of both the lung and chest wall, expressed as a change in pressure per unit flow. A decrease in resistance would reflect reduced airway obstruction, which may be due to the removal of secretions from the upper airways (Main et al., 2004).

Three studies have investigated the effects of MHI and CWV on respiratory compliance and resistance, using a respiratory profile monitor. Change in respiratory compliance was the primary outcome in the Shannon et al. (2015a) study comparing specialist and on-call physiotherapists. There were significant improvements in compliance at 15 minutes following on-call (mean increase

0.07ml/cmH<sub>2</sub>O/kg, 95%CI 0.01 to 0.14, p<0.01) and specialist physiotherapy treatments (0.08ml/cmH<sub>2</sub>O/kg, 95%CI 0.04 to 0.13, p<0.01). These improvements were sustained at 30 minutes post-treatment (p<0.05). The authors reported an immediate fall in respiratory resistance in both groups post-physiotherapy (on-call mean change -6.5cmH<sub>2</sub>O/l/s, 95% CI -11 to -1.5, p<0.05; specialist mean change -12cmH<sub>2</sub>O/l/s, 95%CI -18 to -5.7, p<0.001). This reduction was maintained at 30 minutes (p<0.05, p<0.01 respectively). Main et al. (2004) reported no significant change in compliance post-physiotherapy and although a trend of reduced resistance was observed this was not statistically significant. The authors completed subgroup analysis which displayed a statistically significant fall in compliance at 30 and 45 minutes post-physiotherapy in infants receiving pressure-controlled ventilation (p<0.05). Infants on volume-controlled ventilation demonstrated a reduction in resistance at 15 and 30 minutes following physiotherapy (p<0.05). An improvement in respiratory compliance was reported after chest physiotherapy when compared to suction alone, which approached significance at 15 minutes (mean 0.01 vs -0.01, 95% CI -0.05 to 0.002, p=0.07) and reached significance at 30 minutes (p<0.05). No mean values were presented for the statistics at 30 minutes. No significant change in compliance or resistance was reported in the remaining study (Lanza et al., 2011).

Static compliance recorded via ventilator display was an outcome in the randomised cross over study by Luadsri et al. (2022). Statistically significant improvements in static compliance were reported immediately following treatment involving MHI with suction when compared to suction alone (mean difference 3.4ml/cmH<sub>2</sub>O, 95%CI 2.1-4.7, p<0.05). These differences were not maintained at 15 or 30 minutes post-treatment, questioning the clinical importance of these findings.

Two studies have demonstrated that a recruitment manoeuvre when used in isolation does not influence respiratory compliance or resistance in ventilated children. Morrow et al. (2007) reported no differences between recruitment manoeuvre or control groups, either immediately or at 25 minutes post-intervention. Similar findings have been reported by Acosta et al. (2020). This

study aimed to evaluate the effects of a postural recruitment manoeuvre on anaesthesia induced atelectasis. Following intubation, forty children aged 6 months to 5 years were randomized into two groups: a control group (n = 20) where positive end expiratory pressure (PEEP) was increased from 5 to 10 cmH<sub>2</sub>O for 3 min in supine, and an intervention group (n = 20) involving the same change in PEEP but with positioning for 90 seconds in alternate side lying. The interventions occurred five minutes after anaesthesia and outcomes were measured five minutes post-intervention. No change in compliance was observed in the control group. However, compliance was significantly higher following the postural recruitment manoeuvre compared to baseline (baseline 15 ± 66 mL/cmH<sub>2</sub>O vs post 18 ± 66 mL/cmH<sub>2</sub>O, p=0.001), and also when compared with the control group (18 ± 6 mL/cmH<sub>2</sub>O vs 14 ± 5 mL/cmH<sub>2</sub>O; p=0.0002). No differences in respiratory resistance were reported. As this was a feasibility study the relevance of these findings to longer-term outcomes, such as post-operative recovery or respiratory complications, is unknown.

No significant differences in resistance, or dynamic compliance were reported 30 minutes post EFIT (Almeida et al., 2005). Similarly, Deakins and Chatburn (2002) reported no significant change in static compliance following treatment with intrapulmonary percussive ventilation.

The effects of open ETT suction on respiratory mechanics have been investigated in 54 children, with a median weight of 4kg (1.7-10) (Morrow et al., 2006). A statistically significant drop in median dynamic lung compliance was observed after suction 0.56 (0.41-0.47)ml/cmH<sub>2</sub>O/kg compared to before suction 0.6 (0.45-0.87)ml/cmH<sub>2</sub>O/kg (p<0.001). This equated to a reduction in compliance in 69% of children, however the results also reported an improvement in compliance in 31%. Expired tidal volume was reduced following suction (median 7 (5.45-8.24)ml/kg vs 6.7 (5.38-8.18)ml/kg, p=0.03). Although statistically significant the changes represent very small clinical impact, and the authors recommended further research to enable understanding of the clinical relevance.

Main and Stocks (2004) included dead space volumes as the primary outcome measures in a randomised cross over trial comparing MHI/CWV to suction (n=75). Physiological dead space (VD<sub>phys</sub>) and alveolar dead space (VD<sub>alv</sub>), used

as indicators of gas exchange and regional ventilation, were measured immediately before physiotherapy and for 30 minutes after, using the validated CO<sub>2</sub>SMO Plus respiratory monitor. The results displayed significant increases in  $VD_{phys}$  (mean 3.21ml/kg vs 3.51ml/kg 95%CI 0.15 to 0.42) and  $VD_{alv}$  (mean 1.64ml/kg vs 1.92ml/kg 95%CI 0.16 to 0.41) after physiotherapy compared to before ( $p<0.0005$ ). In addition, there were significant increases in the outcomes after chest physiotherapy compared to suction. Mean change in  $VD_{phys}$  after physiotherapy was 0.29ml/kg versus -0.01ml/kg after suction (95% CI 0.09 to 0.49,  $p<0.005$ ) and mean change in  $VD_{alv}$  following chest physiotherapy was 0.29ml/kg compared to -0.03ml/kg after suction (95% CI 0.12 to 0.51,  $p<0.05$ ). Despite the potential negative implications of these findings in reality they translate to minimal clinical effect. No statistically significant differences in mean alveolar, airway or total dead space volume were reported 30 minutes following EFIT (Almeida et al., 2005).

#### *1.3.2.4 Cardiovascular system*

The impact of physiotherapy on the cardiovascular system and haemodynamics is important to determine the tolerance of treatment and overall stability of the patient. Two studies (Lanza et al., 2011, Hussey et al., 1996) have evaluated the effects of chest physiotherapy (MHI/CWV) on heart rate (HR) measured using electrocardiogram. The outcome was measured at different time points and also in different patient groups. Hussey et al. (1996) investigated the influence of mode of treatment using maximum median change in HR prior to and during physiotherapy. The maximum median change was reported in the group receiving percussion, MHI, CWV and position change (-6bpm,  $p<0.05$ ). Five of the other subgroups demonstrated statistically significant drops in HR ( $p<0.05$ ). However, these changes are not of clinical significance. Furthermore no patient level data or confidence intervals are provided. Lanza et al. (2011) compared HR at five time points: before physiotherapy and then immediately, 15, 30 and 60 minutes after ( $n=10$ ). The authors reported no statistically significant changes and that HR remained within normal limits for age.

Hussey et al. (1996) also included maximum median change in mean arterial blood pressure as a secondary outcome. Two of the treatment groups showed a



statistically significant increase in mean blood pressure during physiotherapy. However, the median changes were 3mmHg and 5mmHg which are not of clinical importance.

No clinically significant differences were reported between open and closed suction when completed by respiratory physiotherapists, in high-risk paediatric cardiac patients (Tume et al., 2017). However, there were statistically significant greater changes in mean heart rate (pre 151bpm vs post 145.5bpm,  $p=0.002$ ), and mean blood pressure (pre 50.5mmHg vs post 55.0mmHg,  $p=0.007$ ) with open suction. This pilot randomised cross over trial included 24 infants, within 36 hours of cardiac surgery. The time between study suction was not controlled and was based on availability of study staff, introducing bias.

#### *1.3.2.5 Atelectasis*

Atelectasis, diagnosed radiologically, is often viewed as an indication for physiotherapy treatment and therefore a popular outcome when assessing effectiveness. Atelectasis can act as a locus for infection and detrimentally impact ventilation (Hedenstierna and Edmark, 2005). The incidence of post-extubation atelectasis on chest x-ray (CXR) in new-borns treated with EFIT was evaluated retrospectively (Demont et al., 2007). The effects of multiple physiotherapy interventions during mechanical ventilation and for 24 hours after extubation were investigated. The outcome was subjectively determined from routine post-extubation CXRs by the attending radiologist. In the subgroup of patients who had a gestational age of > 32 weeks the incidence of atelectasis was 1/124. The relevance of the results to clinical practice is difficult to determine as the incidence of the outcomes in patients with other diagnoses or in a control group were not available. Confounding variables that may have also influenced the development of atelectasis are not included.

Deakins and Chatburn (2002) completed a retrospective study which described the effect of a course of IPV on atelectasis scores. Forty-six patients were included, of whom 41 were mechanically ventilated and received IPV through an artificial airway. A significant improvement in atelectasis score from 3 to 1 was reported ( $p < 0.001$ ). The authors conducted a follow up RCT, in which atelectasis

score was the primary outcome (n=12). The standard physiotherapy group (n = 5) showed no significant change in score after a course of treatment (2.0 to 2.6, p=0.421). A statistically significant improvement in score was seen in the IPV group (n=7) (2.3 to 0.9, p=0.018). Limited details were provided about the two groups, preventing direct comparison. There were no details about whether the atelectasis score had been previously assessed for reliability and validity. No sample size calculation was provided and due to the underpowered nature of the study there was a high risk of type II error.

The use of a 'saline lavage and simulated cough' technique has been described for the treatment of persistent lung collapse in ventilated infants (Galvis et al., 1994). Fifty-seven infants, under 1 year of age, received the treatment over an eight-year period. The technique included four steps: pre-oxygenation, deep saline instillation via a catheter, MHI and CWV, and suctioning. Forty-eight (84%) of the children demonstrated complete resolution of collapse on CXR after one or two treatments. No significant complications of the technique were reported. This is a single centre descriptive case series limiting the generalisability of the results. A novel manoeuvre for persistent atelectasis in ventilated children has been described by Martinez Herrada et al. (2020). Although completed by medical professionals this included several chest physiotherapy components: MHI, saline instillation, expiratory chest wall compression and vibrations, and suction. A validated modified radiology atelectasis score was used to assess 15 patients before and within 15 minutes post-manoevre. Median atelectasis score improved significantly following the manoeuvre (9 vs 1, p<0.01). The generalisability of the results may be limited due to most patients being under 2 years of age (87%).

Improvements in atelectasis following the use of a postural recruitment manoeuvre have been reported by Acosta et al. (2020). A lung ultrasound aeration score was used to measure atelectasis in recently anaesthetised children. The aeration score decreased significantly in the intervention group (9.9+/-2.1 vs 1.5+/-1.6, p < 0.001). Although this study demonstrated a robust design the subjective nature of the aeration score may have introduced bias.

### 1.3.2.6 *Other clinical outcomes*

Other clinical outcomes studied included days of ventilation, and the number of respiratory illnesses and hospitalisations. These are important outcomes to provide an understanding of the longer-term impact of chest physiotherapy. Mehrem et al. (2018) completed a RCT including 60 full term neonates with primary pneumonia. The patients were randomised to receive routine medical treatment or routine medical treatment plus chest physiotherapy. The physiotherapy included postural drainage, percussion and CWV. Patients remained in the study until discharged from the neonatal intensive care. There was a significant difference between the two groups, in favour of the chest physiotherapy group, with regard to days of mechanical ventilation/oxygenation required (mean difference 2.31 days,  $p=0.04$ ). The usefulness of this outcome is limited, as the clinical implications of requiring mechanical ventilation or oxygen alone are considerably different. The neonates who received chest physiotherapy also displayed shorter time to clinical improvement (mean difference 2.57 days,  $p=0.03$ ), establishment of oral feeding (mean difference 5.21 days,  $p=0.03$ ) and hospital discharge (mean difference 4.93 days,  $p=0.03$ ). No details were provided about the data collection processes or the tool used to measure clinical improvement. The groups appeared comparable at the start of the study, but no attempt was made to adjust for other variables or therapies which may influence these longer-term outcomes. It is unclear what proportion of the participants were mechanically ventilated, hence it is difficult to determine the relevance for a mechanically ventilated PICU population.

A retrospective study compared high frequency chest wall oscillation and intrapulmonary percussive ventilation in paediatric patients with a tracheostomy (Bidiwala et al., 2017). Outcomes included the number of respiratory illnesses, lower respiratory tract infections (LRTI), and respiratory illnesses requiring acute care hospitalisations. Eight patients, aged between 1 and 22 years, were recruited. One patient required 24-hour mechanical ventilation and five required overnight ventilation. Data collection was via retrospective chart review, within a period where all patients were treated with one year of HFCWO followed by one year of IPV. The total number of respiratory illnesses were reduced from 32 per

year on HFCWO therapy to 15 per year with IPV ( $p < 0.001$ ). Improvements in the number of lower respiratory tract infections requiring antibiotic use (15 per year to 6 per year,  $p = 0.01$ ) and number of hospitalisations (8 per year to 3 per year,  $p = 0.003$ ) were reported with IPV. This is a single centre experience with a small sample. The influence of time, e.g., potential change in other treatments, staffing, environment, have not been considered.

#### *1.3.2.7 Summary*

The discussed literature demonstrates variable effects of chest physiotherapy in mechanically ventilated children, these are summarised in Figure 1.2. Negative effects of MHI and CWV on oxygenation, the cardiovascular system and respiratory dead space were reported. Small improvements in respiratory mechanics were demonstrated following the use of MHI and CWV. Intrapulmonary percussive ventilation, saline lavage with MHI/CWV, and a postural recruitment manoeuvre demonstrated improvements in atelectasis.

A common theme is that although statistically significant differences were reported these infrequently translated into clinically important changes. Clinically important differences reflect changes in a clinical intervention that are meaningful for the patient and/or clinicians (Kallogjeri et al., 2020). Hence this is an important consideration when interpreting the results of clinical research. Authors should provide definitions for the specific variables under investigation to facilitate interpretation. However, determining what constitutes a clinically meaningful change is a complicated issue, which often involves combining statistical methods with clinical reasoning.

Most of the studies reviewed investigated short term outcomes, in one discrete episode of chest physiotherapy. A wide range of outcome measures and populations were studied, preventing direct comparison or pooling of results, in the form of a meta-analysis. Common limitations include small samples, non-comparable groups and lack of confounding adjustment. Studies with a more robust RCT design had strict inclusion criteria, therefore limiting the generalisability of the findings to today's PICU population.

		Oxygenation			Ventilation		Respiratory mechanics			Cardiovascular system		Atelectasis	Other		
Physiotherapy treatment	Study	SpO <sub>2</sub>	PaO <sub>2</sub> /PO <sub>2</sub>	OI	Distribution	Tidal Volume	Compliance	Resistance	Dead space	Heart rate	MBP		Days of ventilation	Respiratory illnesses	Hospitalisations
MHI	Luadsri et al., 2022					Green	Green								
MHI, manual techniques	McAlinden et al., 2020				Green										
MHI, saline, positioning, manual techniques	Martinez Herrada et al., 2020											Green			
	Elizabeth et al., 2016	Yellow	Yellow			Yellow									
	Shannon et al., 2015					Green	Green	Green							
	Soundararajan et al., 2015		Green									Green			
	Lanza et al., 2011	Yellow					Yellow	Yellow			Yellow				
	Main & Stocks 2004								Red						
	Main et al., 2004	Red					Yellow	Yellow							
	Hussey et al., 1996	Red									Red	Red			
	Galvis et al., 1994												Green		
Postural drainage, manual techniques	Mehrem et al., 2018												Green		
Recruitment maneuver	Acosta et al., 2020						Green	Yellow				Green			
	Morrow et al., 2007	Yellow					Yellow	Yellow							
EFIT	Demont et al., 2007											Green			
	Almeida et al., 2005	Green					Yellow	Yellow	Yellow						
	Bernard-Narbonne et al., 2003	Green				Green									
IPV	Bidiwala et al., 2017													Green	Green
	Deakins et al., 2002	Yellow						Yellow				Green			
Kinetic therapy bed	Schultz et al., 2005			Green											
Open ETT suction	Tume et al., 2017									Red	Red				
	Morrow et al., 2006					Red	Red								
ETT saline instillation	Ridling et al., 2003	Red													

Figure 1.2 Summary of the clinical effects of chest physiotherapy in mechanically ventilated children

(Key: Green – Statistically significant improvements in outcome related to physiotherapy, Yellow – No changes, Red – Statistically significant deterioration in outcome related to chest physiotherapy, White – Outcome not studied. EFIT – Expiratory flow increase technique, ETT – Endotracheal tube, IPV – Intrapulmonary percussive ventilation, MBP – Mean blood pressure, MHI – Manual hyperinflations, OI – Oxygenation index, PaO<sub>2</sub>/PO<sub>2</sub> – Partial pressure of oxygen, SpO<sub>2</sub> – Peripheral oxygen saturations)

### **1.3.3 Safety of chest physiotherapy in mechanically ventilated children**

The clinical effectiveness of chest physiotherapy has been discussed in the previous section. However patient safety is one of the main concerns for physiotherapists on ICU. This section will explore the definition of adverse events. The literature related to the safety of chest physiotherapy in ventilated children and the wider population will be discussed.

#### *1.3.3.1 Defining adverse events*

In critically ill patients significant fluctuations in stability or the occurrence of an adverse event may contribute to further organ failure, a prolonged ICU stay and increased morbidity and mortality (Rafter et al., 2015). Niese et al. (2011) reported that critical incidents often occur in paediatric intensive care. Critically ill children require a higher density of interventions, invasive procedures, and management decisions than other patients. Patient-related factors including male gender, mechanical ventilation, and length of stay are reported as being independently associated with adverse events (Niese et al., 2011).

Adverse events are recognized as clinically significant alterations in respiratory, haemodynamic, metabolic, or intracranial parameters either necessitating stopping an intervention or applying a 'rescue' intervention (Zeppos et al., 2007). However specific definitions are inconsistent in the literature. Varying physiological thresholds are used to define an adverse event. Zeppos et al. (2007) investigated adverse events and chest physiotherapy on adult intensive care and provided a comprehensive description of what could be classified as an adverse event (Figure 1.3).

- Alteration in blood pressure > or < 20% of resting values which necessitates stopping intervention or requires remedial intervention (e.g., inotropes)
- Alteration in heart rate > or < 20% of resting values which necessitates stopping intervention or requires remedial intervention
- New arrhythmia (e.g., atrial fibrillation, increased number of ectopic beats per minute, ST depression or elevation, increased magnitude of ST depression, bigeminy, trigeminy, ventricular tachycardia, ventricular fibrillation, asystole)
- Desaturation of oxyhaemoglobin >10% of baseline levels or a figure which necessitates stopping intervention or requires remedial intervention
- Pulmonary artery pressure (systolic) over 60 mmHg
- Pneumothorax detected immediately following intervention
- Agitation resulting in detachment of equipment or lines or requiring increased sedation
- Episode related to incorrect procedure (e.g., incorrect connection of equipment, level of inspired oxygen too high)
- Fall during mobilisation (e.g., transfer to chair, walking, or tilt table)
- Consultative event (i.e., asking the nurse to turn a patient to specified side or sit a patient out of bed) resulting in an episode as above within 30 minutes of the request

*Figure 1.3 Definitions of adverse physiological changes and events in adult intensive care*

(Reproduced from Zeppos et al., 2007)

Shannon et al. (2015a) categorised adverse events as mild, moderate and severe in a study comparing the clinical effects of specialist and on-call respiratory physiotherapy treatments. Mild adverse events included transient changes in respiratory and haemodynamic stability, whereas occurrence of a pneumothorax was classified as severe. This subjective approach to defining adverse events would be difficult to replicate. More recently LaRosa et al. (2022) provided adverse event definitions in a study evaluating the safety of early mobilisation and rehabilitation on PICU (Figure 1.4).

- Physiologic changes
  - Heart rate (change by >20%)
  - Blood pressure (change by >20%)
  - Respiratory rate (change by >20%)
  - Oxygen saturation (decrease by >15%)
  - FiO<sub>2</sub> (increase by 20%)
  - End-tidal CO<sub>2</sub> (increase by >20%)
- Removal or dislodgement of medical device
  - Dislodged endotracheal tube
  - Dislodged tracheostomy
  - Dislodged feeding tube
  - Dislodged chest tubed
  - Dislodged arterial line
  - Dislodged central line
  - Dislodged peripheral intravenous catheter
- Changes in mental status or behaviour
- Falls
- Provider-perceived fall risk
- Cardiac arrest
- New arrhythmia

*Figure 1.4 Definitions of adverse events in paediatric intensive care*  
(Reproduced from LaRosa et al., 2022)

Although not intended for use with chest physiotherapy these definitions are population specific and based on recently published studies completed in PICU. Given that there is no consensus on adverse event definitions within PICU the parameters described by LaRosa et al. (2022) may represent the best available.

*1.3.3.2 Adverse events associated with chest physiotherapy*

The theoretical basis behind the occurrence of adverse events associated with chest physiotherapy is multifactorial. The physical disturbance of handling the child can result in agitation, distress and even pain, which may negatively influence physiological variables, such as heart rate, blood pressure and intercranial pressure. In neonates and infants reactions can also include breath



holding and splinting of the chest. Disconnection from the ventilator, required for some chest physiotherapy treatments, can result in de-recruitment. A reduction in airway pressure results in a loss of lung volume and alveolar collapse, which in turn increases intrapulmonary shunt and reduces gas exchange. Neonates and children are particularly at risk due to physiological immaturity and lower functional residual capacity. Similar effects may be observed in situations of incomplete removal of airway secretions. A sputum plug may be moved and result in new areas of atelectasis. Negative suction pressure has also been reported to result in increased atelectasis. Furthermore, mucosal damage and oedema caused during suction may proliferate atelectasis (Morrow and Argent, 2008).

A change in intrathoracic pressure because of ventilator disconnection or the use of MHI can have a direct influence on venous return, which consequently affects cardiac output and arterial pressure. Additionally, hyperinflation increases pulmonary vascular resistance which impedes right ventricular function (Mahmood and Pinsky, 2018). Bradycardia due to vagal response has also been described in neonates resulting from suction or saline instillation stimulus (Morrow and Argent, 2008).

There are no published studies involving safety of chest physiotherapy in ventilated children as the primary outcome. Adverse event rates following chest physiotherapy in ventilated children were reported by Shannon et al. (2015a) in the study mentioned above. It compared the clinical effects of specialist and on-call respiratory physiotherapy treatments, which included saline instillation and MHI with CWV. Adverse events occurred in eight (12.7%) on-call therapist and three (4.8%) specialist physiotherapist treatments. Seven of these were categorised as mild and involved transient changes in oxygenation and haemodynamic stability. One involved a rise in intracranial pressure and was defined as moderate (12 to 26mmHg). The remaining three events were severe, including acute haemodynamic instability requiring pharmacological intervention, development of a pneumothorax, and cardiac arrest 30 minutes following chest physiotherapy. Adverse events were a secondary outcome in this study and no attempt was made to identify a causal relationship. Main et al. (2004) reported a 7% adverse event rate following chest physiotherapy (MHI with CWV) and 13%

with suction. These were classified as short-lived, such as a temporary drop in SpO<sub>2</sub> or blood pressure. In contrast no adverse events during MHI with CWV were reported by Gregson et al. (2012). Other physiotherapy techniques included in the systematic review, EFIT, recruitment manoeuvre and IPV, have also been reported as safe, with a statement of no adverse events provided in the publications (Almeida et al., 2005, Deakins and Chatburn, 2002, Morrow et al., 2007). Only general statements were provided and adverse events not included as *a priori* outcome measures, therefore findings need to be interpreted with caution.

Within the UK, non-bronchoscopic bronchioalveolar lavage (NBBAL) is a diagnostic procedure predominantly completed by physiotherapists on PICU. The safety profile of blind bronchial sampling was investigated in a prospective observational study (Gupta et al., 2018a). Forty children, aged 1 month to 16 years, with suspected ventilator acquired pneumonia were recruited. NBBAL was performed according to a standard protocol. No major complications, defined as airway bleeding, cough or discomfort, arrhythmia, air leak, or oedema were reported. During the procedure a statistically significant increase in mean blood pressure ( $75.5 \pm 14.7$ mmHg to  $79.1 \pm 14.2$ mmHg,  $p=0.04$ ) and drop in SpO<sub>2</sub> ( $98.2 \pm 2.3\%$  to  $92.2\% \pm 9.2\%$ ,  $p<0.001$ ) were noted. These changes appeared transient with no difference in variables after the intervention; mean blood pressure  $75.4 \pm 13.7$ mmHg ( $p=1.0$ ) and SpO<sub>2</sub>  $97.5 \pm 1.9\%$  ( $p=0.02$ ). A limitation is the lack of objective criteria to assess airway bleeding and cough.

Open and closed ETT suction when used by nurses on PICU were reported to have equivalent rates of adverse events (3 vs 5,  $p=0.23$ ) (Evans et al., 2014). However open suction resulted in more frequent physiological disturbances than closed suction: decreased oxygen saturation (6.3% vs 4.8%,  $p = 0.01$ ), increased heart rate (4.6% vs 1.6%,  $p < 0.01$ ) and mean arterial pressure (9.2% vs 3.4%,  $p < 0.01$ ). Whether these changes were transient or sustained was not discussed.

Only one study, which involved adults, has exclusively investigated adverse events and chest physiotherapy on intensive care. This was a prospective observational study recording self-reported adverse events during physiotherapy (Zeppos et al., 2007). Physiotherapy intervention included chest physiotherapy,

mobilisation and exercise. Twenty-seven adverse events were documented in a total of 12281 treatments (0.2%). Physiological changes included a drop in mean arterial pressure, rise in intracranial pressure, decreased oxygenation, bradycardia and cardiac arrhythmias. The most common physiotherapy intervention when an adverse event occurred was the administration of increased positive pressure (n=16). Of patients who experienced an adverse event during physiotherapy, 86% were on vasopressor or inotropic support. Methodological limitations included the potential for under reporting of adverse events and the lack of data collection in the period after physiotherapy input. The generalisability to the paediatric population is limited due to the physiological and anatomical differences between adults and children.

#### *1.3.3.3 Summary*

Safety and the incidence of adverse events related to chest physiotherapy are important considerations on PICU. There is inconsistency in the definitions of adverse events used. The safety of chest physiotherapy is yet to be the primary focus of published research. Most published studies provide a generic statement of no adverse events. In the few studies which included adverse events as a secondary outcome, composite rates were reported which varied between 4.8% and 12.7%.

#### **1.3.4 The current status of chest physiotherapy in ventilated children**

The literature related to the effectiveness and safety of chest physiotherapy in ventilated children has been presented. This section will explore the status of chest physiotherapy in ventilated children, including available guidance and description of current practice.

Published guidance related to chest physiotherapy in ventilated children is contradictory. This is not unexpected given the inconclusive evidence to support its effectiveness and safety. The UK Quality Standards for the Care of Critically Ill Children (2021) require PICUs to have access to a physiotherapist 24 hours a day (Paediatric Critical Care Society, 2021). Whereas European recommendations from the Paediatric Mechanical Ventilation Consensus

Conference state that chest physiotherapy for airway clearance cannot be considered a standard of care (Kneyber et al., 2017).

Choong et al. (2014) evaluated rehabilitation practices in PICUs across Canada. In total 45.4% of patients admitted received physiotherapy interventions, with 27.2% having chest physiotherapy treatments. No specific treatment details were provided as the study's main aim focussed on rehabilitation. A recent study of respiratory physiotherapy practice in Spanish paediatric and neonatal intensive care units reported approximately 37.1% of patients received treatment (Torreiro Diéguez et al., 2022). The scope of the study did not involve describing treatments used.

Specific chest physiotherapy practice on PICU has been studied in a single centre retrospective trial (McCord et al., 2013). One hundred and eleven children who received chest physiotherapy over one year were included. The most common indications for chest physiotherapy were pathological changes on CXR and secretion retention. MHI and CWV were the most frequently used techniques (95.5%). Other treatments included percussion, bed mobility and assisted cough. No data were provided regarding the whole population hence the proportion of patients who received chest physiotherapy is unknown. In a survey involving 25 PICUs in India, percussion was the most frequently used chest physiotherapy treatment with 90% (76/84) of respondents using this (Kumar et al., 2014). CWV were used by 68% (57/84) and MHI was not used. This study included both ventilated and self-ventilating patients. Currently there is no published literature describing chest physiotherapy practice in UK PICUs.

#### **1.4 Clinical decision making**

This chapter has introduced the range of chest physiotherapy treatments available for use with ventilated children on PICU. The inconclusive nature of their effectiveness has been discussed, together with the limited understanding of their safety profile. Variation in both guidance and practice has been highlighted. The choice and delivery of chest physiotherapy is an essential element of physiotherapists decision making. An exploration of clinical decision making is particularly important in this project due to the complex nature of the PICU

environment, including high patient turnover, patients receiving multiple therapies and interventions, and distressed parents, together with the necessity for quick decisions and timely treatments. This section will discuss clinical decision making, provide a definition and explore clinical decision making models. The literature related to physiotherapists' decision making will be presented and appraised.

Clinical decision making or clinical reasoning is described by Higgs et al. (2019) as the core competency of professional practice. It enables clinicians to make informed and responsible decisions and address the problems faced by their patients. Clinical decision making can be defined simply as taking the best judged action in a specific context (Higgs et al., 2019). A more comprehensive definition was developed by Tiffen et al. (2014); a contextual, continuous, and evolving process, whereby data are gathered, interpreted, and evaluated to select an evidence-based choice of action. Similarly, Levett-Jones et al. (2010) conceptualised clinical reasoning as a cycle of linked clinical encounters. It is a complex phenomenon, involving multiple layers and components. Authors acknowledge the context dependent nature of clinical decision making, individuality with regards to knowledge and skills, uncertainty of healthcare environments and changing expectations of the system and patients (Higgs et al., 2019, Krishnan, 2018, Tiffen et al., 2014).

Within the literature decision making, clinical reasoning, clinical judgement and critical thinking are used interchangeably. In this study the term clinical decision making will be used.

#### **1.4.1 Clinical decision making models**

Two main models of clinical decision making have been discussed within medical and nursing literature: hypothetico-deductive and intuitive-humanist. These will be discussed individually.

Historically, the hypothetico-deductive model has been the most widely studied and accepted model of clinical decision making (Edwards et al., 2004, Kovacs and Croskerry, 1999). It was derived from a cognitive science perspective and is based on information processing theory and analytical decision making. The

clinical decision making as per this model is based on objective indicators. Theoretical knowledge learned from physiology, anatomy, pathophysiology, and pharmacology is critical to the process (Krishnan, 2018). The hypothetico-deductive approach involves four stages: cue recognition or cue acquisition, hypothesis generation, cue interpretation and hypothesis evaluation (Banning, 2008).

Edwards et al. (2004) also discussed an empirico-analytic model derived from the same cognitive science. This approach focusses on the organisation and accessibility of knowledge stored in the clinician's memory. It is described as pattern recognition, whereby the clinician recognizes features or symptoms of a case which leads to the use of other relevant information. This has been termed 'forward reasoning', where an individual moves from specific observations towards a generalisation. This contrasts with the hypothetico-deductive approach. These models are complementary and can be used in different situations. Pattern recognition is more efficient and used more frequently by expert or experienced clinicians, whereas the hypothetico-deductive model tends to be used by inexperienced clinicians or for unfamiliar or complex problems (Edwards et al., 2004).

These diagnostic style models are logical and objective, being grounded in the positivist paradigm. Krishnan (2018) highlights that the dynamic world with multiple realities and the complexities of decision making that occur in clinical practice are not reflected in these models. A limitation discussed by Banning (2008) is the assumption made by these models that existing knowledge is available and accurate at the time of making the decision.

In contrast to diagnostic models the intuitive-humanist model is based on intuition and the relationship between experience, knowledge and decision making (Banning, 2008). Benner and Tanner (1987) introduced intuition as a legitimate and essential component of clinical judgment. They defined intuition as '*understanding without rationale*'. A more comprehensive definition by Rew (2000) described intuitive judgement as '*the decision to act on a sudden awareness of knowledge, that is related to previous experience, perceived as a whole and difficult to articulate*'.

The six key elements of the intuitive-humanist model are pattern recognition, similarity recognition, common-sense understanding, skilled know-how, use of salience, and deliberative rationality (Benner and Tanner, 1987). Characteristics described within the literature include gut feelings, emotional awareness, apprehension and reassuring feelings (Banning, 2008). This approach relies on an individual's perception of the situation rather than analytical principles (Krishnan, 2018). Experience is recognised as a central component. Krishnan (2018) believes the model allows for complexity of decision making and recognises the holistic nature of healthcare. However, an intuitive approach is generally met with scepticism, due to its basis in the subconscious and lack of transparency, scientific reasoning and confirmatory evidence (Banning, 2008, Tiffen et al., 2014).

#### **1.4.2 Physiotherapists' clinical decision making**

There is no published literature exploring physiotherapists' decision making and the subsequent delivery of chest physiotherapy in PICU. There are only a few studies involving decision making of paediatric physiotherapists. A qualitative study explored the decision making of three physiotherapists during treatment of a child with cerebral palsy (Embrey et al., 1996). Characteristics of decision making included cognitive structures (knowledge), flexibility, psychosocial sensitivity, and self-monitoring. Differences in novice and expert decision making were also reported. These related to increased adaptability and psychosocial sensitivity in the more experienced physiotherapist. A limitation of this study was the use of retrospective 'think aloud' methodology whilst watching a video of a pre-recorded treatment, rather than actual clinical practice. King et al. (2007) examined the clinical decision making of novice, intermediate, and expert paediatric rehabilitation therapists. A similar 'think aloud' method was used, together with retrospective interviews using the critical incident technique. The authors concluded that with time and developing expertise therapists reported a broader, more holistic understanding of the 'big picture'. Supporting the client/family as decision maker was an important theme. Similar to the findings of Embrey et al. (1996) more experienced therapists demonstrated greater appreciation of the psychosocial impact of childhood disability on families and a flexible and responsive approach to decision making during treatment sessions.

Several authors have studied physiotherapists' decision making in the adult respiratory setting, which is more comparable to the PICU. These studies have predominantly used qualitative methods to allow a deeper understanding of practice and behaviour. Physiotherapists' decision making related to airway clearance techniques and mucoactive agents in critically ill adult patients has been investigated using focus group interviews (Connolly et al., 2020). This study involved 15 physiotherapists, with varying levels of experience and data were analysed using thematic analysis. Varied practice around the decision to start treatment was reported, however common themes included an individualised approach and the impact of experience. The authors described decision making as an iterative process in which physiotherapists utilise multiple sources of clinical information.

Smith et al. (2007) used hermeneutic methodology to investigate specific factors influencing cardiorespiratory physiotherapy decision making in adult acute care. Fourteen physiotherapists were observed in clinical practice and completed semi-structured interviews. Decision making in acute respiratory physiotherapy was identified as a dynamic, complex and multidimensional process influenced by multiple factors. Factors were related to the nature of the decision, the context in which the decision occurred, and the physiotherapists themselves. In a related publication the characteristics and processes of physiotherapy decision making were studied (Smith et al., 2008). Physiotherapists' decisions were based around the nature of patients' problems, physiotherapeutic intervention and interaction, and evaluation of effectiveness of actions. The authors concluded that restricting the understanding of decision making to hypothetico-deductive reasoning and pattern recognition poorly represented decision making in the real world of cardiorespiratory physiotherapy.

Smith et al. (2010) subsequently investigated the impact of experience on cardiorespiratory physiotherapy decision making. Participants were observed as they engaged in everyday practice and interviewed about decision making. Texts of the data were interpreted using a hermeneutic approach. Four dimensions characteristic of increasing experience were described. Underpinning these dimensions was evidence of reflection on practice, motivation to achieve best



practice, critique of new knowledge, increasing confidence, and relationships with knowledgeable colleagues. A mixed methods study explored clinical decision-making used by experienced cardiorespiratory physiotherapists (Thackray and Roberts, 2017). Data collection methods included simulation, video recording and think aloud techniques. The authors highlighted that although decision making was similar to the hypothetico-deductive model and five-rights nursing model, it was more complex, iterative, and reflexive than these individual models suggest. They developed a new conceptual model of clinical decision making in cardiorespiratory physiotherapy, which included seven cognitive processes: information perception, information processing, hypothesis formation, diagnosis/problem list, taking action, evaluation/goal setting and reflection.

Similar findings have been reported in other adult physiotherapy specialities, including adult stroke and acute care; factors influencing decision making included cultural, organisational and environmental circumstances, communication, knowledge and clinical experience (Chipchase and Prentice, 2006, Holdar et al., 2013, McGlinchey and Davenport, 2015).

## **1.5 Summary of chapter 1**

Mucociliary clearance and the cough reflex are essential defence mechanisms, protecting the lungs against inhaled pollutants and pathogens. Although lifesaving, PICU therapies, including intubation and mechanical ventilation, can impair airway clearance and cause secretion retention, airway occlusion, atelectasis, and pneumonia. Chest physiotherapy aims to facilitate airway clearance and minimise the complications associated with a PICU stay. A wide range of chest physiotherapy treatments are available for mechanically ventilated children. However, there is no published literature describing current practice within the UK or how physiotherapists approach decision making regarding physiotherapy treatment.

Despite the role of chest physiotherapy being acknowledged, evidence to support its effectiveness in ventilated children remains inconclusive. There are currently few high-quality studies, with heterogeneity in the physiotherapy interventions and populations studied. Important gaps in the literature include lack of

representative populations, the effects of multiple physiotherapy treatments, and the impact on long-term outcomes. Furthermore, there are minimal data exploring the safety profile of chest physiotherapy in ventilated children. Chest physiotherapy adverse event rates described within the literature are variable and should be interpreted with caution. Adverse events have not been studied as a primary outcome and there are discrepancies in the definitions used. Hence the risks and benefits of chest physiotherapy are unknown.

Given the vulnerable nature of this patient group safety should be of primary importance. It is essential to understand in which patients the risk of chest physiotherapy may outweigh the benefit. Therefore, the overall aim of this study was to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children. To achieve this and provide a detailed understanding, six research questions were developed.

1. What is current chest physiotherapy practice within UK paediatric intensive care units?
2. How do physiotherapists make decisions regarding the delivery of chest physiotherapy in UK paediatric intensive care units and what other factors influence this decision making?
3. What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?
4. What is the prevalence of physiological instability and adverse events associated with chest physiotherapy in ventilated children?
5. What are the risk factors/characteristics of children who display instability and/or adverse events associated with chest physiotherapy?
6. What is the long-term impact on the child of instability and adverse events associated with chest physiotherapy?

## **2. Methodology**

### **2.1 Introduction**

Research methodology refers to the general approach used for scientific inquiry and involves the researcher's choice of strategy and methods for undertaking the research (Dyson and Norrie, 2013). The decision is based on the nature of the research problem, preferred research philosophy and the researcher's experience (Creswell and Creswell, 2017, Dyson and Norrie, 2013). Three broad research methodologies are described within the literature: qualitative, quantitative and mixed methods. The traditional approaches, qualitative and quantitative, were historically viewed as distinct, rigid categories. More recently Creswell and Creswell (2017) described these approaches as representing different ends of a continuum with mixed methods occupying the middle. The methodological approach used in this study was mixed methods.

In this chapter mixed methods will be introduced and explored in relation to this study, and the rationale for its use will be discussed. The philosophical perspectives underpinning the study will be considered, and the research design and individual methods introduced. Patient and public involvement and engagement will also be described, together with the ethical approvals obtained.

### **2.2 Mixed methods**

#### **2.2.1 Definition of mixed methods**

Mixed methods research has been used for several decades and is now accepted as a third methodology (Creswell and Plano Clark, 2018, Dyson and Norrie, 2013). Since the initial description of mixed methods by Greene et al. (1989) several definitions have emerged as the research landscape has evolved. The early definitions emphasised the mixing of methods and separation of philosophy. Authors now define mixed methods research in terms of the core characteristics involved. Creswell and Plano Clark (2018) state that in mixed methods studies, the researcher:

- collects and analyses both qualitative and quantitative data rigorously in response to research questions and hypotheses,
- integrates the data and their results,
- organises these procedures into specific research designs that provide the logic and procedures for conducting the study, and
- frames these procedures within theory and philosophy.

### **2.2.2 Reasons for choosing mixed methods**

The rationale for mixing qualitative and quantitative research within one study is based on the principle that neither method is sufficient alone to capture the complexities under investigation (Ivankova et al., 2006). A key advantage of mixed methods is that it capitalises on the strengths of both qualitative and quantitative research whilst minimising the limitations of each approach (Creswell and Plano Clark, 2018). Through this complementary relationship mixed methods enables a thorough investigation and provides a more complete understanding of the research problem. Mixed methods have also been used to cross validate or corroborate findings (Creswell and Plano Clark, 2018, Rauscher and Greenfield, 2009). This is described as ‘triangulation’, and has been reported to minimise research bias and enhance validity of the results through comparison of findings from different methods (Bowling, 2009). Other purposes of a mixed methods approach include the results from one method helping develop the second method, the development, implementation and evaluation of a programme, and the discovery of contradictions and new perspectives (Creswell and Plano Clark, 2018, Greene et al., 1989).

Tashakkori and Teddlie (2010) state that a mixed methods approach is based on problem driven methodological decisions. The authors introduce the concept of ‘*methodological eclecticism*’, discussing how being able to combine methods allows the researcher to choose the best tools for answering the research questions, maximising design quality. With the focus on the research problem mixed methods is becoming increasingly popular in health care research. The real-life contextual understanding and multilevel perspectives it provides make it well suited to the complex research problems encountered in medicine and congruent

with holistic models of care (Creswell and Plano Clark, 2018, Larkin et al., 2014). The use of mixed methods has been reported as leading to greater confidence in research findings (O'Cathain et al., 2007). This is an important consideration in health care and applied research where the findings will influence clinical practice.

This study was both exploratory (i.e., research that attempts to explore and investigate a problem which is not clearly defined) and explanatory (i.e., research that attempts to explain why certain phenomenon occur) in nature and aimed to address a multifaceted problem, within a complex PICU environment. Therefore, given the advantages and considerations discussed above, mixed methods was deemed the most suitable methodology. The complementary and triangulation features, together with the ability to use a range of research tools, were important considerations in this study. By using qualitative and quantitative approaches this study has provided a comprehensive and deeper contextual understanding of the research problem, which would not have been achieved if only a single method had been used.

### **2.2.3 Challenges associated with mixed methods**

Researcher skills are an important consideration when choosing a mixed methods approach. Creswell and Plano Clark (2018) recommend experience of both qualitative and quantitative research prior to undertaking a mixed methods study. It is essential to complete all components of the study in a rigorous manner. In this study the primary researcher (ES) had a solid grounding in quantitative research and exposure to qualitative methods. A strong supervisory team was in place, one of whom was an expert in mixed methods (JW). Furthermore, a comprehensive methodology training programme was completed, including qualitative data collection and analysis skills, and statistical methods (Appendix 2).

Practical challenges related to time and resources are also reported with mixed methods research. Collecting, analysing, and integrating multiple data sets is a lengthy process (Creswell and Plano Clark, 2018, Rauscher and Greenfield, 2009). The increased demands of multiple data sets also includes additional expenses related to participants, transcription and analysis software (Creswell and Plano Clark, 2018). A mixed methods approach was deemed feasible within the time frame available for this study and a detailed timetable was developed to

ensure it was completed in a timely manner (Appendix 3). Expenses, including travel to participants and transcription fees, were accounted for within the study budget.

#### **2.2.4 Conducting mixed methods research**

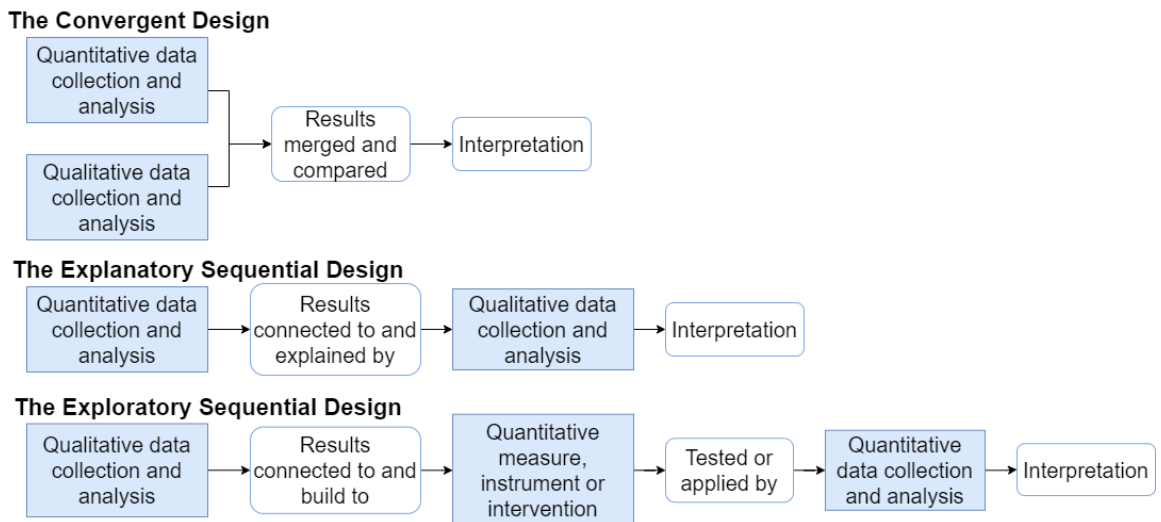
There are three areas which require consideration when designing a mixed methods study: priority, implementation, and integration (Creswell and Plano Clark, 2007). It is important these factors are addressed at the outset to establish the study's rigour. These will be discussed individually and explored in relation to this study.

##### *2.2.4.1 Priority*

Priority relates to the relative emphasis placed on the quantitative and qualitative strands within a mixed methods study (Creswell and Plano Clark, 2018). Some studies will place greater emphasis on one type of method and data, with the other viewed in a secondary role. In some circumstances the strands will be of equal importance. Decisions regarding priority should be based on the study's overall aim (Rauscher and Greenfield, 2009). Given the exploratory and explanatory nature of this study equal priority was given to the quantitative and qualitative components (Creswell and Plano Clark, 2007).

##### *2.2.4.2 Implementation*

Implementation refers to the sequence in which data are collected and analysed in a mixed methods study (Creswell and Plano Clark, 2007). Numerous typologies for classifying mixed methods designs have been presented and discussed over the last 20 years. As mixed methods research has evolved these have been refined and consolidated. Creswell and Plano Clark (2018) now identify three core mixed methods designs: convergent, explanatory sequential, and exploratory sequential, described in Figure 2.1.



*Figure 2.1 Diagram of the three core mixed methods designs (Adapted from Creswell and Plano Clark (2018))*

The overarching mixed methods design of this study was convergent. A convergent design was chosen to provide different but complementary data on the same topic, resulting in a comprehensive understanding of the research problem (Morse, 1991). It was also chosen to ensure the whole breadth of research questions were answered. A further advantage has been reported as giving a voice to participants whilst also reporting statistical trends (Creswell and Plano Clark, 2018). The four main stages to a convergent design, as completed in this study, are outlined in Table 2.1.

Table 2.1 Procedures involved in implementing a convergent mixed methods design

<b>Step 1</b>	<b>Design the quantitative strand</b>  <b>Collect the quantitative data</b>	<b>Design the qualitative strand</b>  <b>Collect the qualitative data</b>
<b>Step 2</b>	<b>Analyse the quantitative data</b>	<b>Analyse the qualitative data</b>
<b>Step 3</b>	<b>Use strategies to merge the two sets of results</b> <ul style="list-style-type: none"> <li>• Identify content areas in both datasets: compare, contrast and/or synthesise</li> <li>• Identify differences and similarities</li> <li>• Create joint display, comparison discussion, transform data</li> </ul>	
<b>Step 4</b>	<b>Interpret the merged results</b> <ul style="list-style-type: none"> <li>• Summarise and interpret the separate results</li> <li>• Discuss to what extent and in what ways results converge, diverge, or relate to each other</li> <li>• Explain any divergence</li> <li>• Plan for further analysis/data collection to explain divergence</li> </ul>	

(Adapted from Creswell and Plano Clark (2018))

Given the complexity of the research problem a more advanced approach was adopted. Instead of including a purely qualitative component within the convergent design an explanatory sequential approach was used. This embedded a mixed methods design within a mixed methods study. There are two distinct, interactive phases in explanatory sequential design. Quantitative data are collected and analysed first, this is followed by a qualitative phase used to explain or expand on the results of the first phase (Creswell and Plano Clark, 2018). An explanatory sequential design was selected to provide a deeper contextual understanding. Ivankova et al. (2006) reported that the quantitative data and subsequent analysis provides a general understanding of the research problem, with the qualitative



component allowing refinement and explanation of these results by exploring participants' views in more depth. This is of particular value in situations with outliers or unexpected findings (Creswell and Plano Clark, 2018).

#### 2.2.4.3 Integration

Integration relates to the stage or stages in the research process where mixing of the quantitative and qualitative methods occurs (Greene et al., 1989, Ivankova et al., 2006). Integration is one of the most important features of mixed methods and is what separates it from a study which merely presents qualitative and quantitative information (Plano Clark, 2019, Rauscher and Greenfield, 2009). Integration can be implemented at the design, methods, and interpretation and reporting levels of research (Fetters et al., 2013). In Section 2.2.4.2 integration of data from a design perspective has already been discussed. Fetters et al. (2013) contextualise the use of integration in methods in several ways: connecting, building, merging and embedding (Table 2.2). Narrative discussion, data transformation and joint display are reported as approaches to integration during interpretation and reporting (Fetters et al., 2013, Plano Clark, 2019).

*Table 2.2 Integration through methods*

<b>Approach</b>	<b>Description</b>
<b>Connecting</b>	One database links to the other through sampling
<b>Building</b>	One database informs the data collection approach of the other
<b>Merging</b>	Two databases are brought together for analysis
<b>Embedding</b>	Data collection and analysis link at multiple points

(Fetters et al., 2013)

As a defining feature it is important to explicitly plan the integration of data within a mixed methods study (Plano Clark, 2019). Integration within the overarching convergent design of this study included merging of the results and side by side comparison during interpretation. Narrative discussion was used to report the integrated findings. In addition, a 'building' approach was used, in which one

section of results from the explanatory sequential work package was used to inform the quantitative data analysis.

Integration within the explanatory sequential design included two linking points. Firstly, the results of phase one were used to help plan the follow up qualitative data collection. Following completion of phase 2, the results were merged and interpreted. As described within explanatory sequential design the qualitative findings were used to expand upon and explain the quantitative results. Triangulation was also used between all components of this work package. The integrated results were presented using joint displays and narrative discussion.

### 2.3 Philosophical perspectives

It is important to consider the philosophical assumptions that provide the foundation for a research study. These assumptions shape the processes of research and the conduct of inquiry (Creswell and Plano Clark, 2018). Philosophical or paradigm worldviews are defined as a basic set of beliefs that guide action (Denzin and Lincoln, 2017). In mixed methods research four main paradigms are discussed, these are displayed in Figure 2.2.

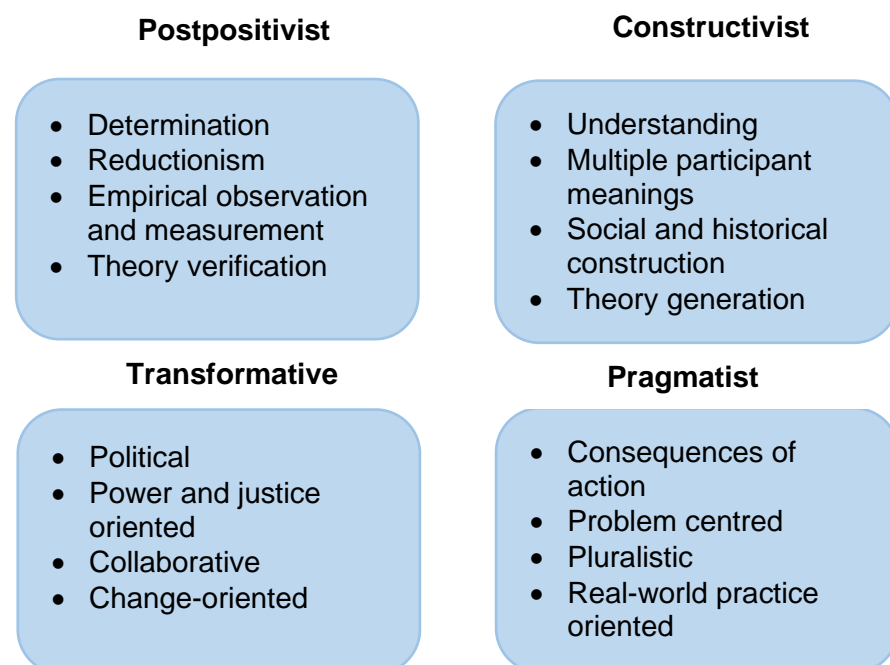


Figure 2.2 Four worldviews used in mixed methods research (Creswell and Creswell, 2017)

Postpositivism is often connected to quantitative research, and constructivism aligned with qualitative research. Several authors have highlighted pragmatism as the optimal paradigm for mixed methods research (Creswell and Plano Clark, 2018, Tashakkori and Teddlie, 2010). Pragmatism is a worldview that arises out of actions, situations, and consequences rather than prior conditions, which is the case with postpositivism (Creswell and Creswell, 2017). The individual philosophical assumptions of pragmatism are outlined in Table 2.3.

*Table 2.3 Elements of a pragmatic worldview and implications for practice*

<b>Philosophical Question</b>	<b>Pragmatist assumption</b>
<b>Ontology</b> (What is the nature of reality?)	Singular and multiple realities e.g., researchers test hypotheses and provide multiple perspectives.
<b>Epistemology</b> (What is the relationship between the researcher and that being researched?)	Practicality e.g., researchers collect data by using best methods available.
<b>Axiology</b> (What is the role of values?)	Multiple stances e.g., researchers include both biased and unbiased perspectives
<b>Methodology</b> (What is the process of research?)	Combining e.g., deductive and inductive approaches, quantitative and qualitative.
<b>Rhetoric</b> (What is the language of research?)	Formal or informal e.g., researchers include both formal and informal styles of writing.

(Adapted from Creswell and Plano Clark (2018))

Within the pragmatic paradigm the emphasis is on the research problem rather than the methods, providing freedom to choose methods that work best to answer the research questions (Creswell and Creswell, 2017, Tashakkori and Teddlie, 2010). Creswell and Plano Clark (2018) highlight its orientation towards real-world practice. Pragmatists value both objective and subjective knowledge, in line with my personal epistemological position. Given these considerations and the practical and clinical context of this study, it was positioned within the pragmatic paradigm.

## 2.4 The methodology of this study

### 2.4.1 Aim

The overall aim of this study was to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children. To achieve this, six research questions were answered (see Section 1.5).

### 2.4.2 Research design

This study was mixed methods using a convergent design with an embedded explanatory sequential approach. Figure 2.3 displays the individual work packages and phases involved in the study. The integration between the work packages is highlighted, together with the overall data integration.

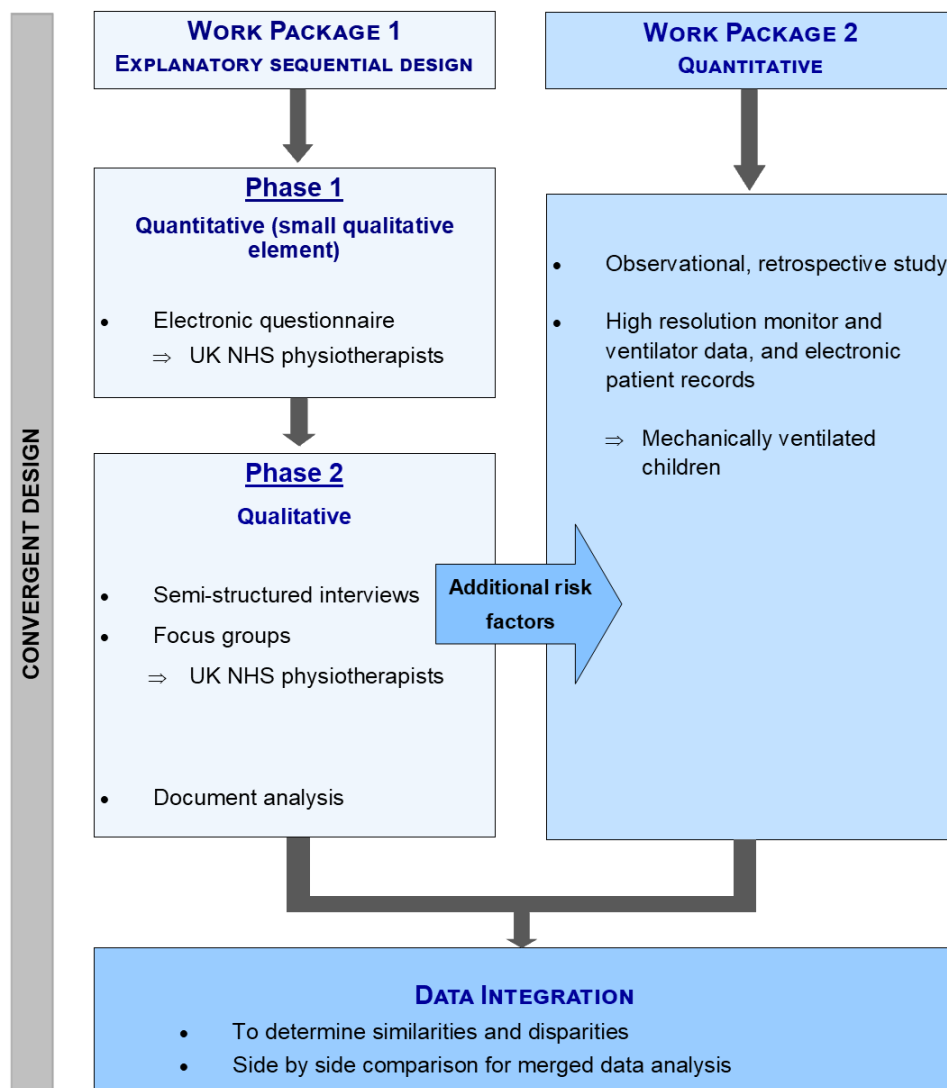


Figure 2.3 The mixed methods design of this study

### **2.4.3 Research methods**

The final methodological decisions were based around the specific research methods chosen. Figure 2.3 includes the individual methods employed in each work package. Work package 1 involved a questionnaire, semi-structured interviews, focus groups and document analysis. The quantitative work package 2 was a retrospective study, using high-resolution data and electronic patient records. Document analysis in phase 2 was included in response to the findings from phase 1. The rationale for selecting these research methods will be discussed at the start of each chapter for context.

## **2.5 Patient and public involvement and engagement**

Patient and public involvement and engagement (PPIE) is an active partnership between researchers and patients, carers and/or the public, which influences and shapes research. PPIE has been reported to improve the quality and relevance of research (NIHR, 2021). This study was developed in collaboration with parents/carers of children across the three intensive care units at GOSH. Six families were consulted using questionnaires and face to face interviews about:

- Research priorities
- Importance of the research questions posed
- Acceptability of the research methods proposed
- Best methods for disseminating findings

The importance of the research area and questions posed were well supported. Feedback informed the development of the study as outlined below:

- Investigation into everyday/routinely performed procedures was highlighted as a priority, hence the decision to investigate standard chest physiotherapy was made rather than focusing on one specific (more specialist, less frequently implemented) physiotherapy technique.
- The parents/carers provided detailed insight about the distressing and highly stressful nature of having a child on PICU. All the families interviewed stated that they would prefer not to be approached for research purposes

whilst their child was critically ill. Therefore, a retrospective data collection method was selected for work package 2.

- The parents/carers interviewed stated their interest in receiving feedback about all PICU studies taking place, irrespective of involvement. They suggested a generic summary and recommended social media and email as dissemination methods. The dissemination plan was altered accordingly.

A parent advisory group was created and included two parents/carers of children previously on PICU. The scope of the group was to assist with plain English summaries/updates and dissemination, whilst also providing patient representation and parent perspective.

## **2.6 Ethical approvals**

The study was registered as one entity with the GOS ICH research and development department (18BA19). Given the differences in methods between work packages these were treated individually from an ethical perspective.

### **2.6.1 Work package 1**

Work package 1 was granted HRA (IRAS 278215) and UCL Research Ethics (ID 16837/001) approval on 6<sup>th</sup> February 2020. NHS ethics approval was not required as only NHS staff were involved. A non-substantial amendment, to include additional research sites, was submitted to the HRA on 13<sup>th</sup> February 2020 and approval received on 20<sup>th</sup> April 2020. A further non-substantial amendment, to allow the focus groups to be completed, was made on 11<sup>th</sup> May 2021 and approval received on 12<sup>th</sup> May 2021. The associated UCL Research Ethics approval was gained on 2<sup>nd</sup> July 2021. Refer to Appendix 4 for approval documentation.

### **2.6.2 Work package 2**

The GOSH Digital Research, Innovation, and Virtual Environment (DRIVE) ethics approval 17/LO/0008 "Use of routine GOSH data for research" was used for this study. This approval allowed use of routine data for research without explicit patient/family consent, provided the data were non-identifiable and the project had local research and development department approval.

## **2.7 Conclusion**

This chapter has presented the rationale for choosing a mixed methods approach for this study. The research design and various methods have been discussed together with the pragmatic perspective in which the study has its foundations. The key role parents/carers played in the development of the study has been outlined and the appropriate ethical approvals required to complete the study discussed.

## **3. Work package 1 - Phase 1**

### **3.1 Introduction**

Work package 1 was a mixed methods study of explanatory sequential design. The methodology has been described and justification for its use provided in Chapter 2. Work package 1 consisted of two phases. Phase 1 involved a national questionnaire. Phase 2 was qualitative and included three components: semi-structured interviews, focus groups and document analysis. This Chapter will present phase 1 as a standalone study and include methods, results and discussion of key findings.

#### **3.1.1 Aim**

The aim of phase 1 was to describe chest physiotherapy practice for mechanically ventilated children in the UK and to explore the clinical decision making related to its provision and delivery. A secondary aim was to provide data to inform phase 2, a more in-depth exploration of decision making and perceived risks for instability and adverse events.

#### **3.1.2 Research questions**

1. What is current chest physiotherapy practice within UK paediatric intensive care units?
2. How do physiotherapists make decisions regarding delivery of chest physiotherapy in UK paediatric intensive care units, and what other factors influence this decision making?
3. What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?

### **3.2 Methods**

#### **3.2.1 Study design**

A cross-sectional survey was conducted, using an anonymous electronic questionnaire. Surveys are widely used amongst health care professionals and, if conducted rigorously, can provide valuable information about attitudes, knowledge, and behaviour (Coates, 2004, Latour and Tume, 2021, Bowling,



2009). A cross-sectional survey aims to describe certain phenomena at a single point in time (Kelley et al., 2003). Surveys via a questionnaire have been used previously to gather information on physiotherapy practice in adult intensive care units (Koo et al., 2016, Lottering and van Aswegen, 2016, Tadyanemhandu and Manie, 2015, Tan et al., 2017, Van der Lee et al., 2017). Chokshi et al. (2013) and Kumar et al. (2014) used questionnaires to investigate physiotherapy practice in Indian neonatal and paediatric intensive care units. Physiotherapy input to other paediatric cardiorespiratory populations has also been studied in this way (Andersson-Marforio et al., 2021, Phillips et al., 2021). Results from these studies provided detailed descriptions of physiotherapy treatments, determined variations in practice and provided recommendations for future research.

Questionnaires are relatively economical to conduct with regards to time and cost and they enable the recruitment of participants over a wide geographical area (Bowling, 2009, Levin, 2006). This was an important feature in this study where the aim was to reach the whole population of UK PICU physiotherapists to describe current practice. Whilst questionnaires provide the ability to collect a large breadth of data, a reported disadvantage includes a lack of depth on the topic being investigated (Kelley et al., 2003). The mixed methods approach used in this work package helped to mitigate this limitation. Non-response is a common problem with questionnaires and can lead to response bias, where the characteristics of responders differ from those of non-responders (Bowling, 2005, Levin, 2006). Strategies used in this study to maximise response rate included an email reminder, together with the use of a cover letter, to increase engagement and highlight the importance of the study (Bowling, 2009).

An anonymous questionnaire approach was selected, with the aim of maximising participation and facilitating honest responses about practice. A higher quality of data and greater disclosure have been reported with anonymous surveys, especially topics of a sensitive nature (Bowling, 2005, De Vaus et al., 2013, Mutepfa and Tapera, 2019). These were important considerations in this study. The UK PICU physiotherapy community is small and individual physiotherapists may have been identifiable through combinations of demographics and characteristics. Additionally, an anonymous strategy avoided concerns from

participants regarding judgement of practice by the researcher or other physiotherapists.

An electronic questionnaire was used in this study. This approach is more popular than traditional methods due to lower costs, being more user and environmentally friendly, reduced measurement error and faster data processing (Boynton and Greenhalgh, 2004, Mutepfa and Tapera, 2019). Furthermore, functionalities within electronic survey platforms provide greater control over how participants complete the questionnaire, ensuring questions are not skipped. This prevents item non-response which is a common limitation with postal/paper methods (Bowling, 2009). An advantage of traditional methods, which include postal and telephone administration, is reduced demographic discrepancies resulting in greater representation (Mutepfa and Tapera, 2019). Electronic methods require access to an appropriate device on which to complete the questionnaire and technological literacy. Whilst these factors may require consideration in international studies involving low-middle income countries or those including the public or patients, this was less of a concern in this study. All participants had equitable access to technology through their work and similar levels of education, given that they were qualified physiotherapists. It is more straightforward to generate anonymous data using an electronic questionnaire, which was a key component of this study.

### **3.2.2 Sample**

Physiotherapists from all 27 UK NHS paediatric intensive care units were invited to participate (PICANet, 2021) (Appendix 5). The precise number of physiotherapists was unknown, but it was estimated from a prior small benchmarking study, in which 33 whole-time-equivalent qualified physiotherapists were identified across seven sites, providing an average of four per site. Extrapolating this for the 27 UK PICUs gave an estimated population of 108 UK paediatric intensive care physiotherapists. The whole population was used as the sample.

#### *3.2.2.1 Inclusion criteria*

Full or part time, static or rotational, qualified physiotherapists working in a UK NHS PICU.

### *3.2.2.2 Exclusion criteria*

Physiotherapists who only work in paediatric intensive care as part of on-call/emergency overnight or weekend shifts.

### **3.2.3 Recruitment**

The lead physiotherapist for each PICU was contacted directly via email. The researcher's clinical role provided access to contact details and the study was regarded as legitimate interest for GDPR. The lead physiotherapists were invited to participate and asked to disseminate the study invitation to all physiotherapists who met the study inclusion criteria. The study invitation included a participant information sheet (Appendix 6) and a link to the electronic questionnaire. The participant information sheet included study details, confidentiality and data protection information, funding sources, and study personnel contact details. The lead physiotherapists were also asked to inform the researcher, via email, of the number of physiotherapists the invitation was sent to, allowing calculation of an approximate response rate.

On distribution of the invitation the electronic questionnaire link remained active for eight weeks and a reminder email was sent to each lead physiotherapist after four weeks.

### **3.2.4 Data collection**

A bespoke, anonymous, electronic questionnaire was developed in SmartSurvey™. This package was chosen due to its competitive cost, question features and well-designed participant interface.

Due to the specific research questions and lack of existing instrument, a bespoke questionnaire was created. An advisory group involving five experienced respiratory physiotherapists was used to guide the initial development. This was in conjunction with input from the research team, who included experts in paediatric intensive care, respiratory physiotherapy and mixed methods research. See Appendix 7 for a pre-pilot text version of the survey.

The questionnaire was piloted with seven paediatric physiotherapists, who were not eligible for inclusion in the final sample. This was in line with the recognised

guideline of 5-20% of the intended sample size (Gearing et al., 2006, Braun et al., 2021). Adjustments were made to improve clarity, language and layout, with ambiguous questions being modified.

The final questionnaire included 21 questions across four domains: demographic information, chest physiotherapy treatments, decisions regarding delivery of treatment and instability and adverse events. Due to the anonymous nature of the questionnaire only basic demographic information was collected. This included geographical region and years of PICU experience of the participant, and the diagnoses encountered on the unit.

A variety of question types were included to maintain participant engagement (De Vaus et al., 2013). The majority (16/21) were closed questions to prevent leading of participants, minimise non-response and reduce the time required to complete the questionnaire (Boynton and Greenhalgh, 2004, De Vaus et al., 2013). Participants were provided with the opportunity to expand further by the inclusion of a free text box with each question.

A combination of dichotomous, multiple choice and 5-point Likert scale questions were used. Likert scales are a psychometric tool which are simple to construct and can produce reliable responses (Taherdoost, 2019). There is debate between authors regarding the optimum number of points, with scales ranging from 2 to 11. A 5-point Likert scale was chosen for this survey, as shorter scales have been reported to be easier to use, whilst having similar criterion validity to longer scales (Taherdoost, 2019). The 5-point structure aligned with the specific measurements required of confidence and frequency. Vignettes were also included to give context and facilitate responses regarding clinical scenarios. Open questions, using free text responses, were kept to a minimum (5/21) and used predominantly for items related to clinical decision making. Figure 3.1 displays example questions as viewed by participants. See Appendix 8 for the final text version of the survey.

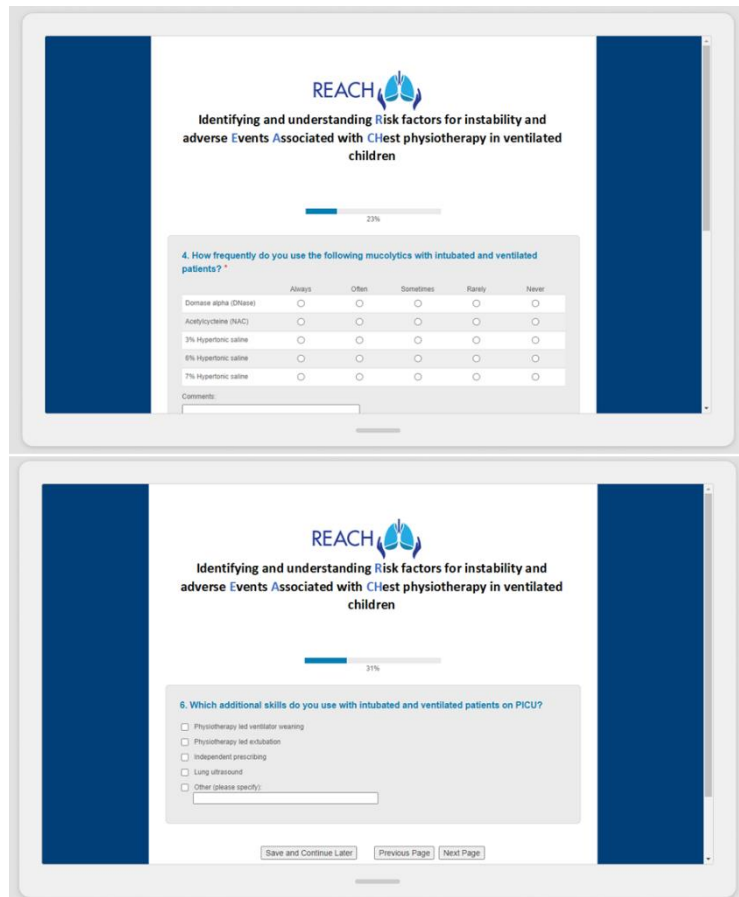


Figure 3.1 Examples of electronic survey display

### 3.2.5 Data security

SmartSurvey™ allowed anonymous responses, ensuring data were non-identifiable. Data were stored and backed up on UK/EU based servers, which were fully compliant with EU privacy laws and General data protection regulation (GDPR) and registered under the Data Protection Act 2018.

### 3.2.6 Consent

Consent was implied if a completed questionnaire was submitted. This is an accepted method for acknowledging consent with questionnaires and was described in the information sheet.

### 3.2.7 Data analysis

The anonymous questionnaire results were downloaded directly into MS Excel from SmartSurvey™. Data were in the form of raw values per question, with each

participant identifiable by a unique number which was automatically generated. The data pertaining to the quantitative results were transferred into SPSSv27 statistical software (IBM Corp, Chicago, Illinois, USA).

#### *3.2.7.1 Quantitative data*

Data were analysed using SPSSv27 statistical software. Frequency counts and percentages were used for nominal and ordinal data. Post-hoc subgroup analysis, including geographical region and years of experience, was completed using Fisher's exact test. This non parametric test was chosen due to small cell counts, including some with expected value of  $< 5$ . Statistical significance was set at  $p < 0.05$ . Given the post-hoc nature of this analysis Fisher's exact test was used to determine statistically significant associations between the categorical variables from an overarching perspective. The test does not provide data related to the direction of effect or specific differences, therefore this interpretation is provided as a descriptive narrative alongside each result. Quantitative data were displayed using Visual Individual Likert Data (VILD) charts (Wray and Oldham, 2020).

#### *3.2.7.2 Qualitative data*

Data collected from free text responses were analysed using inductive content analysis (Elo and Kyngäs, 2008, Hsieh and Shannon, 2005). Content analysis allows subjective interpretation of text data through a systematic classification process of coding and identifying categories or patterns (Hsieh and Shannon, 2005, Powers and Knapp, 2006). Using an inductive approach, coded categories are derived directly from the data and advantages include flexibility and a content-sensitive approach (Banning, 2008). In addition to description, content analysis can include quantitative counts of the codes (Vaismoradi et al., 2013). Inductive content analysis is generally used to describe phenomena with limited existing literature, providing rationale for its use in this study (Hsieh and Shannon, 2005). The structured, replicable approach and option to include a quantitative component to fit alongside the other questionnaire results were also factors in its selection. Content analysis has three phases: preparation, organisation and reporting, see Figure 3.2 (Elo and Kyngäs, 2008).

During the preparation phase the primary researcher immersed herself within the data by collating and repeatedly reading the text responses, ensuring familiarisation. Data for each question were then coded, by highlighting words/phrases from the text that captured key thoughts or concepts. These codes were grouped, and categories generated. For each question, a description and interpretation of the categories were created. The frequency of the codes was also counted. Text data and initial codes were reviewed by a second coder for face validity (JW). The qualitative results are presented using illustrative quotes, including the participant ID number.

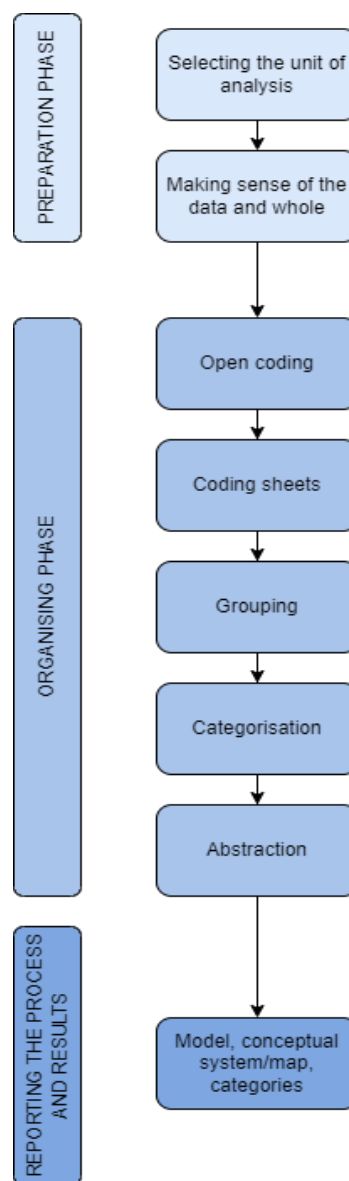


Figure 3.2 Preparation, organisation and resulting phases in the inductive content analysis process

(Adapted from Elo and Kyngas, 2007)

### **3.3 Results**

#### **3.3.1 Response rate**

Twenty-six of the 27 (96%) UK PICUs responded. Based on lead physiotherapist feedback the questionnaire link was disseminated to 118 physiotherapists. Seventy-two completed questionnaires were submitted, providing a response rate of 61% (72/118). Data were collected between 29th July 2020 and 8th February 2021.

#### **3.3.2 Missing data**

Only one question was not completed by all the participants (Question 6, Appendix 8). This question related to extended-scope skills. As 'none of the above' was not a response option, it is possible that those who did not complete the question had no extended-scope skills to report.

#### **3.3.3 Demographics**

Physiotherapists from all regions of the UK participated. Due to the anonymous nature of the survey geographical data were collected in broad geographical regions only and hence are presented accordingly (Figure 3.3). The proportion of participants from each region closely matched the geographical spread of PICUs in the UK (Table 3.1). All participants reported providing chest physiotherapy assessment and treatment to mechanically ventilated children. All but one physiotherapist reported that their PICU had access to an overnight and weekend service



Table 3.1 Comparison of geographical spread of PICUs and proportion of participants

Region	PICUs in region, n (%)	Participants in region, n (%)
East Anglia, South East and Greater London	11 (40.7)	31 (43.1)
Midlands	5 (18.5)	14 (19.4)
Scotland, Northern Ireland, and North East	5 (18.5)	11 (15.3)
North West, Yorkshire and The Humber	4 (14.8)	9 (12.5)
Wales and South West	2 (7.4)	7 (9.7)

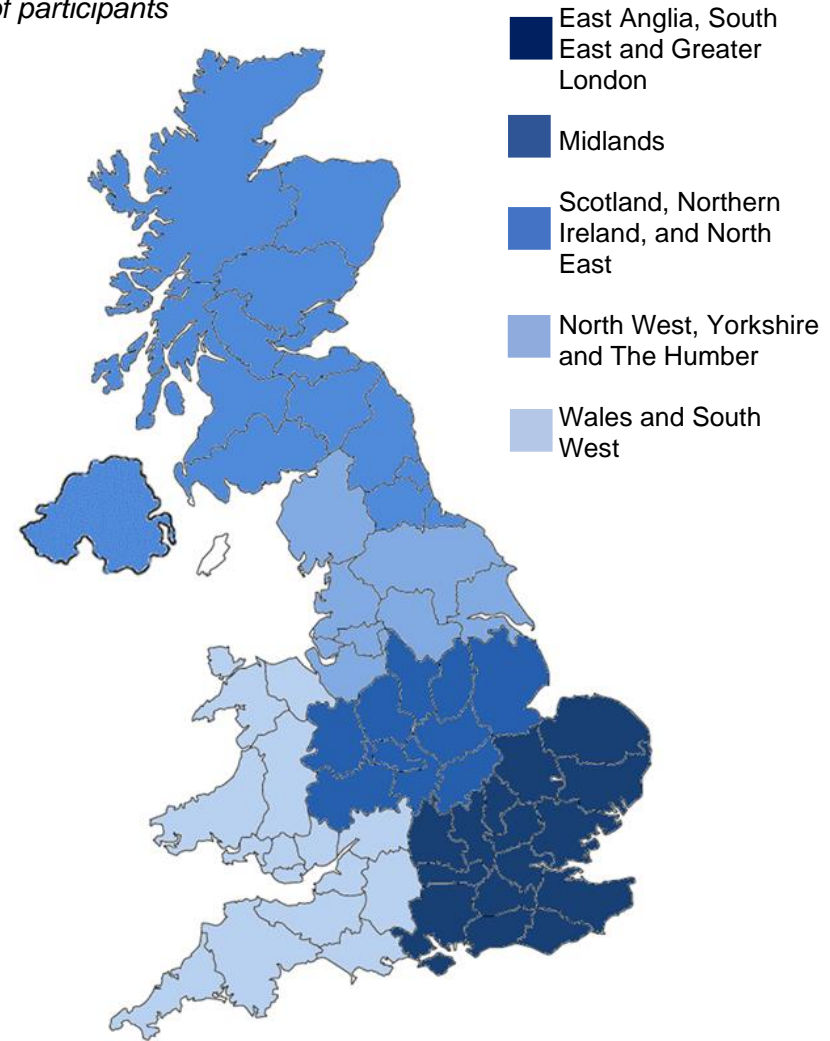
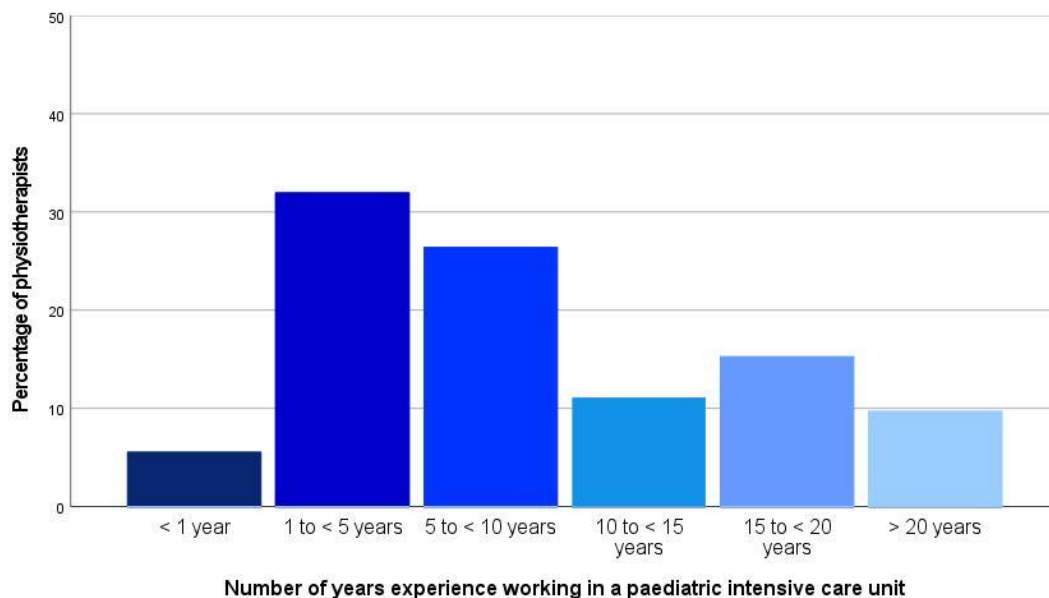


Figure 3.3 Map display of regions

Physiotherapists ranged in years of PICU experience (Figure 3.4), with the highest proportion (23/72, 32%) reporting 1 to < 5 years of experience. Five physiotherapists (10%) had > 20 years of experience.



*Figure 3.4 Years of PICU experience of participating physiotherapists*

Wales/South-West and East Anglia/South-East/Greater London had the highest proportion of physiotherapists with fewer than five years of experience (Table 3.2). The Midlands region had the highest percentage of participants with over 20 years of PICU experience, although this was not statistically significantly different from the other regions ( $p=0.247$ ).

Table 3.2 Comparison of region and years of PICU experience

Region	Years of experience working in a PICU, n (%)					
	< 1 year	1 to 5 years	5 to < 10 years	10 to < 15 years	15 to < 20 years	>20 years
East Anglia, South East and Greater London	2 (7)	14 (45)	6 (19)	3 (10)	3 (10)	3 (10)
Midlands	1 (7)	3 (21)	5 (36)	1 (7)	1 (7)	3 (21)
Scotland, Northern Ireland, and North East	1 (9)	1 (9)	4 (36)	2 (18)	3 (27)	0
North West, Yorkshire and The Humber	0	1 (11)	3 (33)	1 (11)	4 (44)	0
Wales and South West	0	4 (57)	1 (14)	1 (14)	0	1 (14)

(Fishers exact,  $p=0.247$ )

When asked about case-mix 70/72 (97%) physiotherapists reported that patients with a respiratory diagnosis were admitted to their PICU. Figure 3.5 displays the range of patient diagnoses reported by physiotherapists. Additional diagnoses reported in the comment box were liver transplant, burns/plastics, haematology/oncology and neuromuscular.

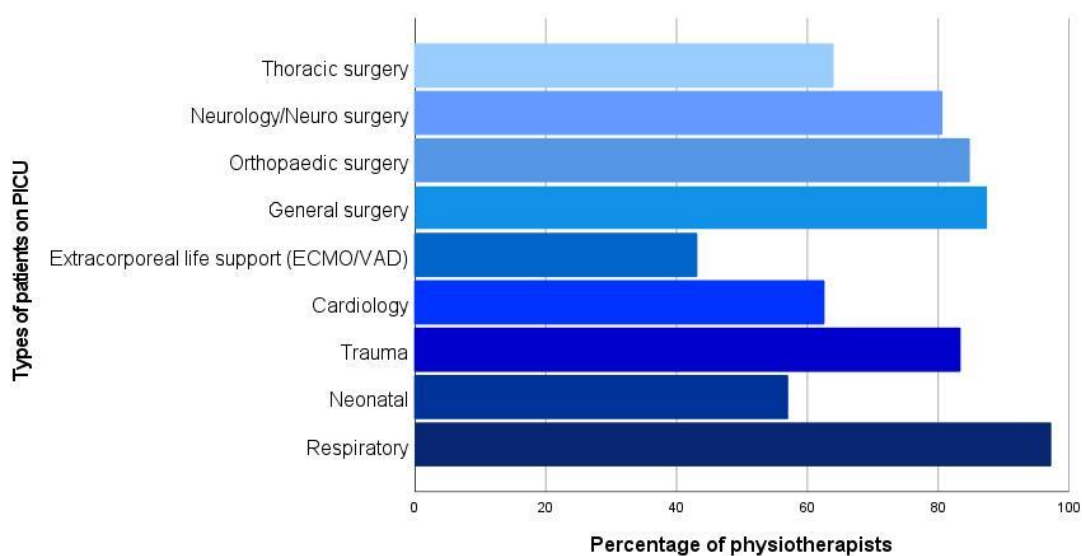


Figure 3.5 Diagnoses of patients admitted to PICU as reported by physiotherapists

(ECMO – Extracorporeal membrane oxygenation, VAD – Ventricular assist device, PICU – Paediatric intensive care unit)

### 3.3.4 Chest physiotherapy practice

#### 3.3.4.1 Delivery of chest physiotherapy

When the physiotherapists were asked how they usually deliver chest physiotherapy the most common approach was in conjunction with the bedside nurse (48/72, 67%). Nineteen (26%) physiotherapists preferred to treat alone, whilst five (7%) reported treating with another physiotherapist. There were statistically significant regional variations in the delivery of chest physiotherapy (Table 3.3). Physiotherapists from Scotland, Northern Ireland and the North East reported only treating with the bedside nurse (Fishers exact,  $p=0.026$ ). No physiotherapists with < 1 year of experience reported treating independently. There were no other relationships between delivery of treatment and years of PICU experience (Appendix 9).

*Table 3.3 Physiotherapist preferences for delivery of chest physiotherapy by geographical region*

Region	Delivery of chest physiotherapy, n (%)		
	Alone	With bedside nurse	With another physiotherapist
East Anglia, South East and Greater London	12 (38)	18 (58)	1 (3)
Midlands	5 (36)	6 (43)	3 (21)
Scotland, Northern Ireland, and North East	0	11 (100)	0
North West, Yorkshire and The Humber	1 (11)	7 (78)	1 (11)
Wales and South West	1 (14)	6 (86)	0

(Fishers exact,  $p=0.026$ )

The physiotherapists who treated alone were asked when they would treat with another person. Three themes were derived from the content analysis of free text responses. Physiotherapists reported practical reasons for needing two people to deliver chest physiotherapy. These included the patient's size, specific

procedures, or an awake patient who might respond unpredictably, as illustrated in the following quotes:

*“If the patient is large and paralysed and so needs one person to vib and the other to bag/suction” (#20)*

*“If the patient was quite active or minimally sedated and there was a risk to the ETT I would seek a second pair of hands” (#30)*

The second reason for treating with another person was for teaching and supervision purposes. The final theme included patients perceived to be medically unstable or more critically unwell, where greater efficiency was required, illustrated by the quotes below:

*“An unstable patient – where you want to minimise disconnection time or to allow multiple things to happen at once, e.g. HFOV, position change, turn, filter change.” (#11)*

*“Children on HFOV will usually be treated in pairs, to prevent the need to keep going back on to HFOV in between MHI/suction” (#24)*

#### 3.3.4.2 Chest physiotherapy treatments

*A variety of treatments were used with intubated and ventilated children (*

Figure 3.6). MHI and position changes were used ‘always’ or ‘often’ by all participants. Most physiotherapists used ETT saline instillation (65/72, 90%) and CWV (64/72, 89%) ‘always’ or ‘often’. Treatments consistently used ‘never’ or ‘rarely’ included intrapulmonary percussive ventilation (67/72, 93%), Metaneb (63/72, 88%), high frequency chest wall oscillation (60/72, 83%) and physiotherapy assisted bronchoscopy (57/72, 79%). There was greater variation in the use of other treatments including closed ETT suction, chest wall decompression, manual insufflation/exsufflation and percussion (Figure 3.7). Seven participants provided additional treatments, these included manual assisted cough, manual autogenic drainage, and overpressures. Two physiotherapists

reported adaptations due to COVID19, including the use of closed suction and avoiding ventilator disconnection.



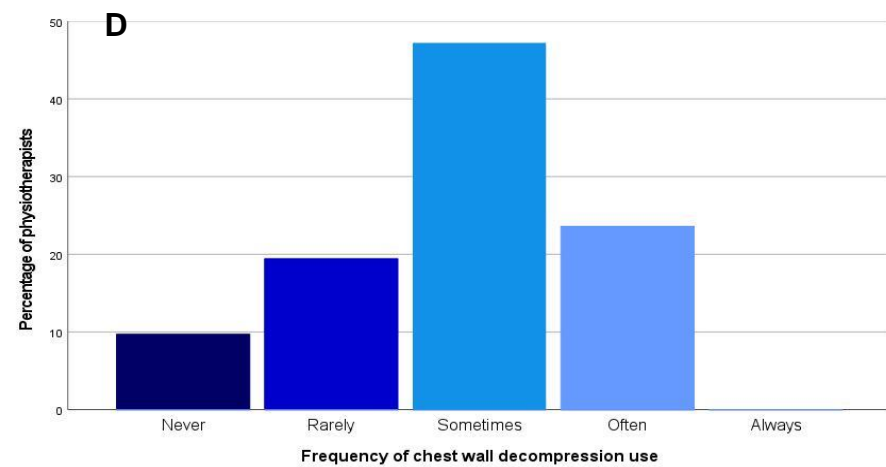
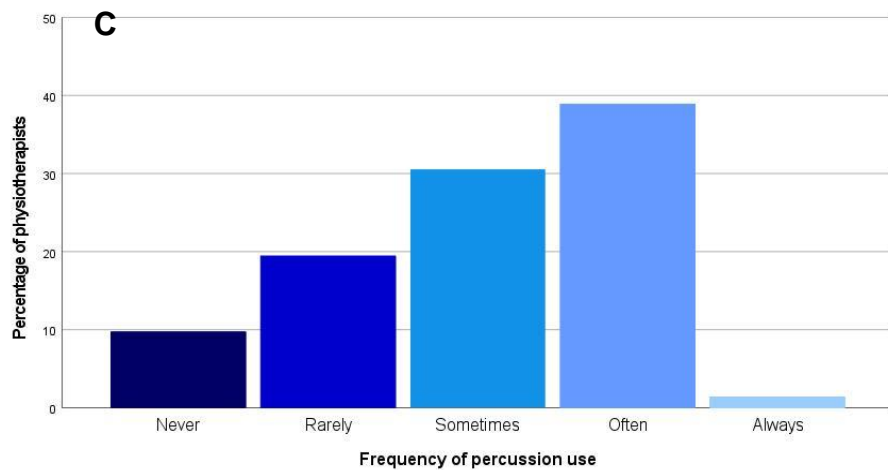
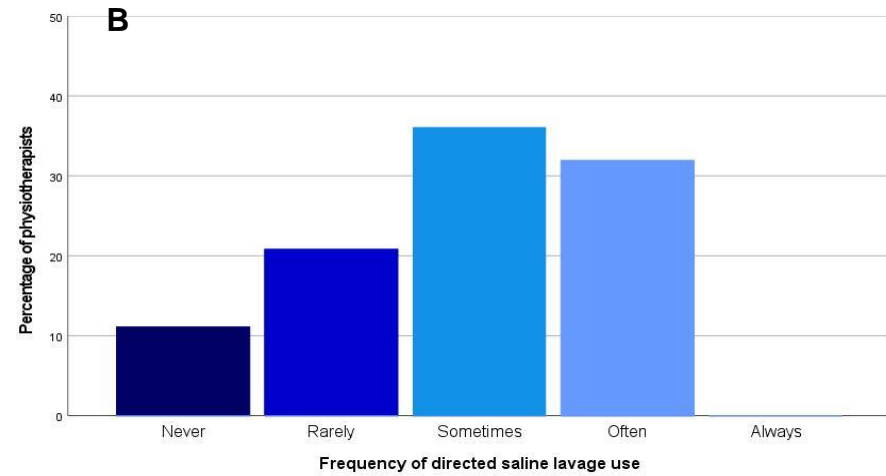
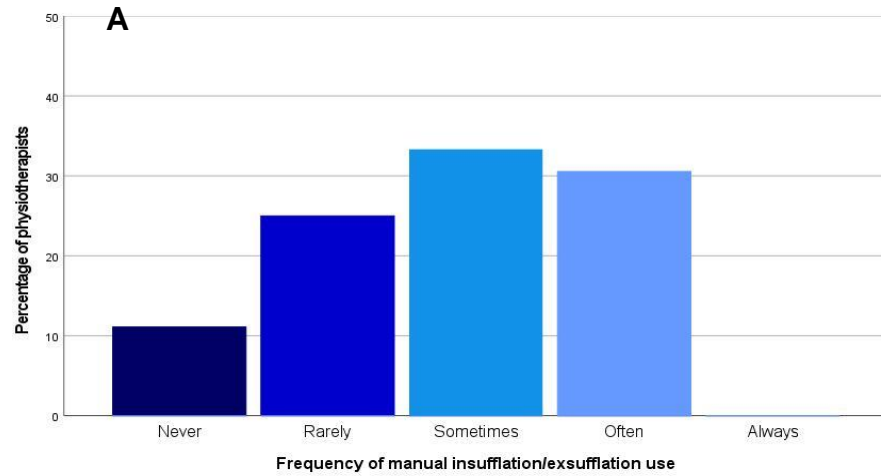


Figure 3.7 Frequency of use of chest physiotherapy treatments

(Treatments which demonstrated variation, A – Manual insufflation/exsufflation, B – Directed saline lavage, C – Percussion, D – Chest wall decompression)



The Visual individual Likert data chart grouped by geographical region is displayed in Figure 3.8. Chest wall vibrations and closed suction were used less frequently by physiotherapists in Scotland, Northern Ireland, and the North East when compared to the other regions (Table 3.4 and 3.5 respectively). Although these physiotherapists used Metaneb more frequently (Table 3.6). Percussion was used less frequently by physiotherapists in the North West, Yorkshire and the Humber, and Wales and South West (Table 3.7). Physiotherapists from the Midlands reported using HFCWO more frequently than physiotherapists from the other regions (Table 3.8) and ETT saline instillation less frequently (Table 3.9). Further statistically significant differences were reported in the use of MHI and IPV, however these were not of clinical significance (Appendix 10). There were no statistically significant differences in use of the remaining 10 treatments (Appendix 10).



Table 3.4 Frequency of use of chest wall vibrations by geographical region

Region	Frequency of use of chest wall vibrations, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	0	0	1 (3)	26 (84)	4 (13)
Midlands	0	1 (7)	1 (7)	12 (86)	0
Scotland, Northern Ireland, and North East	2 (18)	0	2 (18)	6 (55)	1 (9)
North West, Yorkshire and The Humber	0	0	1 (11)	8 (89)	0
Wales and South West	0	0	0	4 (57)	3 (43)

(Fishers exact,  $p=0.029$ )

Table 3.5 Frequency of use of closed ETT suction by geographical region

Region	Frequency of use of closed ETT suction, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	0	7 (23)	3 (10)	11 (35)	10 (32)
Midlands	0	8 (57)	2 (14)	3 (21)	1 (7)
Scotland, Northern Ireland, and North East	0	4 (36)	7 (64)	0	0
North West, Yorkshire and The Humber	0	1 (11)	4 (44)	3 (33)	1 (11)
Wales and South West	0	1 (14)	5 (71)	0	1 (14)

(Fishers exact,  $p<0.0001$ , ETT – Endotracheal tube)

Table 3.6 Frequency of use of Metaneb by geographical region

Region	Frequency of use of Metaneb, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	28 (90)	3 (10)	0	0	0
Midlands	8 (57)	5 (36)	1 (7)	0	0
Scotland, Northern Ireland, and North East	4 (36)	1 (9)	4 (36)	2 (18)	0
North West, Yorkshire and The Humber	7 (78)	0	2 (22)	0	0
Wales and South West	7 (100)	0	0	0	0

(Fishers exact,  $p<0.0001$ )

Table 3.7 Frequency of use of percussion by geographical region

Region	Frequency of use of percussion, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	1 (3)	6 (19)	9 (29)	14 (45)	1 (3)
Midlands	0	0	6 (43)	8 (57)	0
Scotland, Northern Ireland, and North East	4 (36)	2 (18)	0	5 (45)	0
North West, Yorkshire and The Humber	2 (22)	2 (22)	4 (44)	1 (11)	0
Wales and South West	0	4 (57)	3 (43)	0	0

(Fishers exact,  $p=0.01$ )

Table 3.8 Frequency of use of HFCWO by geographical region

Region	Frequency of use of HFCWO, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	16 (52)	10 (32)	4 (13)	1 (3)	0
Midlands	5 (36)	4 (29)	3 (21)	2 (14)	0
Scotland, Northern Ireland, and North East	9 (82)	0	2 (18)	0	0
North West, Yorkshire and The Humber	8 (89)	1 (11)	0	0	0
Wales and South West	2 (29)	5 (71)	0	0	0

(Fishers exact,  $p=0.033$ , HFCWO – High frequency chest wall oscillation)

Table 3.9 Frequency of use of ETT saline instillation by geographical region

Region	Frequency of use of ETT saline instillation, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	0	0	0	28 (90)	3 (10)
Midlands	0	4 (29)	1 (7)	9 (64)	0
Scotland, Northern Ireland, and North East	0	0	2 (18)	8 (73)	1 (9)
North West, Yorkshire and The Humber	0	0	0	9 (100)	0
Wales and South West	0	0	0	6 (86)	1 (14)

(Fishers exact,  $p=0.013$ , ETT – Endotracheal tube)

There was a trend of more frequent use of physiotherapy assisted bronchoscopy by participants with greater PICU experience (Table 3.10). Directed saline lavage was used more frequently by physiotherapists with 1 to < 5 years of experience and those with > 10 years of experience ( $p=0.039$ ) (Table 3.11). There were no relationships with years of experience for the remaining treatments (Appendix 11).

*Table 3.10 Frequency of use of physiotherapy assisted bronchoscopy by years of PICU experience*

Years of PICU experience	Frequency of use of bronchoscopy, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	4 (100)	0	0	0	0
1 to < 5 years	9 (39)	12 (52)	2 (9)	0	0
5 to < 10 years	11 (58)	4 (21)	4 (21)	0	0
10 to < 15 years	5 (63)	1 (13)	2 (25)	0	0
15 to < 20 years	2 (18)	4 (36)	4 (36)	1 (9)	0
> 20 years	3 (43)	2 (29)	0	2 (29)	0

(Fishers exact,  $p=0.025$ )

*Table 3.11 Frequency of use of directed saline lavage by years of PICU experience*

Years of PICU experience	Frequency of use of directed saline lavage, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	3 (75)	0	1 (25)	0	0
1 to < 5 years	1 (4)	4 (17)	9 (39)	9 (39)	0
5 to < 10 years	2 (11% (2)	8 (42)	7 (37)	2 (11)	0
10 to < 15 years	1 (13)	1 (13)	1 (13)	5 (63)	0
15 to < 20 years	1 (9)	1 (9)	4 (36)	5 (46)	0
> 20 years	0	1 (14)	4 (57)	2 (29)	0

(Fishers exact,  $p=0.039$ )

### 3.3.4.3 Use of mucoactive agents

All physiotherapists reported using at least one mucoactive agent, with 67/72 (93%) using at least three different agents. Three percent hypertonic saline, 7% hypertonic saline and DNase were the most frequently used (Figure 3.9). Three percent hypertonic saline was used 'always' or 'often' by 41/72 (57%) physiotherapists, 7% hypertonic saline by 32/72 (44%) and DNase by 18/72 (25%). Six percent hypertonic saline was used 'never' or 'rarely' by 76% (55/72) of physiotherapists, with three reporting that it was not stocked at their hospital.

There was regional variation in the frequency of use of 3% hypertonic saline, DNase, and N-acetylcysteine (NAC) (Figure 3.9). Physiotherapists in the Midlands reported using 3% hypertonic saline more frequently than those from other regions, with 93% (13/14) using it 'often' ( $p < 0.0001$ ) (Table 3.12). DNase was used more frequently by physiotherapists in Scotland, Northern Ireland, and the North-East, compared to the other regions ( $p = 0.02$ ) (Table 3.13). NAC was used less frequently by physiotherapists from the North-West, Yorkshire and The Humber ( $p = 0.021$ ) (Table 3.14). No regional differences were observed in frequency of use of 6% and 7% hypertonic saline (Appendix 12).



Table 3.12 Frequency of use of 3% hypertonic saline by geographical region

Region	Frequency of use of 3% hypertonic saline, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	1 (3)	1 (3)	7 (23)	20 (65)	2 (7)
Midlands	0	1 (7)	0	13 (93)	0
Scotland, Northern Ireland, and North East	1 (9)	4 (36)	5 (46)	1 (9)	0
North West, Yorkshire and The Humber	1 (11)	1 (11)	2 (22)	5 (56)	0
Wales and South West	2 (29)	3 (43)	2 (29)	0	0

(Fishers exact,  $p < 0.001$ )

Table 3.13 Frequency of use of DNase by geographical region

Region	Frequency of use of DNase, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	1 (3)	5 (16)	22 (71)	3 (10)	0
Midlands	0	0	10 (71)	4 (29)	0
Scotland, Northern Ireland, and North East	0	2 (18)	2 (18)	7 (64)	0
North West, Yorkshire and The Humber	0	4 (44)	2 (22)	3 (33)	0
Wales and South West	0	2 (29)	4 (57)	1 (14)	0

(Fishers exact,  $p = 0.02$ )



Table 3.14 Frequency of use of N-acetylcysteine by geographical region

Region	Frequency of use of N-acetylcysteine, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	9 (29)	12 (39)	9 (29)	1 (3)	0
Midlands	4 (29)	1 (7)	4 (29)	5 (36)	0
Scotland, Northern Ireland, and North East	2 (18)	4 (36)	5 (46)	0	0
North West, Yorkshire and The Humber	5 (56)	2 (22)	2 (22)	0	0
Wales and South West	0	4 (57)	1 (14)	2 (29)	0

(Fishers exact, p=0.021)

NAC was used less frequently by physiotherapists with 15 to < 20 years of experience when compared to the other groups; 64% (7/11) reported 'never' using NAC (p=0.047) (Table 3.15). Seven percent hypertonic saline was used less frequently by physiotherapists with < 1 year of experience and those with 15 to < 20 years of experience, compared to the other groups (p=0.014) (Table 3.16). No differences were observed in subgroup analysis of DNase, 3% or 6% hypertonic saline (Appendix 12).

*Table 3.15 Comparison of years of PICU experience and frequency of use of N-acetylcysteine*

Years of PICU experience	Frequency of use of N-acetylcysteine, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	1 (25)	2 (50)	0	1 (25)	0
1 to < 5 years	1 (4)	9 (39)	11 (48)	2 (9)	0
5 to < 10 years	6 (32)	7 (37)	4 (21)	2 (11)	0
10 to < 15 years	3 (38)	2 (25)	2 (25)	1 (13)	0
15 to < 20 years	7 (64)	1 (9)	3 (27)	0	0
> 20 years	2 (29)	2 (29)	1 (14)	2 (29)	0

(Fishers exact, p=0.047)

*Table 3.16 Comparison of years of PICU experience and frequency of use of 7% hypertonic saline*

Years of PICU experience	Frequency of use of 7% hypertonic saline, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	0	3 (75)	0	1 (25)	0
1 to < 5 years	0	4 (17)	6 (26)	13 (57)	0
5 to < 10 years	0	3 (16)	8 (42)	8 (42)	0
10 to < 15 years	1 (13)	1 (13)	3 (38)	3 (38)	0
15 to < 20 years	4 (36)	3 (27)	0	4 (36)	0
> 20 years	1 (14)	0	3 (43)	3 (43)	0

(Fishers exact, p=0.014)

Nebulisation was the only delivery method used by 96% (26/27) of physiotherapists for 6% hypertonic saline, 92% (60/65) for 7% hypertonic saline,

and 91% (59/65) for 3% hypertonic saline (Table 3.17). Most physiotherapists (49/71, 69%) used DNase in both nebulised and instilled forms. The method of delivery of NAC was inconsistent and demonstrated regional variation.

Table 3.17 Delivery methods of mucoactives

Mucoactive Agent	Nebulised only, n (%)	Instilled only, n (%)	Both, n (%)
DNase	14 (20)	8 (11)	49 (69)
N-acetylcysteine	26 (55)	7 (15)	14 (30)
3% Hypertonic saline	59 (91)	0	6 (9)
6% Hypertonic saline	26 (96)	0	1 (4)
7% Hypertonic saline	60 (92)	1 (2)	4 (6)

(Fishers exact,  $p=0.007$ )

Physiotherapists in Scotland, Northern Ireland and the North-East reported not instilling NAC and very few physiotherapists used instillation in the Midlands (3/14, 21%) ( $p=0.007$ ) (Figure 3.11). There were no geographical differences in relation to the other mucoactives and no differences on subgroup analysis with years of PICU experience (Appendix 13).

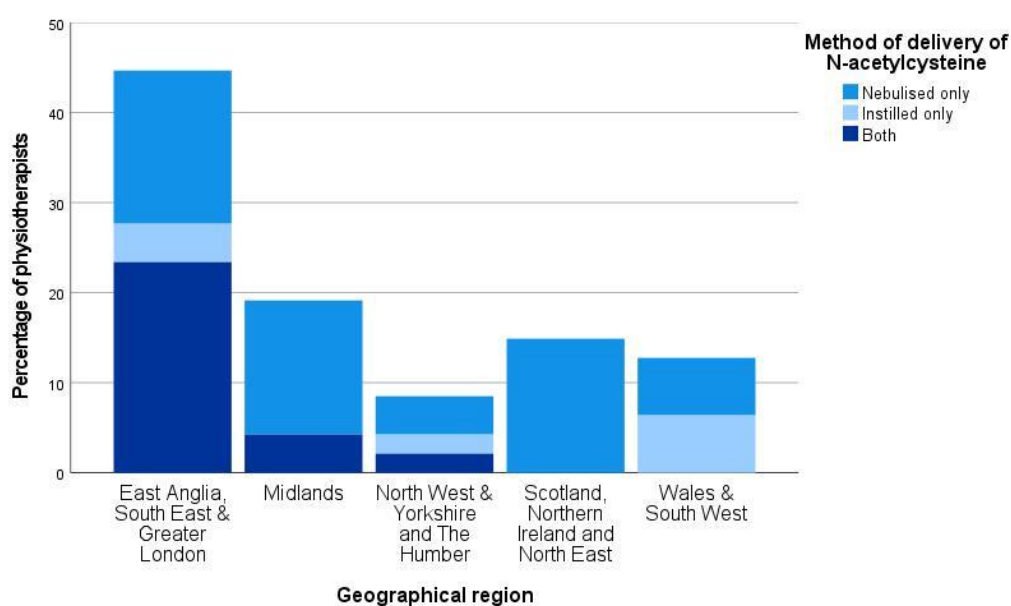


Figure 3.11 Delivery of N-acetylcysteine by geographical region

### 3.3.4.4 Extended scope skills

Thirty-eight (53%) physiotherapists responded to this question. It was presumed the 34 (47%) who skipped it had no extended skills to report. Figure 3.12 displays the number of skills used. Thirty-seven physiotherapists (97%) reported completing ventilator weaning and 45% (17/38) physiotherapy led extubation (Figure 3.13). No relationship between geographical region or years of PICU experience was demonstrated with number of extended-scope skills (Appendix 14). However, all physiotherapists with < 1 year of experience (n=4) reported no extended-scope skills.

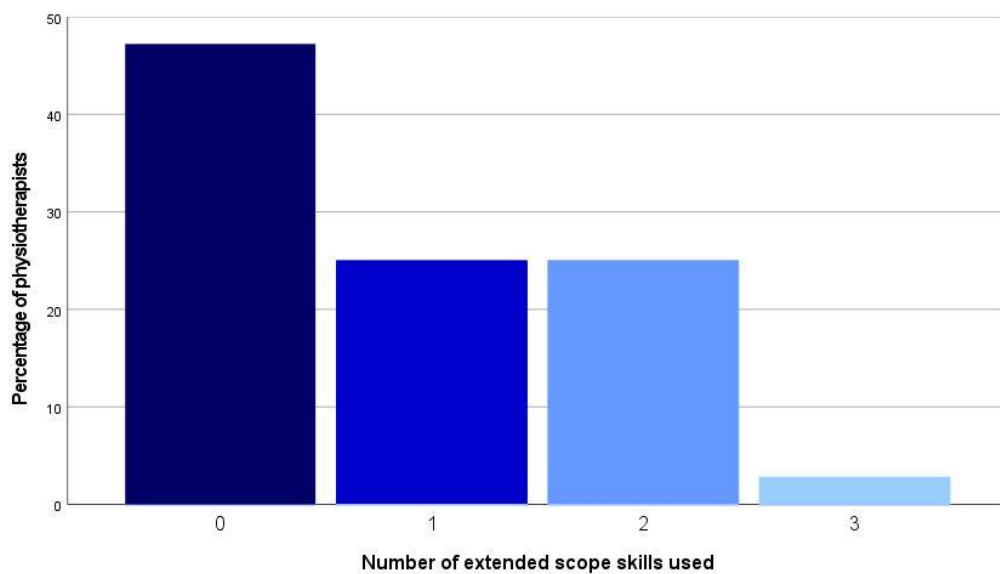


Figure 3.12 Number of extended scope skills used by physiotherapists

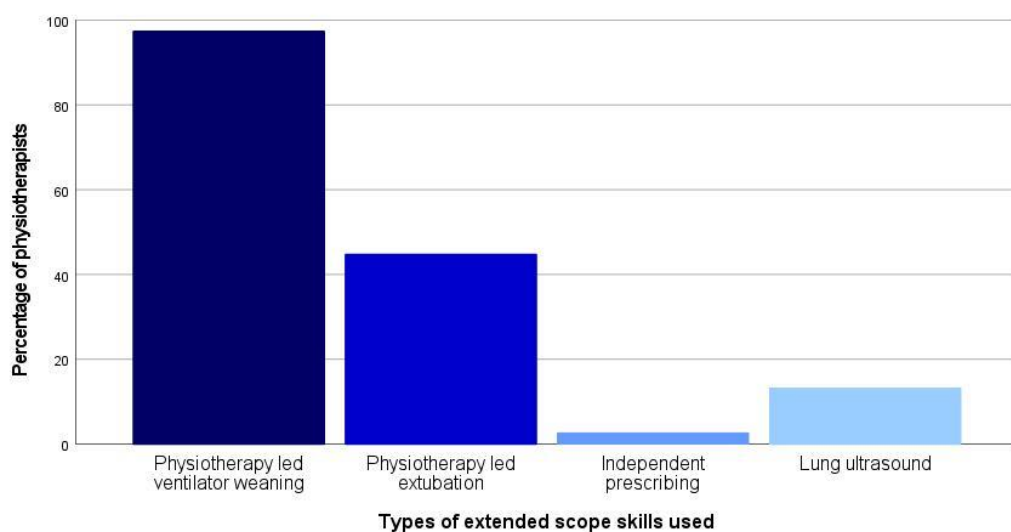


Figure 3.13 The types of extended scope skills used by physiotherapists

### 3.3.5 Clinical decision making

#### 3.3.5.1 Referral processes

Two overarching themes were derived from the content analysis of the free-text responses to question 2: how are intubated and ventilated patients on your PICU referred for physiotherapy? These were first line referral processes and secondary/back-up pathways (Table 3.18). First line pathways were the primary methods used by physiotherapists to determine which patients required chest physiotherapy. Secondary pathways accounted for additional or emergency referrals. This combined approach was described by 78% (56/72) of physiotherapists.

Table 3.18 Content analysis for referral processes

Pathway	Strategies	Number of physiotherapists (%)
First line	Handover/MDT ward round	43 (60)
	Daily screening	21 (29)
	Automatic/routine	14 (19)
	Blanket referral	10 (14)
Secondary	Direct referral from MDT	58 (81)
	Urgent on call referral	15 (21)

(n=72, respondents could offer more than one response. MDT – Multidisciplinary team)

First line referral processes were physiotherapy led and included handovers and MDT ward rounds. Daily screening and automatic/routine referral were also mentioned frequently. These approaches are illustrated in the following quotes:

*“Attending ward round twice a week, open MDT discussions.*

*Daily screening of online notes and imaging” (#16)*

*“Patients within specific subgroups i.e., neuromuscular or SCI automatically seen” (#25)*

Secondary pathways were predominantly direct referrals from the MDT via bleep, telephone, electronic notes or face-to-face. Out of hours referrals were received by bleep or telephone.

### 3.3.5.2 Treatment frequency

The most frequently reported factors that influenced how physiotherapists made decisions about frequency of treatment were individual patient assessment using clinical reasoning and severity of symptoms/clinical presentation (Table 3.19). This is illustrated by the following quote:

*“Based on their clinical need; If the patient is seen in the morning, then the treating therapist will clinically reason how many more times the patient may need seeing throughout the rest of the working day and whether would benefit from on-call physiotherapist reviewing them overnight” (#33)*

*Table 3.19 Content analysis of the factors which influence the frequency of physiotherapy assessment and treatment*

<b>Factors</b>	<b>Number of physiotherapists (%)</b>
Individual assessment/clinical reasoning	55 (76)
Severity of symptoms/clinical presentation	44 (61)
Effectiveness/impact of treatment	36 (50)
Tolerance of treatment	24 (33)
General stability	16 (22)
MDT discussion	13 (18)
Ability of nursing staff to manage secretions	11 (15)
Directed by medical/nursing team	5 (7)
Related to timing of other procedures	5 (7)
Unit practice/protocol	3 (4)
Dependent on staffing levels	2 (3)

(n=72, respondents could offer more than one response. MDT – Multidisciplinary team)

Thirty-eight physiotherapists provided specific symptoms or indicators for treatment, the most common being increased secretion yield or viscosity (36/38, 95%) and CXR changes (14/38, 37%) (Table 3.20).

Table 3.20 Content analysis of clinical symptoms which influence decision making

Symptoms	Number of physiotherapists (%)
Increased secretion yield/viscosity	36 (95)
CXR changes	14 (37)
Ventilation requirements	6 (16)
Oxygenation	5 (13)
Ventilator tidal volume	4 (11)
Arterial blood gas	2 (5)
End tidal carbon dioxide	2 (5)
Weak cough	2 (5)
Increased work of breathing	2 (5)
Due for extubation	2 (5)
Auscultation	1 (3)

(n=38, respondents could offer more than one response. CXR – Chest x-ray)

The child’s response to physiotherapy treatment was also described as a factor, which included both tolerance and effectiveness of the treatment (Table 3.19).

These findings are illustrated in the quotes below:

*“Based on outcome of initial treatment i.e. if successful, safe and beneficial” (#6)*

*“How did they tolerate treatment? If poorly then likely will not do it multiple times” (#54)*

Discussion and liaison with the MDT were stated as contributing to decision making. Physiotherapists also reported that the confidence and effectiveness of the nurse to complete secretion clearance would influence the frequency of their intervention (Table 3.19).

Five key themes were identified from physiotherapists’ responses when asked to outline any patient groups that would not receive chest physiotherapy whilst mechanically ventilated (Table 3.21).

Table 3.21 Content analysis of specific patient groups who do not receive chest physiotherapy

Rationale	Number of physiotherapists (%)
No acute need	32 (44)
Based on individual patient assessment	23 (32)
Specific contra-indications	20 (28)
Too unstable	10 (14)
Risk vs benefit	7 (10)
Asked not to by medics	3 (4)

(n= 72, respondents could offer more than one response)

Physiotherapists stated that, for some patients, there was “no acute need” for treatment. Examples included non-respiratory diagnoses, patients at the end of life, and those with a short period of ventilation. The second theme was that treatment was based on individual assessment, but no specific groups would be avoided, as illustrated below:

*“No blanket rule but would be based on morning screening/handover and physiotherapists clinical reasoning” (#6)*

*“No specific groups – patients very much assessed on an individual basis” (#32)*

Specific contra-indications to chest physiotherapy emerged as the third theme. The most frequently reported were acute haemorrhage, unstable neurology, pneumothorax, cardiovascular system instability and arrhythmias. The final themes were based around a perception of the patient being too unstable for physiotherapy and the need for a risk vs benefit assessment, as described in the following quotes:

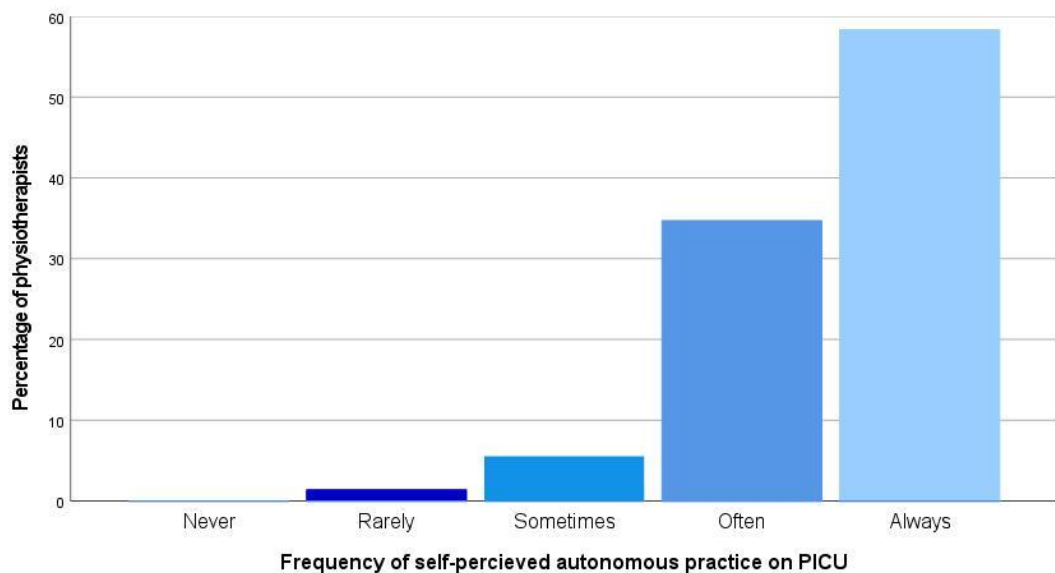
*“Children who are unstable. Benefits of any physio intervention must always outweigh the risk” (#5)*



*“Only when the risk of doing physiotherapy outweighs the risk of not doing it. It’s a balancing act of all the systems” (#12)*

### 3.3.5.3 *Autonomy*

Forty-two physiotherapists (58%) reported that they were ‘always’ able to work as an autonomous practitioner on PICU (Figure 3.14). One participant reported that they worked autonomously only ‘rarely’, this individual had < 1 year of experience (Table 3.22). Physiotherapists with > 10 years of experience felt they had greater levels of autonomy (Table 3.22) ( $p=0.019$ ), with those who had between 10 to < 15 years of experience reporting the most autonomy. There were no relationships between perceived autonomy and geographical regions (Appendix 15).



*Figure 3.14 Perceived frequency of autonomous practice on PICU*

Table 3.22 Comparison between years of PICU experience and self-reported autonomy

Years of PICU experience	Frequency of self-reported autonomy, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	0	1 (25)	1 (25)	0	2 (50)
1 to < 5 years	0	0	2 (9)	12 (52)	9 (39)
5 to < 10 years	0	0	0	9 (47)	10 (53)
10 to < 15 years	0	0	0	1 (13)	7 (88)
15 to < 20 years	0	0	0	2 (18)	9 (82)
> 20 years	0	0	1 (14)	1 (14)	5 (71)

(Fishers exact, p=0.019)

### 3.3.6 Instability and adverse events

#### 3.3.6.1 Monitoring stability

All physiotherapists (n=72) reported using heart rate and SpO<sub>2</sub> to monitor patient stability during chest physiotherapy (Figure 3.15). Blood pressure was used by 99% (71/72) and end tidal carbon dioxide (EtCO<sub>2</sub>) by 97% (70/72) of physiotherapists. Additional variables reported were ventilator parameters, extracorporeal membrane oxygenation (ECMO) flows and observation of the patient including colour, chest movement and work of breathing.

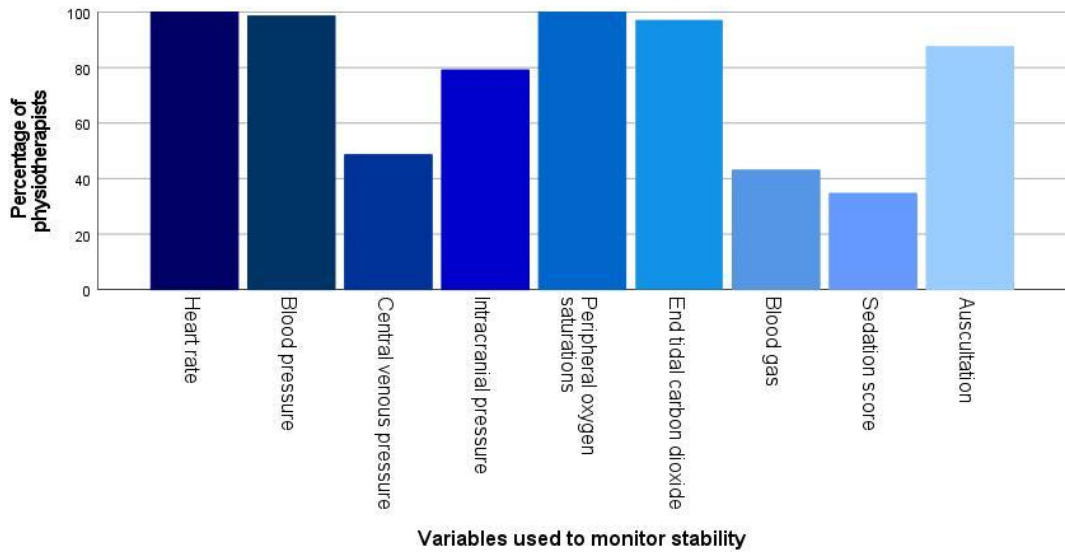


Figure 3.15 Variables used by physiotherapists to monitor the stability of patients during chest physiotherapy

### 3.3.6.2 Reported frequency of instability and adverse events

Physiotherapists reported that the most frequently encountered events during chest physiotherapy were changes in heart rate and blood pressure, and oxygen desaturation (Figure 3.16). Changes in heart rate were reported as occurring ‘always’ or ‘often’ by 78% (56/72) of physiotherapists and changes in blood pressure by 50% (36/72). Twenty-two (31%) physiotherapists reported desaturation occurred ‘often’ during treatment. Free-text comments from the physiotherapists included that changes were “*temporary*”, “*controlled*”, and “*within a normal physiological response*”. All physiotherapists reported that accidental extubation and cardiac or respiratory arrest occurred ‘never’ or ‘rarely’ during treatment.



Physiotherapists with 15 to < 20 years of PICU experience reported less frequent changes in blood pressure during chest physiotherapy ( $p=0.009$ ) (Table 3.23). There was a trend of greater reported incidence of loss of a line or central access with increasing years of PICU experience ( $p=0.018$ ) (Table 3.24). Remaining subgroup analysis demonstrated no statistically significant differences (Appendix 16).

*Table 3.23 Comparison of reported frequency of changes in blood pressure and years of PICU experience*

Years of PICU experience	Frequency of changes in blood pressure, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	0	1 (25)	3 (75)	0	0
1 to < 5 years	0	1 (4)	8 (35)	14 (61)	0
5 to < 10 years	0	0	7 (37)	11 (58)	1 (5)
10 to < 15 years	0	1 (13)	2 (25)	4 (50)	1 (13)
15 to < 20 years	0	10 (91)	1 (9)	0	0
> 20 years	0	3 (43)	4 (57)	0	0

(Fishers exact,  $p=0.009$ )

*Table 3.24 Comparison of reported frequency of loss of a line/central access and years of PICU experience*

Years of PICU experience	Frequency of loss of a line/central access, n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year	4 (100)	0	0	0	0
1 to < 5 years	9 (39)	14 (61)	0	0	0
5 to < 10 years	6 (32)	13 (68)	0	0	0
10 to < 15 years	2 (25)	6 (75)	0	0	0
15 to < 20 years	2 (18)	9 (82)	0	0	0
> 20 years	0	6 (86)	1 (14)	0	0

(Fishers exact,  $p=0.018$ )

### 3.3.6.3 *Management of instability and adverse events*

Physiotherapists reported feeling more confident managing instability compared to adverse events (Figure 3.17). Forty-eight (67%) physiotherapists reported feeling 'completely confident' when dealing with desaturation during chest physiotherapy, whilst 57% (41/72) felt 'completely confident' when faced with a bradycardic infant. In the event of self-extubation, 40% (29/72) of physiotherapists reported feeling 'completely confident'. Twenty-one (29%) physiotherapists reported feeling 'completely confident' managing a cardiac arrest, whilst 13% (9/72) reported 'slight confidence' or 'no confidence' in this situation.



There was a trend of increased confidence managing desaturation, bradycardia and accidental extubation in physiotherapists with greater PICU experience. Twenty-five (96%) physiotherapists with  $\geq 10$  years of experience felt 'completely confident' dealing with desaturation compared to 49% (23/46) of those with  $< 10$  years' experience ( $p < 0.0001$ ) (Figure 3.18). Twenty-three (88%) physiotherapists with  $\geq 10$  years of experience felt 'completely confident' managing bradycardia during chest physiotherapy, compared to 39% (18/48) of those with  $< 10$  years' experience ( $p < 0.002$ ) (Figure 3.19). In the event of accidental extubation 65% (17/26) of physiotherapists with  $\geq 10$  years' experience reported feeling 'completely confident' compared to 24% (11/48) of those with  $< 10$  years' experience ( $p = 0.014$ ) (Figure 3.20). No trends were apparent for confidence managing a cardiac arrest ( $p = 0.503$ ) (Figure 3.21).

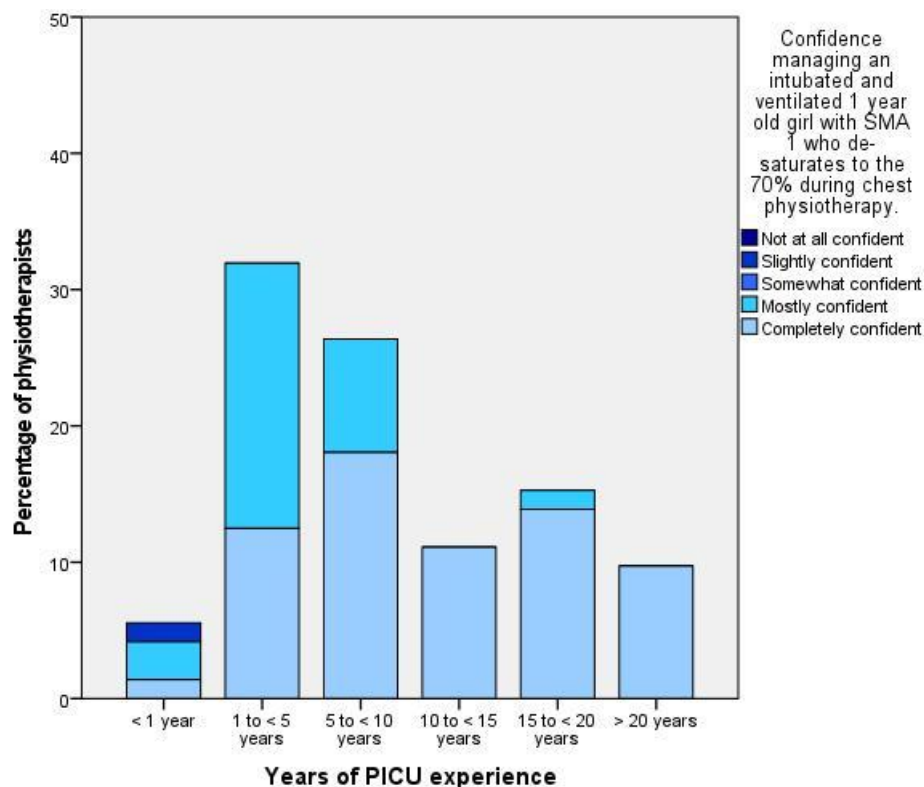


Figure 3.18 Comparison of physiotherapists reported confidence managing desaturation and years of PICU experience



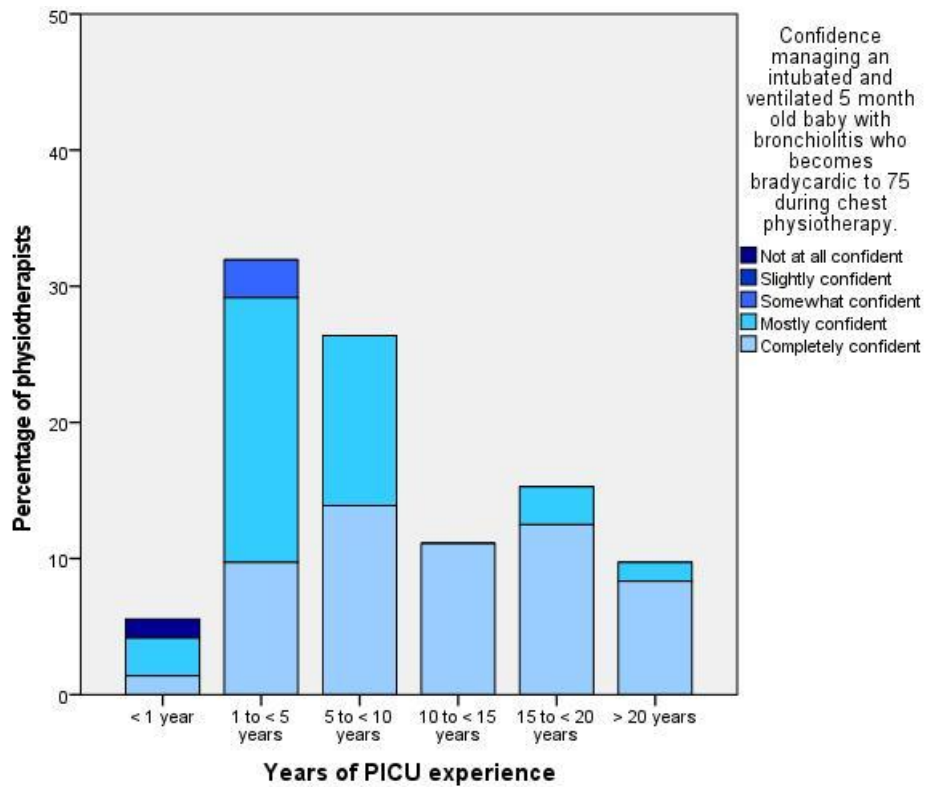


Figure 3.19 Comparison of physiotherapists' reported confidence managing bradycardia and years of PICU experience

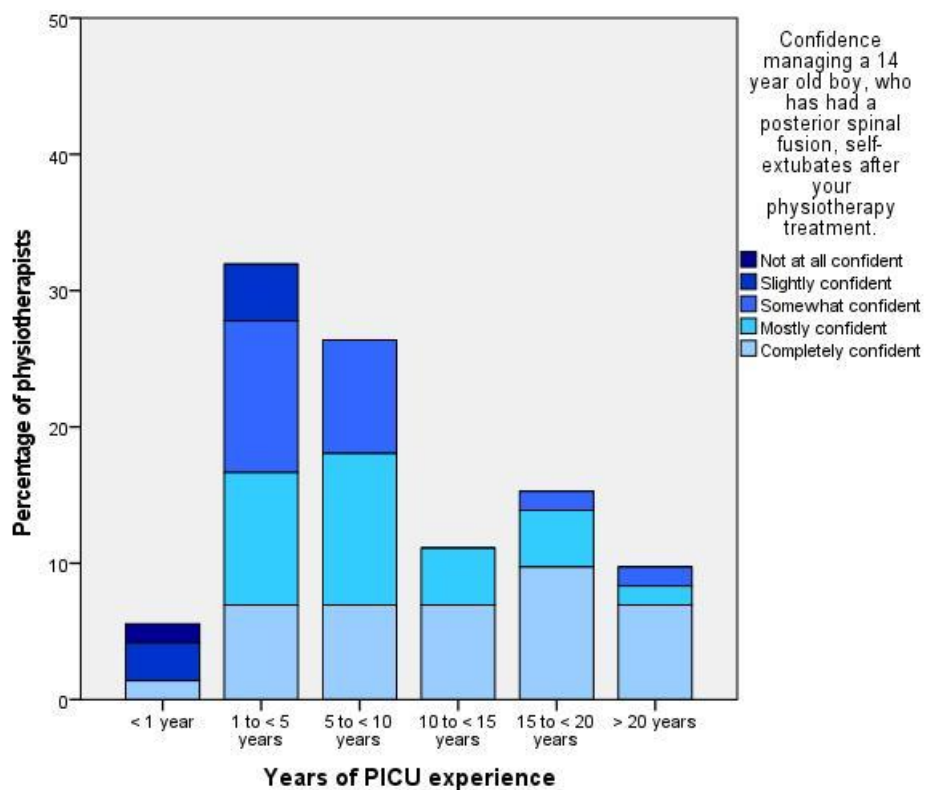


Figure 3.20 Comparison of physiotherapists' reported confidence managing self-extubation and years of PICU experience

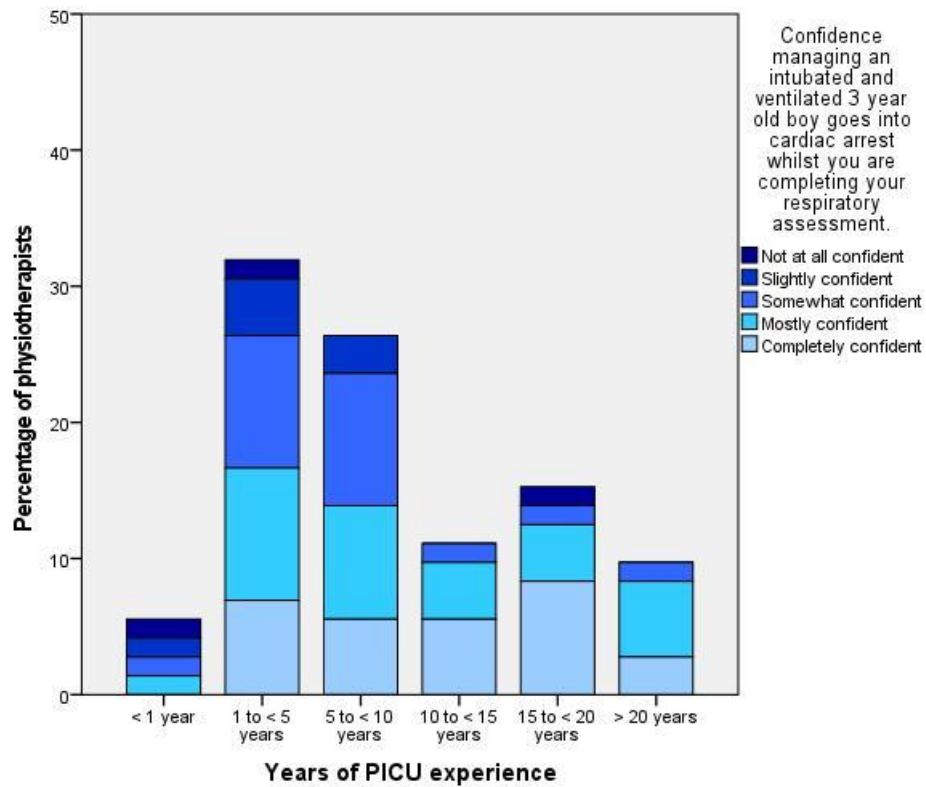


Figure 3.21 Comparison of physiotherapists reported confidence managing a cardiac arrest and years of PICU experience

A variety of management strategies were reported to minimise or prevent instability and adverse events during chest physiotherapy (Table 3.25).

Table 3.25 Content analysis of management strategies used to minimise instability and adverse events during chest physiotherapy

Strategy	Number of physiotherapists (%)
Practical/clinical	66 (92)
Communication/liaison	32 (44)
Senior support/back up	16 (22)
Planning/escalation plan	15 (21)
Thorough assessment	14 (19)
Risk assessment	10 (14)
Pre-defined parameters	6 (8)
Clear roles	4 (6)
Training/competencies	4 (6)
Family role	2 (3)

(n=72, respondents could provide multiple responses)

Practical, clinical strategies were the most commonly reported approach to minimising instability and adverse events (Table 3.25). Specific strategies described by the physiotherapists are displayed in Table 3.26.

*Table 3.26 Content analysis of practical strategies used by physiotherapists to minimise instability and adverse events*

<b>Practical strategies</b>	<b>Number of physiotherapists (%)</b>
Sedation bolus/ensure well sedated	42 (64)
Monitoring throughout	26 (39)
Pre-oxygenation	26 (39)
Time efficiency	11 (17)
Treat with a second person	9 (14)
Ensure other medication/products available	9 (14)
Ensure security of lines/ETT	8 (12)
Minimise disconnection	6 (9)
Use of manometer for MHI	4 (6)
Timing with turns/cares	4 (6)
Use of recruitment maneuverer	4 (6)
Measure suction catheter	2 (3)
Clamp ETT	2 (3)
Swaddle	2 (3)

(n=66, respondents could provide multiple responses. ETT – Endotracheal tube)

The necessity for effective communication and appropriate liaison with the multidisciplinary team was frequently reported by the physiotherapists (Table 3.25). This linked to having quick access to more senior support, as illustrated by the quotes below:

*“Regular discussion with bedside nurse and Dr’s re: stability, response to handling or disconnection” (#27)*

*“Always liaise with the medical team prior to any treatment. If patients are particularly unstable ensure that medics are present during treatment” (#38)*

Preparation of an action plan in the event of instability or an adverse event was also discussed by the physiotherapists, as illustrated in the following quote:

*“Awareness of where treatment could go with each patient.  
Preparation of the bed space with emergency equipment” (#55)*

### **3.3.7 Summary of results**

The key findings which will be discussed in the next section are summarised below.

- Manual hyperinflations, chest wall vibrations, ETT saline instillation and positioning were the most frequently used treatments
- Mucoactive agents as an adjunct to physiotherapy were used by all physiotherapists, with 3% and 7% hypertonic saline most popular.
- Variation in practice was apparent, related to personnel involved in chest physiotherapy, some techniques, and the frequency and delivery method of NAC
- Decisions regarding treatment were based on individual patient assessment and severity of clinical symptoms. Physiotherapists also considered the effectiveness and tolerance of treatment, completing a risk versus benefit analysis.
- Physiotherapists reported high levels of autonomy, which was linked to increasing experience.
- Adverse events were reported as occurring infrequently.
- Practical strategies were the main approach described for management of instability and adverse events including sedation, close monitoring and pre-oxygenation.

## **3.4 Discussion**

This section will discuss the key findings of the questionnaire in relation to the research questions and relevant literature.

### **3.4.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

In this study the most common approach to delivering chest physiotherapy was with another person. This was predominantly the bedside nurse, although physiotherapists also reported using a physiotherapy colleague to assist. Due to

the study design further exploration of this approach, e.g., roles adopted and supporting rationale, was not possible. The specifics of the personnel involved in chest physiotherapy have not been described within published literature.

The physiotherapists surveyed in this study reported using a variety of chest physiotherapy techniques. These findings support chest physiotherapy as a multicomponent treatment, in which techniques are used in combination. The most frequently used treatments reported in this study were position changes, ETT saline instillation, MHI and CWV. These results are in line with a retrospective study of chest physiotherapy in a Canadian PICU (McCord et al., 2013). Chest physiotherapy treatments for 111 mechanically ventilated children were identified through a retrospective chart review. MHI with CWV (96%) and bed mobility (20%) were the most frequently used techniques. Different practice has been reported in Indian paediatric intensive care units. Percussion was the most frequently used chest physiotherapy treatment reported in 25 PICUs in Punjab, India, with 90% (76/84) of respondents using this (Kumar et al., 2014). CWV were used by 68% (57/84) and MHI was not used. This study included both mechanically ventilated and self-ventilating children which may provide rationale for the differences observed in treatment popularity. MHI is only appropriate for use in ventilated children.

More extensive research has been completed in adult ICUs and published results are comparable to the current findings. A point prevalence study conducted in 47 Australian and New Zealand adults ICUs, collected data on 84 ventilated patients requiring airway clearance (Ntoumenopoulos et al., 2018). The most common treatments were CWV (34/84, 40%) and MHI (24/84, 29%). Vibrocompression (a manual technique similar to CWV), hyperinflations and postural drainage were the most frequently used treatments in five Brazilian adult ICUs (Matilde et al., 2018). Van der Lee et al. (2017) reported similar findings in a cross-sectional study using an electronic questionnaire. Suction, mobility, hyperinflations and CWV were the most common treatments used by 75 Australian physiotherapists for ventilated adults with community acquired pneumonia.

Data collection was completed during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) 2019 pandemic (COVID19). SARS-CoV-2 is highly

contagious and transmitted through respiratory droplets (World Health, 2020). Chest physiotherapy, including MHI and open ETT suction, is classified as an aerosol generating procedure (CSP, 2020, Thomas et al., 2020). Therefore, the COVID19 pandemic had implications for the treatment of mechanically ventilated patients. The published guidance advised against ventilator disconnection and recommended VHI and closed suction as appropriate treatments (Battaglini et al., 2020, Lazzeri et al., 2020, Righetti et al., 2020, Thomas et al., 2020). In this study 72% of physiotherapists reported using VHI 'never' or 'rarely', potentially suggesting the recommendations described above were not adopted by PICU physiotherapists. This is likely due to the lower prevalence of COVID19 in children. PICUs may not have been exposed to cases or they may have been re-purposed to accommodate adults. Additionally, this blanket approach may have been deemed inappropriate for children, given their smaller airway diameter, and higher risk of mucus plugging and ETT obstruction (Main and Denehy, 2016). Another explanation for the infrequent use of VHI may be related to participants focusing on usual practice, pre-COVID19, rather than changes related to COVID19.

All physiotherapists in this study reported using at least one mucoactive agent, with hypertonic saline and DNase the most popular. In a UK survey of mucoactive use for ventilated asthmatic children, 63% (55/87) of PICU consultants reported using DNase and 54% (46/85) hypertonic saline (Snoek and Brierley, 2015). DNase was used by 86% (6/7) of PICUs in the Netherlands (den Hollander et al., 2020). This national survey focused exclusively on DNase practice, and reported it was most frequently prescribed for bronchiolitis, neuromuscular disease, and pneumonia. Mucoactive agents are also becoming increasingly popular in adult intensive care. Within the UK, 83% (106/128) of adult intensive care units use mucoactives (Borthwick et al., 2020). Mode of delivery varied between agents in the current study. DNase was delivered via nebulisation and instillation, whereas hypertonic saline was predominantly nebulised. This is in line with practice described in published literature (den Hollander et al., 2020, Snoek and Brierley, 2015).

The reported mechanisms of action of mucoactives include improved mucus rheology, restoration of the periciliary layer, anti-inflammatory properties and cough

induction (Balsamo et al., 2010). 3% hypertonic saline has been reported as safe in a range of mechanically ventilated neonatal and paediatric patients, however the clinical effects are mixed (Dilmen et al., 2011, Shein et al., 2016, Stobbelaar et al., 2019). In children with RSV bronchiolitis, nebulised 3% hypertonic saline reduced the duration of respiratory support by 28% (95% CI: 0.56–0.92,  $p = 0.01$ ) when compared to a historical control group who did not receive hypertonic saline (Stobbelaar et al., 2019). A randomised double-blind study investigated the use of prophylactic 3% hypertonic saline in mechanically ventilated children ( $n=18$ ) (Shein et al., 2016). No significant differences in length of ICU or hospital stay or re-intubation rates were reported.

Fedakar et al. (2012) presented a small case series ( $n=22$ ) of ventilated new-borns with persistent atelectasis. A combination of nebulised and instilled DNase resulted in complete resolution of atelectasis in all cases (mean CXR score 1.67(0.79) vs 0,  $p<0.001$ ). A reduced incidence of atelectasis with the use of nebulised DNase has also been reported in patients following cardiac surgery (Ozturk et al., 2014, Riethmueller et al., 2006). Two studies have compared mucoactive agents in mechanically ventilated children. Dilmen et al. (2011) randomised 40 new-born babies with persistent atelectasis to receive nebulised DNase or 3% hypertonic saline. The authors concluded that 3% hypertonic saline was superior to DNase in relation to improvements in mean CXR score ( $p<0.001$ ) and  $SpO_2$  (3% 98.4 +/- 1.4%, DNase 97.1 +/- 2.1%,  $p < 0.05$ ), although on examination the changes in  $SpO_2$  are not clinically significant. Altunhan et al. (2012) reported contrasting findings, concluding that DNase was more effective than 7% hypertonic saline. Ventilated new-borns with persistent atelectasis were retrospectively divided into four groups ( $n=87$ ). Group 1 was a control group, group 2 received 7% hypertonic saline, group 3 received DNase and group 4 received both hypertonic saline and DNase. The median duration of time to complete recovery of atelectasis was 8.1 days (2–14) in group 1, 3.3 days (1–7) in group 2, 2.9 days (1–6) in group 3 and 2.4 days (1–4) in group 4 ( $p < 0.05$ ). A combination of agents was most effective.

Despite the popularity of hypertonic saline and DNase there is limited evidence of their effectiveness in mechanically ventilated children. Common limitations of the

studies described above include small and inadequately powered samples, observational design, and subjective nature of outcome measures. The role of mucoactives has been well established in other, non-ventilated, paediatric populations, including cystic fibrosis, bronchiectasis and, more recently, mild-moderate bronchiolitis (Hsieh et al., 2020, Rosenfeld et al., 2012, Zhang et al., 2017). PICU physiotherapists' decisions to use mucoactives may be based on published literature in these other respiratory populations, anecdotal evidence and personal experience.

NAC was used less frequently in our study. In the UK survey of ventilated asthmatics only 19% of consultants reported using NAC (Snoek and Brierley, 2015). The apparent lack of popularity may be due to minimal published research. Studies are limited to single case-studies, involving neonatal ECMO, neonatal pneumonia and pertussis (Dilek et al., 2019, Mata and Sarnaik, 2013, Vamplew et al., 2021). They describe the successful use of instilled NAC for mucus plugging and subsequent lung recruitment.

The results demonstrated variation in practice, which included the approach to delivery of chest physiotherapy, choice of treatment components and type and delivery method of mucoactives. Regional differences accounted for some of this variation. National variation in chest physiotherapy practice on adult ICU has been described in both the UK and India (Connolly et al., 2020, Yeole et al., 2015). International variation is also apparent from the adult literature; MHI is used less frequently in Zimbabwe and India compared to Australia, New Zealand and Brazil (Matilde et al., 2018, Ntoumenopoulos et al., 2018, Tadyanemhandu and Manie, 2015, Van der Lee et al., 2017, Yeole et al., 2015). Regional differences may be due to individual preferences of those training staff or historical practice. Whilst there is flow of healthcare professionals between centres within the UK, this predominately relates to junior staff or trainees. It is unlikely to impact more senior roles which have greater responsibility for education and overarching unit practice. Adherence to local policies or protocols may also account for variation in practice. Length of experience influenced treatment choice in Brazilian adult ICUs; percussion and postural drainage were chosen more often by physiotherapists with greater experience (Matilde et al., 2018). Physiotherapy assisted



bronchoscopy, a complex procedure, was used more frequently by physiotherapists with greater PICU experience in our study. However, there were no other relationships between years of PICU experience and treatment or mucoactive selection, which is in line with adult data from Australia (Van der Lee et al., 2017). Variation in practice observed in adult ICUs in Zimbabwe has been attributed to differences in patient diagnoses (Tadyanemhandu and Manie, 2015). This level of data was not available in our study and warrants further investigation.

### **3.4.2 Research question 2: How do physiotherapists make decisions regarding delivery of chest physiotherapy and what other factors influence this decision making?**

This is the first study to explore physiotherapists' decision making on paediatric intensive care. The approaches described by the physiotherapists were consistent. Decisions regarding the provision and frequency of physiotherapy were described as patient focussed, through individual assessment and clinical reasoning. Consideration of the effectiveness and tolerance of treatment was also important. Physiotherapists' use of airway clearance and mucoactive agents in adult intensive care has also been described as patient centred and targeted to individual need (Connolly et al., 2020). This qualitative study involved focus groups with 15 UK physiotherapists. Similar findings have been reported in the field of acute adult respiratory care. Smith et al. (2008) concluded that treatment decisions were based around the patients' problems, physiotherapy intervention, and evaluation of effectiveness. Decision making was also described as a social and collaborative process. Although not a key focus in the current study, discussion with the MDT was highlighted as a factor in decision making. The questionnaire approach has provided preliminary data only, with further exploration of the intricacies of clinical decision making not possible. These initial findings were used to inform the design of phase 2.

In adult intensive care, decision making and provision of chest physiotherapy has been related to work-load and staffing levels (Connolly et al., 2020, Van der Lee et al., 2017). Van der Lee et al. (2017) stated that 61% (36/59) of physiotherapists reported that duration and frequency of treatment were influenced by staffing resources. This was not a common theme in the current study. This may be related

to the differing demands of paediatric and adult patients. In general adults are larger and heavier, requiring multiple individuals to re-position and/or complete interventions. Furthermore, given the lack of standardised guidance regarding physiotherapy staffing levels on intensive care units and the sensitive nature of working with children, PICUs may experience better staffing levels.

Clinical reasoning and decision making are fundamental aspects of physiotherapy and being an autonomous practitioner (Edwards et al., 2004, Smith et al., 2007). Self-reported autonomy was high within the physiotherapists in this study and increased with greater PICU experience. To be registered as a physiotherapist within the UK, The Health and Care Professions Council stipulate that individuals must be able to practice as an autonomous professional, exercising their own professional judgement (HCPC, 2018). These standards are in line with the self-reported behaviour described in this study. It is likely that physiotherapists within UK PICUs expect to make decisions to initiate, continue, modify or cease techniques, whilst taking responsibility for the patient. Greater autonomy can improve job satisfaction, motivation, and self-confidence. Data from a survey of chest physiotherapy practice on paediatric and neonatal ICUs in India suggest that level of autonomy may vary internationally. Only 7% (6/84) of respondents were able to make treatment choices independently, with 36% (29/84) completing treatments chosen by the doctor (Kumar et al., 2014). The remaining 58% discussed treatment choices with either the doctor (48/84) or nurse (1/84). These differences may reflect cultural and hierarchical differences in healthcare systems. Variation in referral processes may also influence autonomous practice. In certain healthcare settings orders are placed by the medical team for physiotherapy or respiratory therapy input. This contrasts with those described in this study where the screening of patients was physiotherapy led. Whilst professional autonomy for physiotherapists has increased over the last 30 years as medical dominance has declined and the importance of the MDT increasing recognised, the concept of complete autonomy has been challenged (Sandstrom, 2007). Within paediatric intensive care it is important to view autonomy in the landscape of shared decision making with the MDT and family/carers, and the complex ICU environment.

The individual patient approach described by the physiotherapists in this study supports literature suggesting that practice has moved away from routine or prophylactic chest physiotherapy on PICUs (Hawkins and Jones, 2015, Morrow, 2015). Secretion yield/viscosity and CXR changes were the most frequently reported clinical indications for treatment. These findings are in line with those of McCord et al (2013), who reported the most common reasons for referral on PICU were pathological changes on CXR and secretion retention (McCord et al., 2013). Facilitation of sputum clearance was also the most frequent rationale provided by physiotherapists for treatment in adult ICU (98%, 60/61) (Van der Lee et al., 2017).

### **3.4.3 Research question 3: What do physiotherapists perceive to be risk factors for physiological instability and adverse events, and how do they manage these?**

In this study physiotherapists reported that changes in physiological variables, including heart rate, blood pressure and SpO<sub>2</sub>, occurred frequently with chest physiotherapy. However, these were considered to be within the limits of a normal physiological response. Adverse events were reported as occurring infrequently. The safety profile of chest physiotherapy in mechanically ventilated children has not been explicitly studied. Several studies have included adverse events as secondary outcome measures. In two small studies no adverse events were reported with the use of EFIT or IPV in ventilated children (Almeida et al., 2005, Deakins and Chatburn, 2002). Main et al. (2004) reported a 7% adverse event rate following MHI with CWV, and suction, in 83 ventilated children. Adverse events were classified as short-lived, such as a temporary drop in SpO<sub>2</sub> or blood pressure. Eleven adverse events were reported in a study investigating the clinical effects of chest physiotherapy in specialist and on-call respiratory physiotherapy treatments (Shannon et al., 2015a). The majority (7/11) were categorised as mild, involving transient alterations in SpO<sub>2</sub> or hemodynamic stability. Adverse events occurred more frequently in patients treated by the less experienced on-call physiotherapists. The role of experience did not appear to influence the frequency of self-reported instability or adverse events in the current study, as there were no clear trends with years of PICU experience. These findings should be interpreted with caution given their self-reported and subjective nature.

Practical strategies were the most common approach to minimising and managing instability and adverse events in this study. Several strategies were described. The use of sedation boluses was the most popular method reported. The European recommendations for physiotherapy in adult patients with critical illness suggest the use of sedation to prevent detrimental side effects, however this is not formally discussed within paediatric physiotherapy literature (Gosselink et al., 2008). Theoretically, increased sedation may reduce unexpected or unpredictable patient movements, anxiety and stress responses, and additional metabolic demands (Kudchadkar et al., 2014, Vet et al., 2013).

The use of pre-oxygenation was reported frequently by the physiotherapists surveyed. Pre-oxygenation has been described as a treatment component in several studies involving chest physiotherapy in ventilated children (Hawkins and Jones, 2015, Main et al., 2004). Pre-oxygenation, prior to airway clearance in mechanically ventilated adults and children, is a well-documented strategy to minimise desaturation (Blakeman et al., 2022, Gosselink et al., 2008, Morrow and Argent, 2008). However, the appropriateness of this strategy is being challenged. There is debate around the optimal  $\text{FiO}_2$  for pre-oxygenation purposes and recommendations now suggest avoiding hyperoxygenation with  $\text{FiO}_2$  1.0. There is emerging evidence of the detrimental effects of supra-physiological levels of oxygenation (>97%) in paediatric patients (Balcarcel et al., 2022, Peters et al., 2018).

Pre-oxygenation with a 10% increase of baseline  $\text{FiO}_2$  has been shown to prevent desaturation below baseline in mechanically ventilated new-borns ( $n=15$ , gestational age  $\geq 37$  weeks) (González-Cabello et al., 2005). In this randomised crossover study  $\text{SpO}_2$  was significantly higher in the preoxygenation group compared to the control group at 0, 1, and 5 minutes post-suctioning (time 0, pre- $\text{O}_2$  group  $87.1 \pm 1.8\%$  vs control group  $76.9 \pm 2.3\%$ ,  $p < 0.01$ ). Vianna et al. (2017) compared the effectiveness of preoxygenation of  $\text{FiO}_2 + 0.20$  above baseline, with  $\text{FiO}_2$  1.0 in preventing hypoxemia in ventilated adults ( $n=68$ ). This randomised crossover study reported that  $\text{SpO}_2$  was higher in both groups one-minute pre- and post-suction ( $\text{FiO}_2 + 0.2$ , pre  $95.7\% \pm 3.3$  post  $97.4\% \pm 2.7$ ,  $p < 0.001$ ;  $\text{FiO}_2$  1.0 pre  $95.0\% \pm 3.3$  post  $98.0\% \pm 2.7$ ,  $p < 0.001$ ). The authors concluded that

pre-oxygenation at  $FiO_2 + 0.2$  was as effective as  $FiO_2 1.0$  in preventing hypoxaemia. Data regarding specific levels of pre-oxygenation used by physiotherapists were not available in the current study. However, this area requires further consideration as practice moves away from routinely using  $FiO_2 1.0$ .

Recruitment manoeuvres and the use of a manometer during MHI were additional management strategies reported by a few physiotherapists in this study. A recruitment manoeuvre is the application of a sustained inspiratory pressure to the lungs for a specific period (Matthews and Noviski, 2001). It is thought to reverse ventilator disconnection and suctioning induced lung volume loss, whilst improving arterial oxygenation, by reinflating collapsed lung segments before resuming ventilation (Lindgren et al., 2004, Matthews and Noviski, 2001). Duff et al. (2007) reported a significant sustained decrease in  $FiO_2$  (6.1%) lasting up to 6 hours post-manoeuve. This was an observational study involving 32 ventilated children which used a sustained inflation technique (30-40cmH<sub>2</sub>O for 15-20s) in several situations: following suction or ventilator disconnection, with hypoxaemia, and routinely every 12 hours. Conversely Morrow et al. (2007) reported insufficient evidence to support the use of recruitment manoeuvres following suction in infants and children. This RCT (n=34) compared a single sustained inflation (30cmH<sub>2</sub>O for 30s) performed by a physiotherapist after suction, to a suction only group. There were no differences between groups in respiratory compliance, resistance or SpO<sub>2</sub>. This conflicting evidence and the potential risks associated with high peak inspiratory pressures may account for the lower popularity of recruitment manoeuvres in this study compared to other strategies, e.g., sedation and pre-oxygenation.

Manometers allow pressure measurement during MHI and are used to prevent barotrauma and haemodynamic instability (Comellini et al., 2019, Pathmanathan et al., 2015, Redfern et al., 2001). de Oliveira et al. (2013) recommended using a manometer for safe ventilation in neonatal and paediatric patients. In UK adult ICUs 42% of physiotherapists reported using a manometer during MHI to determine the pressure delivered (O'Donnell, 2019). The use of a manometer has been described as an effective tool to improve the accuracy and minimise the

variability of peak airway pressures delivered by student physiotherapists during MHI (Redfern et al., 2001). It is reasonable to assume the use of manometers within manual ventilation systems is now standard practice on most paediatric intensive care units. Therefore the majority of physiotherapists in this study may not have acknowledged this as an additional strategy to manage instability and adverse events.

### **3.5 Limitations**

A bespoke questionnaire was created due to the lack of an existing tool and the niche area under investigation. To improve face and content validity it was developed with a group of specialist physiotherapists and panel of experts, whilst also being piloted prior to use. Likert scales were used to improve reliability. However, inconsistencies in the interpretation and understanding of category descriptions between individuals (e.g., 'often' and 'rarely') may have influenced the inter-rater reliability. As with any questionnaire, there is a risk of self-report bias, and responses may not reflect what happens in the clinical setting. Participants may have responded with socially desirable answers. To mitigate this the questionnaire was anonymous. This approach has been reported to improve the quality of responses and it was used in this study to encourage accuracy and honesty (Bowling, 2005, De Vaus et al., 2013, Mutepfa and Tapera, 2019).

The response rate of 61% was lower than anticipated, particularly when compared to a physiotherapy survey in adult intensive care, which reported a 72% response rate (Van der Lee et al., 2017). However, surveys involving professionals on PICU appear to have lower response rates (46-65%) (den Hollander et al., 2020, Kumar et al., 2014, Snoek and Brierley, 2015). The lower response rate in this study was attributed to data collection taking place during the COVID19 pandemic, where PICUs within the UK were re-purposed and health professionals re-deployed. Staff within the NHS were under significant stress and may not have had time or capacity to take part. Selection bias also requires consideration due to the unknown characteristics and practice of non-responders. However, the sample included physiotherapists with the full range of years of PICU experience, all geographical regions were represented, and the physiotherapists treated a variety of patient diagnoses. Furthermore, only one question was not completed by all the

participants. UK NHS trusts reopened to non-COVID19 research at different times, preventing the survey being sent to all PICUs simultaneously. The data collection period was 6 months, resulting in practice being compared over an extended time frame.

The anonymous nature of the questionnaire and collection of only basic demographic data are further limitations to this study. Although participants were representative of geographical regions there is a risk that individual institutions may be over-represented, introducing sampling bias. Whilst the anonymous approach may have been advantageous in increasing participation and honesty of responses, it prevented more detailed interpretation of the results with regards to variation in practice.

Subgroup analysis was completed post-hoc and not powered to detect statistically significant differences. Data need to be interpreted with caution and focus placed on the narrative description provided.

A general limitation of questionnaires is the lack of depth gathered on a topic and inability to gain additional information on phenomena occurring within the data. Areas which require further exploration include the practicalities of a 2-person technique for chest physiotherapy and reasons for variation in practice. Specific components of the research questions also remain unanswered. These include factors influencing clinical decision making and perceived risk factors for instability and adverse events. These findings were used to inform the design of phase 2 and enable the unanswered elements to be addressed.

### **3.6 Conclusion**

This study has provided the first exploration of chest physiotherapy practice in UK PICUs. Despite the discussed limitations the results are generalisable to current UK practice. Chest physiotherapy was provided by all responding physiotherapists and decisions about treatment provision determined by individual patient needs. A range of chest physiotherapy treatments and adjuncts were used. Position changes, ETT saline instillation, MHI and CWV were the most frequently used treatments, with DNase and, 3% and 7% hypertonic saline the most popular mucoactive agents. Variation was apparent in the personnel involved in delivery

of physiotherapy and the use of NAC. Adverse events during physiotherapy were reported as occurring infrequently. Physiotherapists most frequently used practical strategies to manage instability and adverse events.



## **4. Work package 1 – Phase 2 Interviews**

### **4.1 Introduction**

As outlined in Chapter 2, work package 1 was a mixed methods study of explanatory sequential design, involving two phases. In Chapter 3 the methods, results and discussion of the phase 1 questionnaire, have been presented. Phase 2 was a qualitative study involving three components: semi-structured interviews, focus groups and document analysis. Due to the varying data collection methods used in phase 2, each component will be presented in a separate chapter. The findings of phase 1 and 2 will be synthesised, together with work package 2 in Chapter 8.

This Chapter presents the aim, methods, results, and discussion related to the semi-structured interviews.

#### **4.1.1 Aim**

The aim of phase 2 was to gain a more in-depth understanding of the decision making that guides delivery of chest physiotherapy in UK PICUs. This phase also allowed further exploration of the findings of phase 1. Specific areas from phase 1 that required investigation were:

- The 2-person technique for chest physiotherapy
- Reasons for variation in practice
- Factors influencing clinical decision making
- Physiotherapists' perceived risk factors for instability and adverse events

#### **4.1.2 Research questions**

The research questions relating to phase 2 were:

1. What is current chest physiotherapy practice within UK paediatric intensive care units?

2. How do physiotherapists make decisions regarding delivery of chest physiotherapy in UK PICUs, and what other factors influence this decision making?
3. What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?

## **4.2 Methods**

### **4.2.1 Study design**

The first component of phase 2 was a qualitative study, involving semi-structured interviews with PICU physiotherapists. Similar to phase 1, this was a cross-sectional study to explore certain phenomena at a single time point (Kelley et al., 2003). Interviews are a common data collection tool, particularly when gathering in-depth qualitative information or opinions from a select sample of individuals. They have been used to explore physiotherapists' decision making in a variety of clinical settings (Holdar et al., 2013, McGlinchey and Davenport, 2015, Smith et al., 2010). A key feature of qualitative interviews is the depth of focus on the individual (Ritchie and Lewis, 2013). They allow detailed investigation of each person's perspective within the context of their personal history and experience. In-depth or semi-structured interviews are also recommended when researching complex systems or processes, and when aiming to understand decision making (Ritchie and Lewis, 2013). These were important considerations in this study. Bowling (2009) highlights that interviews provide greater depth of data than is possible with a questionnaire and can be used to further explore topics of interest. This feature was also relevant in the context of work package 1. Interviews are described as versatile and flexible, enabling the interviewer to improvise follow-up questions based on participants' responses (Kallio et al., 2016, Ritchie and Lewis, 2013).

A virtual interview approach, using video-conferencing software, was adopted due to COVID19 restrictions, which prevented face-to-face meetings. Advantages of virtual methods include convenience and time effectiveness (Archibald et al., 2019, Saarijärvi and Bratt, 2021). Virtual interviews provide the researcher with access to geographically dispersed participants and allow more flexibility with

regards to interview timing. These were important considerations for this study given the time restrictions imposed by the PhD and COVID19 delays. Virtual interviews are also more cost effective, preventing the need for travel, and the organisation of space and refreshments (Archibald et al., 2019, Lo lacono et al., 2016).

Researchers have described building rapport to be easier with video-based interviews than telephone interviews (Archibald et al., 2019). However there is debate around the ability to establish rapport and build trust in virtual interviews compared to face-to-face interviews. Lo lacono et al. (2016) reported no issues developing rapport with interview participants using SKYPE. Reduced participant apprehension and creation of a more comfortable environment for more reserved or introverted participants have also been attributed to virtual methods (Lo lacono et al., 2016, Silverman, 2020). Conversely a lack of direct contact and loss of intimacy have been described with video-based interviews (Seitz, 2016). To facilitate rapport and participant engagement in this study, both video and audio functions were used and the researcher maintained awareness of non-verbal communication. Well-documented disadvantages to virtual interviews include technical issues, related to access problems, connectivity, or technology illiteracy (Archibald et al., 2019, Saarijärvi and Bratt, 2021). Throughout the COVID19 pandemic health professionals relied heavily on video-conferencing software and virtual meetings. Hence the physiotherapists suitable for recruitment to this study had access to, and were familiar with, digital platforms.

#### **4.2.2 Sample**

Nine UK PICUs were pre-selected to take part in phase 2. This was completed in advance to enable HRA and UCL ethics approvals to be received in a timely manner. Recruiting from nine units was thought to provide sufficient representation whilst ensuring a realistic sample size for data collection. A purposive sampling strategy was used to maximise representation of all 27 UK NHS PICUs, based on the following characteristics: size of paediatric critical care unit (based on number of admissions < 16 years in 2019 (PICANet, 2021) small < 500, medium < 800, large  $\geq$  800), geographical region (as per Phase 1 regions) and regional and sub-regional services/specialities offered. Table 4.1 displays a summary of the size

and locations of the nine PICUs. Individual details have not been displayed to ensure units remain unidentifiable.

*Table 4.1 Characteristics of the paediatric intensive care units pre-selected for phase 2.*

		<b>Number of paediatric intensive care units</b>
<b>Size</b>	Small	3
	Medium	4
	Large	2
<b>Geographical region</b>	East Anglia, South East and Greater London	2
	Midlands	2
	Scotland, Northern Ireland, and North East	2
	North West, Yorkshire and The Humber	1
	Wales and South West	2

PICU physiotherapists at each site were invited to take part (see inclusion/exclusion criteria below). The aim was to recruit two physiotherapists from each PICU, generating a sample size of up to 18. This decision was based on recommendations for qualitative interviews and previous studies involving physiotherapists' decision making (Connolly et al., 2020, Morse, 2000, Saunders et al., 2018, Smith et al., 2008). Qualitative studies are often based on small samples, with the emphasis on quality and richness of data rather than quantity (Bowling, 2009).

#### *4.2.2.1 Inclusion criteria*

Full- or part-time, static or rotational qualified physiotherapists working in a UK NHS PICU.

#### *4.2.2.2 Exclusion criteria*

Physiotherapists who only work in paediatric intensive care as part of on-call/emergency overnight or weekend shifts.

### **4.2.3 Recruitment**

As with phase 1, the lead PICU physiotherapist at each site was contacted directly via email. They were invited to participate in the study and asked to disseminate the study invitation to all physiotherapists who met the inclusion criteria. The invitation included a participant information sheet with study details, confidentiality and data protection information, funding sources and study personnel contact details (Appendix 17). Physiotherapists who were interested in taking part were asked to email the researcher directly. They were given the opportunity to discuss the study and ask questions. Following this the physiotherapists were provided with the consent form for completion (Appendix 18). A reminder email was sent to the lead physiotherapist if no interest had been shown after two weeks.

### **4.2.4 Consent**

All participants provided written consent prior to the interview and reaffirmed their consent verbally and at the start of the interview. Participants had the right to withdraw from the study at any time prior to the interview and withdraw their data for up to 4 weeks following the interview.

### **4.2.5 Data collection**

#### *4.2.5.1 The interviews*

Virtual semi-structured interviews were completed using MS Teams. The date and time of the interview was determined by the physiotherapist and interviews were scheduled to last for up to 60 minutes. During the interview physiotherapists were encouraged to have both camera and microphone functions on. The interviews were audio recorded using a Dictaphone. The researcher completed field notes during each interview, to provide context and document non-verbal cues. A researcher reflection was written after each interview.

#### *4.2.5.2 Interview structure*

The extent to which an interview is structured depends on the purpose of the study. Data collection may be more structured in an evaluative or investigative study of services or policy, compared to an exploratory study (Ritchie and Lewis, 2013). This study used a model of flexible, semi-structured interviewing (Kallio et al.,

2016, Miles and Gilbert, 2005, Ritchie and Lewis, 2013). Specific topics were generated from the research questions and phase 1 findings. The researcher also needed scope to alter the sequence of questions and phrasing salient to each participant. A topic guide was developed for the interviews (Appendix 19). Topic guides are an essential tool when completing interviews, enhancing the consistency of data collection, whilst ensuring all relevant issues are covered (Ritchie and Lewis, 2013).

The topic guide was developed using the principles described by Ritchie and Lewis (2013) (Figure 4.1). It was an iterative process involving the research team (HS, JW). There were four main sections within the topic guide. The interview started with an introduction to the researcher, study, and practicalities of the interview. The confidential nature of the interview was reinforced and further verbal consent requested. The first question was designed as an ice breaker, to relax participants, create a non-threatening environment and provide the researcher with background information (Ritchie and Lewis, 2013, Whiting, 2008). The core section of the interview included four key areas of enquiry. The line of questioning was open and required the participants to draw on their individual experiences. The aim of this approach was to generate in-depth descriptions and allow participants to reflect and identify their true opinions and feelings (Whiting, 2008). The topics were linked, allowing the researcher to be dynamic and alter the order of questioning in response to the discussion. Prompts and probing questions were included in the topic guide to help facilitate responses. The researcher ended the interview by providing the participant with the opportunity to make any additional comments and ask questions.

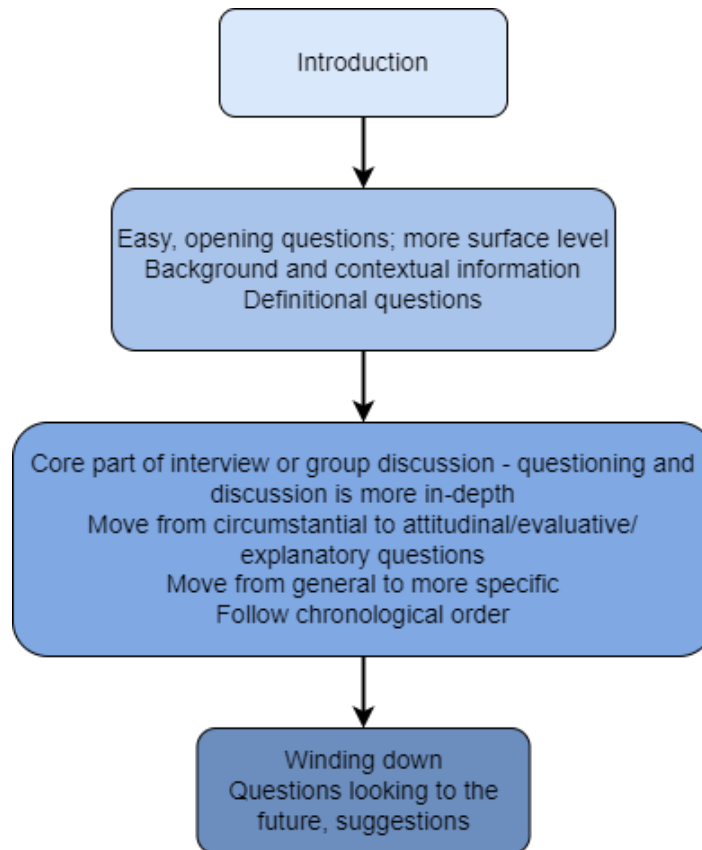


Figure 4.1 Stages of discussion in interviews and focus groups

(Adapted from Ritchie and Lewis 2013)

Demographic data for each participant were collected as part of the interview, these included:

- Gender
- Ethnicity
- Geographical region of PICU (as per phase 1)
- Size of PICU
- Agenda for change banding
- Years of PICU experience

#### 4.2.5.3 Piloting

The study included several pilot phases. Piloting of the topic guide is a critical part of interview-based research. It aims to assess the scope and content of the guide, check consistency of use, improve reliability and provide information about

research integrity (Kallio et al., 2016, Ritchie and Lewis, 2013, Silverman, 2020). Two initial pilot interviews took place with PICU physiotherapists not eligible for inclusion in the final sample. The practicalities of the interview, including testing the audio-visual software, recording devices and timing were assessed. It was also an opportunity for the researcher to practice interviewing techniques and assess the phrasing of the questions and prompts. The interviews were observed by a member of the research team (HS), who assessed for interviewer bias. Feedback was also sought from the interviewees. Changes were made to the consent section, to involve guiding the participant through the completed consent form to gain additional verbal consent. Feedback for the researcher was to elicit specific experiences from the participants rather than allowing them to talk in general terms and having more awareness of non-verbal communication.

The first two interviews involving recruited physiotherapists were used as a second pilot phase. This approach to '*field testing*' is popular within qualitative research (Kallio et al., 2016). The data collected does not need to be excluded from the final data set unless a fundamental change of direction occurs (Ritchie and Lewis, 2013). Prior to embarking on further interviews the anonymised transcripts from the first two interviews were read by members of the research team (HS, JW). The team then discussed what worked well in the interviews and highlighted areas for improvement. These focussed on the researcher's ability to probe deeper into the emotions associated with the physiotherapists' experiences. As only minor changes were made to the questioning style the interviews were included in the final data set.

#### **4.2.6 Data analysis**

The audio-recordings were transcribed verbatim, including conversational fillers such as 'umm' and 'huh' or other such nuances. The Framework method was used for data analysis.

##### *4.2.6.1 Framework analysis*

Framework analysis was originally developed in the context of large-scale social policy research, however it is now popular within healthcare research (Gale et al., 2013, Ritchie and Spencer, 1994). It sits within a broad family of analysis methods



often termed thematic analysis or qualitative content analysis. These approaches aim to identify similarities and differences within qualitative data and explore the relationships between sections of the data, to provide descriptive and explanatory conclusions focussed around themes (Gale et al., 2013). Framework analysis provides the researcher with a systematic structure to manage, analyse and identify themes. It allows in-depth analysis whilst ensuring transparency, enhancing the rigour of the analysis process and credibility of the findings (Ritchie and Spencer, 1994, Smith and Firth, 2011). Although Framework analysis provides a structured approach it remains flexible and iterative, which is fundamental in qualitative analysis (Hackett and Strickland, 2019).

Ritchie and Spencer (1994) describe four types of research questions appropriate for use with Framework analysis:

- Contextual: identifying the form and nature of what exists
- Diagnostic: examining the reasons for, or causes of, what exists
- Evaluative: appraising the effectiveness of what exists
- Strategic: identifying new theories, policies, plans or actions

Many studies will address more than one of these groups (Ritchie and Spencer, 1994). The research questions in phase 2 fit both the 'contextual' and 'diagnostic' categories, confirming the suitability of Framework as an analysis method in this study. The defining feature of Framework analysis is the matrix output: rows (cases), columns (codes) and 'cells' of summarised data. Most commonly a 'case' is an individual interviewee, however a variety of other data types can be used such as focus groups, observations, and documents (Gale et al., 2013, Ritchie and Spencer, 1994). Within the matrix output, cells may remain empty which indicates that the code was not relevant to that case. Codes should be based on key ideas and recurrent themes but may not be present in each case. A combined, deductive and inductive, approach to developing themes/codes can be used in Framework analysis (Gale et al., 2013, Parkinson et al., 2016). This flexibility was integral to its selection for use in this study. The research questions and findings from phase 1 provided *a priori* issues for exploration, whilst emergent data driven themes were also included.

Interpretative phenomenological analysis (IPA) was considered as an option for use in this study. However its focus on unique experience, microlevel explorations and use of smaller samples was deemed unsuitable to address the research aims (Smith and Fieldsend, 2021). Framework analysis provided greater opportunity to balance breadth and depth of data. Furthermore, Framework analysis is not aligned to a particular epistemological, philosophical, or theoretical approach, it is flexible to meet the specific needs of a particular project (Gale et al., 2013). Therefore, it is aligned with the pragmatic approach adopted throughout this project, as discussed in Chapter 2. Initially, focused ethnography was thought to be another suitable option. This approach has been described as a pragmatic and efficient way to capture cultural perspectives and to make practical use of that understanding (Higginbottom, 2011, Knoblauch, 2005). However, given the constraints imposed by COVID19, the additional '*field work*' element required was unachievable. Thematic analysis, as described by Braun and Clarke (2006), did not provide the flexibility required in this study to use both an inductive and deductive approach to generating themes. The adaptability of Framework to other units of analysis, including focus groups and documents, was also important in this study to allow a consistent approach to analysis across all components of phase 2.

#### 4.2.6.2 *The use of NVivo*

Framework analysis has been integrated with the NVivo qualitative software package. However, there is debate regarding the usefulness of computer assisted qualitative data analysis software (CAQDAS). Odena (2013) raised concerns around auto-coding, superficial analysis focussing on frequency counts rather than meaning, and de-contextualisation of the data. Reported advantages include the management of large data sets, the ability of multiple researchers to work simultaneously, and increased possibilities to substantiate research claims (Odena, 2013, Parkinson et al., 2016). NVivo was used in this study as a data management and storage tool, to improve transparency and provide a clear audit trail, allowing decisions and interpretations to be traced back to the raw data. No automated processes were used, with analysis, coding, interpretation and decision making completed by the researcher.

#### 4.2.6.3 The analysis process

Framework analysis comprises five interconnected stages that provide clear guidance on data analysis, outlined in Table 4.2 (Pope et al., 2000, Ritchie and Spencer, 1994). This structure was followed for data analysis in this study.

Table 4.2 The five key stages in Framework analysis

Stage	Description
<b>Familiarisation</b>	Immersion in the raw data; listening to tapes, reading transcripts, studying notes. Gain an overview of the data. List key ideas and recurrent themes.
<b>Identifying a thematic framework</b>	Identify all key issues, concepts, and themes to construct the framework. Use <i>a priori</i> issues and questions derived from the aims and objectives of the study, as well as issues raised by the respondents themselves and views or experiences that recur in the data.
<b>Indexing</b>	Apply the framework to all the data by annotating the transcripts with numerical codes from the index, usually supported by short text descriptors to elaborate the index heading. Single passages of text can encompass several themes, each of which must be recorded, usually in the margin of the transcript.
<b>Charting</b>	Rearrange the data into the thematic framework and create matrices. Unlike simple cut and paste methods that group verbatim text, the charts contain summaries of views and experiences. The charting process involves a considerable amount of abstraction and synthesis.
<b>Mapping and interpretation</b>	Use the charts to define concepts, map the range and nature of phenomena, create typologies, and find associations between themes with a view to providing explanations for the findings. The process of mapping and interpretation is influenced by the original research objectives as well as by the themes that have emerged from the data themselves.

The familiarisation process was completed for all interviews. This involved listening to the audio-recordings and repeatedly reading the transcripts, together with the field notes taken at the time of the interviews. The field notes provided insight into non-verbal communication during each interview and any abbreviations used in the transcripts. Initial themes and issues documented during familiarisation were reviewed and preliminary Frameworks constructed. The

individual transcripts were then indexed. The de-identified transcripts were loaded into NVivo, the electronic Frameworks created, and charting completed. This stage required the researcher to generate case summaries for each Framework theme and reference any illustrative text for possible quotation. During the final stage the researcher mapped the range of responses, including similarities and differences, created descriptions of concepts, and interpreted the themes in relation to the research questions.

#### **4.2.7 Data security**

An encrypted Dictaphone was used to record the interviews. TakeNote, a secure UK transcription service, was used for transcription. Participants were assigned a unique study number and all data were pseudonymised. Identifiable data were removed from the transcripts, including names and places. Participants' names and associated study number were stored securely and separately to the data, using an NHS password protected computer.

### **4.3 Results**

#### **4.3.1 Recruitment**

Sixteen physiotherapists from eight of the pre-selected PICUs were recruited. Although capacity and capability had been confirmed at the remaining unit, no physiotherapists responded to the invitation email or reminder. Table 4.3 displays the number of physiotherapists recruited from each PICU. Physiotherapists from the two large PICUs demonstrated high levels of interest and engagement, therefore more than two physiotherapists were recruited.

Table 4.3 The number of physiotherapists recruited from each PICU

<b>PICU</b>	<b>Number of physiotherapists recruited</b>
<b>1</b>	4
<b>2</b>	2
<b>3</b>	1
<b>4</b>	1
<b>5</b>	2
<b>6</b>	3
<b>7</b>	2
<b>8</b>	1
<b>9</b>	0

## **4.3.2 Demographics**

### *4.3.2.1 Participants*

Basic demographics were collected for each participant. To maintain participant anonymity these are presented in summary format in Table 4.4. Length of PICU experience ranged from 4 months to 26 years (mean 7.2 years).

Table 4.4 Summary of participant characteristics

<b>Demographic</b>	<b>Categories</b>	<b>Number of physiotherapists n (%)</b>
<b>Gender</b>	Female	13 (81)
	Male	3 (19)
<b>Ethnicity</b>	White British	16 (100)
<b>Size of PICU</b>	Large	7 (44)
	Medium	5 (31)
	Small	4 (25)
<b>Agenda for change band</b>	Band 8	2 (13)
	Band 7	9 (56)
	Band 6	4 (25)
	Band 5	1 (6)
<b>Geographical region</b>	East Anglia, South East and Greater London	1 (6)
	Midlands	6 (38)
	Scotland, Northern Ireland, and North East	4 (25)
	North West, Yorkshire and The Humber	1 (6)
	Wales and South West	4 (25)

(n=16)

#### 4.3.2.2 Interviews

Due to the virtual nature of the interviews, participants were free to choose the environment in which they completed the interview. Ten of the interviews were completed with physiotherapists in the hospital, with the remaining six at home. Of the physiotherapists who were in the hospital during the interview, seven were in a private room and three in an open environment with a head set on. Four of the interviews had interruptions, including having to answer a bleep, people entering the room and loss of internet connection. One physiotherapist completed the interview wearing a surgical face mask. Fourteen interviews were completed using

both audio and visual software. Two physiotherapists had technical issues and were only able to connect via audio. The interviews ranged from 33 to 55 minutes. The researcher had previously met six of the physiotherapists due to her clinical role as a paediatric critical care physiotherapist.

### 4.3.3 Data analysis process

All 16 transcripts were used in the data analysis. From the initial familiarisation stage five preliminary Frameworks, including 26 themes, were generated. The overarching framework topics were developed deductively from the research questions and findings of phase 1. The themes were generated inductively from the interview data. Indexing of the transcripts was completed by hand, using a colour coding system rather than numbering to improve clarity. An example is displayed in Figure 4.2.

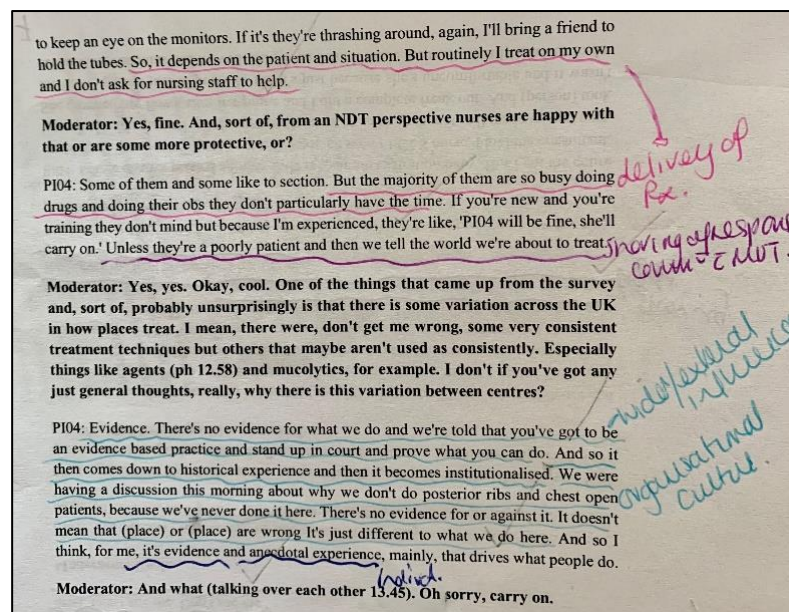


Figure 4.2 An example of an indexed transcript

The charting stage of the Framework analysis was completed in NVivo. Case summaries were created and illustrative quotes from the transcripts highlighted (Figure 4.3).

Strategies for managing instability and AEs			
A: Preparation and planning	B: Sharing of responsibility	C: Specific risk factors	
<p>P105</p> <p>Prior to going to treat considers all potential consequences and how would deal with them, when to ask for help.</p> <p>Also important to prepare parents/family fully.</p> <p>Weights up risk vs benefit. Awareness that may benefit despite additional interventions needed.</p>	<p>joint DM with consultant, in depth conversations and treating together.</p> <p>Discusses and de-briefs with wider MDT.</p>	<p>Ex-prem, CLD, PHTN, INO, HFOV, Bleeding, oncology, HFOV, not disconnected from vent, FIO2 1.0</p> <p>If don't do something not going to survive, could maybe improve situation. But felt like sped up process.</p> <p>Asked to see patient as a last resort. Difficult situation.</p>	<p>Reference 20 - 3.91% Coverage:</p> <p>P105: I think, experience and learning from different situations I guess, I think, unfortunately, I have, not to sound like a bad physio, but I have been in situations where things haven't gone as well, and learned from that. And, I think having the MDT and consultants are very supportive and seeking almost that debrief sessions after treatment or when things have gone well or haven't gone so well, actually reflecting on those things to say actually yes, I probably should have asked or got help at this point, or etcetera. So I think reflecting on situations and experiences I have had, discussing them with people, not just physios but the wider MDT as well. Learning more about the condition as well, so I think, learning about pulmonary, in this example pulmonary hypertension, so, how do you manage it, what are the risks, what does a pulmonary crisis look like etcetera. In my head, before I even enter, into putting on my gloves and gowns with everything on to touch that, maybe, making sure I have thought of what can go on in this bed space and what have I got on hand to manage it, and where is my ceiling as a physiotherapist and when do I need to seek help.</p>
Autonomy as a physiotherapist			
A: Barriers and facilitators	B: Developing autonomy	C: Levels of autonomy	
<p>P116</p> <p>Long-serving nurses practice engrained.</p> <p>Smaller centre not able to provide same level of service. Conversely allows for more in depth discussion.</p> <p>Differences in MDT approaches and training, consultants feel need to intervene.</p>	<p>All about maintaining good relationships. Has been able to develop trust over time.</p>	<p>Has complete autonomy within own practice. Has issues with MDT outside of profession using physio techniques.</p> <p>Consultants very open to discussion. Although times when disagree and has to stick with own decision.</p>	<p>P116: The longer I've been here, and it's all -. I think it's all around the relationships, how can I put this? So, yes, so there are battles you pick, and there's battles I think, and as I talked in the last question around empowering people to ensure patient safety, rather than just trying to kind of put a flat no to something, or start to push through adverse incidents or something like that. You need to maintain relationships, otherwise it breaks down essentially, and over the time I've worked here, I've built really nice relationships with my consultancy group. And, that allows me to kind of, very, very rarely (TC 00:40:00) to ever have any true conflict regarding differences of an opinion, because we'll always work through it, essentially. But, that comes with time, trust as well.</p> <p>I hope over the years kind of, they develop trust in me, I've got trust in them, and that allows for that conversation. But, I have seen, you know, the opposite of that, so I've seen when I've been in fives and sixes with different people in my role, that breakdown in communication and trust, and that's where the issues come. But thankfully, yes, half of my job is, I feel sometimes is about people management and personal skills and into relationships, essentially, so as long as you keep those up I think it's fine, yes.</p>

Figure 4.3 Examples of charting in NVivo

The Frameworks went through several iterations as analysis stages were repeated and themes refined. The preliminary Frameworks were shared with one member of the research team (JW), these were discussed and explored to ensure transparency and minimise interviewer bias (Odena, 2013). The final analysis included 16 themes across five Frameworks, these are outlined below:

#### *Delivery of treatment*

- Delivery of treatment

#### *Explanations for variation in practice*

- Individual physiotherapist practice
- Influence of teachers
- Organisational culture
- Wider influences

#### *Factors influencing decision making*

- The physiotherapist
- Physiotherapist knowledge



- Consideration of family
- Other health care professionals
- External influences

#### *Autonomy as a physiotherapist*

- Levels of autonomy
- Developing autonomy
- Barriers

#### *Strategies for managing instability and adverse events*

- Specific risk factors
- Preparation and planning
- Sharing of responsibility

Once analysis was complete, members of the research team (JW, HS) were provided with two de-identified transcripts and the Frameworks. They were asked to follow the data from its raw form to the final themes, checking the transparency and credibility of the data analysis.

#### **4.3.4 Final frameworks**

This section will present and examine the five Frameworks and their individual themes. The Frameworks, which include case summaries for each participant, are displayed. Where cells are empty, and no case summary displayed the theme was not relevant to that participant. Themes are illustrated within the narrative using a combination of direct quotes and diagrams.

##### *4.3.4.1 Delivery of treatment*

The first Framework related to the delivery of chest physiotherapy treatment and is displayed in Table 4.5.

Table 4.5 Framework I - Delivery of treatment

Participant	Delivery of treatment
<b>PI01</b> Band 8 Medium	Nursing staff involved but predominantly for suction. Feels safer and patient more stable than treating on own. Occasional needs to do suction to be effective or will treat on own if time pressures Occasionally must be flexible to coordinate treatment timing with nursing staff.
<b>PI02</b> Band 7 Medium	Always treats with someone to ensure good technique, safety purposes and logistical reasons due to being short. Physiotherapist does manual hyperinflations and chest wall vibrations, nurses suction.
<b>PI03</b> Band 7 Large	Prefers to treat alone as much as possible. Likes to be hands on, get more feel and feedback.
<b>PI04</b> Band 6 Large	Routinely treats on own. Nurses assist if specific intervention required. Nurses often busy with own responsibilities.
<b>PI05</b> Band 7 Large	Usually treats on own unless unstable and then will get nurse to suction.
<b>PI06</b> Band 6 Large	Use nursing staff for re-positioning or occasionally for suction.

<p><b>PI07</b> Band 7 Medium</p>	<p>Ideally would treat with another physiotherapist, more efficient and effective. But usually treats with nurse, who would do suction/bag. Nurses encouraged not to do manual techniques, not trained and unable to identify contraindications. Would be like a physiotherapist attempting to use medication pumps.</p>
<p><b>PI08</b> Band 7 Large</p>	<p>Nursing staff involved in treatment; they are trained to bag. Move towards not routinely seeing patients.</p>
<p><b>PI09</b> Band 5 Large</p>	<p>Works closely with nurses, they would bag and physiotherapist do hands on treatment. Can be difficult at times to find a nurse to help, challenging and frustrating.</p>
<p><b>PI10</b> Band 7 Small</p>	<p>Who treats with depends on caseload/teaching. Treats on own when wants to get a good feel of patient. Standard treatment, manual hyperinflations with chest wall vibrations, saline, suction.</p>
<p><b>PI11</b> Band 8 Medium</p>	<p>Prefers to treat with another physiotherapist or on own, dependent on size of patient. Need more hands to be effective. Empowering nurses to do more manual hyperinflations/suction prior to calling physiotherapist.</p>
<p><b>PI12</b> Band 6 Large</p>	<p>Nurses will predominantly do manual hyperinflations, part of their role. Will use a physiotherapist if nurse is busy.</p>
<p><b>PI13</b> Band 6 Small</p>	<p>Treats either with nurse or physiotherapist, changed since COVID19 more joint physio treatments. Nurse would be used for manual hyperinflations. Although prefers to do with another physiotherapist, technique different. Feels more confident now as band 6 to ask nurses to adapt techniques. Need 2 people to be effective with larger patients.</p>

<p><b>PI14</b> Band 7 Small</p>	<p>Aim to treat with 2 physiotherapists as much as possible. Nurses tend to use it as opportunity for break. Nurse would MHI/suction. Physiotherapy manual hyperinflations technique different.</p>
<p><b>PI15</b> Band 7 Small</p>	<p>Approach depends on staffing. Prefers to treat with another physiotherapist but can also be a nurse. Physiotherapists use manual hyperinflations differently.</p>
<p><b>PI16</b> Band 7 Medium</p>	<p>Predominantly treats alone, finds it easier. Also nurses very stretched. Will involve nurse if patient unstable and may need a non-physiotherapy intervention. Band 5/6 will treat with another person. Have had to upskill nurses due to staff shortages.</p>

Two preferences for delivery of treatment were discussed during the interviews: treating alone or with another person. A few physiotherapists described treating patients on their own where possible. This was based on a strong personal preference but also related to not having a second person available for treatment. These physiotherapists felt treating independently was more efficient and effective. They commented that nursing staff were busy and not available to assist. These were predominantly physiotherapists from the larger centres. The following quote illustrates these findings:

*“It's predominantly alone, our nurses particularly are stretched, they're one to two on most patients, so you might have the luxury of having assistance from the nurse but that's few and far between... And, then myself, just because I find it easier, most of the hands on or clinical skills that I use I find it much easier to time and coordinate if I'm doing them both.” (PI16)*

The physiotherapists talked about circumstances where they would treat with another person. These were related to practical and logistical factors, as described below:

*“So, if it was an older patient that we needed hands for positioning and that sort of type of thing, then we might ask the nursing staff to help. But I'm a little bit-, I like to suction, because I like to suction a certain way. So, generally speaking I would treat on my own, if I was capable of it in terms of the age of the patient.” (PI03)*

In contrast most of the physiotherapists interviewed reported that they would routinely treat with a second person. Rationale behind this approach included improved stability of the patient and maintaining a good technique, as illustrated below:

*“I actually probably now prefer this way. Now whether that's just because that's what I've got used to. I remember at (place) to start with, I was like, 'Oh my goodness,' it was quite a lot, and I think it was just that putting them back on the vent in between*

*the suction each time, I think can sometimes be a bit more destabilising for the patient than when we've got an experienced physio holding them on the bag and you can just alter that PEEP or give a few more breaths or give less, you know, type of volume if the blood pressure's dropping or something like that. You can just be a bit responsive all the time because it's in your hand. And I think it maybe just feels a bit less rushed.”(PI01)*

A nurse was most frequently used to help, however opinion was divided about the role they completed. Approaches varied between the nurse only being used for the suction versus them completing both the MHI and suction. The majority of physiotherapists reported that nursing staff were discouraged from completing manual techniques, describing that it was outside their scope of practice. One physiotherapist provided a detailed account of this:

*“So, as a rule we don't encourage them to do any manual techniques because we feel that's a physio's specific skill. I've had conversations with nursing staff before about I'd be happy to teach people how to do it because it's not a difficult skill to learn. It's more about assessing the need for it and assessing the effectiveness of it and can you identify contra- indications. If you can't do all of that, you shouldn't be doing it as a treatment technique... Often what we'll get is, 'Oh, well we've watched physios during the day so we do it on the evening.' Where I say to them, 'If I was to come back with you and say, well I've watched you to use your IV pumps and your syringes during the day. Does that mean I would-, would you feel-, if I came and pressed lots of buttons on that?' And they were like, 'Oh no.’”  
(PI07)*

A few physiotherapists described the challenge of coordinating an appropriate time with nursing staff. Several of the senior physiotherapists reported that in this situation they would sometimes become impatient and treat the child alone. Additionally in situations where they felt the nurse was not being effective they would move to treat alone, as described below:

*“It really depends on what nurse is on, but sometimes it is quite difficult to get somebody to help you at that time, whether it's, like, between breaks and things like that. It could be quite frustrating because you're like, 'I would like to come in and do this,' and it's like, 'Oh, well, actually so and so at that bed space is away on her break,' so we need to, kind of, look after the room and keep an eye, so now is maybe not the best time.” (PI09)*

*“And there have been times when I'll be with a nurse and I'll just be like, 'Just give me the bag,' and I'll just treat just because you want to feel what's going on and especially more-, you know, if it's a newly qualified nurse or something, you just sometimes want to have a feel yourself, don't you, and actually feel what you're trying to achieve.” (PI10)*

Physiotherapists from the smaller centres reported predominantly treating with another physiotherapist. Two additional participants also reported preferring to treat with a physiotherapist, but due to staffing shortages they were normally assisted by a nurse. Participants felt that treatment was easier and more effective with another physiotherapist, with both parties understanding the treatment goals and techniques, as highlighted in the following quote:

*“Yes, generally it would be with a nurse because there's not enough of us. It's great when you can treat with another physio, it's so much quicker, you both know what you're thinking or what you want to get out of it, and sometimes it can be much quicker and a bit more effective.” (PI07)*

Treating with another physiotherapist for teaching and supervision purposes was also mentioned by most physiotherapists, irrespective of their individual treatment preferences. Several of the physiotherapists who prefer to treat alone described that they would encourage junior physiotherapists to treat with a nurse.

The topic of upskilling nursing staff to complete appropriate airway clearance and not routinely treating all PICU patients was raised by several physiotherapists. One physiotherapist talked about a change in practice to a more hands off,

advisory approach. The other linked this strategy to a need for nursing staff to complete more effective, regular secretion clearance:

*“We will empower the nursing staff to do a lot more bagging, say on suction techniques before they ask for a physio review, so if the secretion is moved easily enough, they don't need shaking per se or cough assist or anything, then we will get them to do that regularly through the day. I think that's really helped in terms of speeding up improvement in some of the patients.” (PI11)*

#### *4.3.4.2 Explanations for variation in practice*

The second Framework related to the physiotherapists' explanations and understanding of the variation seen in physiotherapy practice on PICU. Table 4.6 presents the Framework. Four themes were derived from the data, these are summarised in Figure 4.4.



Table 4.6 Framework II - Explanations for variation in practice

Participant	Individual physiotherapist practice	Influence of teachers	Organisational culture	Wider influences
<b>PI01</b> Band 8 Medium	Related to the confidence of the physiotherapist.	Methods used by seniors filters down to other staff. Related to training received.	Feels as a manager is open to use of new ideas and treatments, as long as safe and able to justify.	
<b>PI02</b> Band 7 Medium	Own practice has changed over time. Increasing experience and confidence impact practice.	Influence of educators when first start on PICU shapes practice.	Being able to change historical practice, trying something new and comparing with current practice. Treatment choices limited by financial constraints. Use of protocols for certain populations to guide treatment.	Practice changes related to what is happening nationally. Would like things to be more open, places to share guidelines/protocols. Would like to hear what other centres are doing, be inspired and improve.
<b>PI03</b> Band 7 Large	Down to experience, time, and confidence. Personal preference.	Learnt techniques from seniors.	Use of protocols will change development of practice.	The level of 'sickness' a centre sees, need to understand full spectrum, which influences treatments used.
<b>PI04</b> Band 6 Large	Individual experience.		Reliance on historical practice, develops into institutional practice.	Lack of evidence to guide clinical decision making.
<b>PI05</b> Band 7 Large	Own experience, what has worked previously.		Pressure from consultant/wider team to use specific treatments.	Lack of evidence to guide practice.
<b>PI06</b>				

Band 6 Large				
<b>PI07</b> Band 7 Medium	Previous experience.		Availability of equipment. Consultant preferences.	Which treatments are 'on trend' at the time. Interested to know what other centres do.
<b>PI08</b> Band 7 Large	People are driven by their experiences and what is familiar.		Which treatments are accepted within PICU and expectations of staff. Dependent on person leading the team, age and experience. Ability for historical practice to be changed and moved forward. Specific practice engrained in older, more senior staff.	A network of PICU physiotherapists would be useful to share experiences, especially with new devices/treatments.
<b>PI09</b> Band 5 Large	Comes down to individual clinical preference.	Learning from senior colleagues, therefore influenced by them. Can be difficult to choose own path with conflicting viewpoints.	What centres have done historically. Currently lots of new starters, challenging practice more.	Limited evidence to guide practice.
<b>PI10</b> Band 7 Small	Where physiotherapist has worked before.		Experience of the unit and doctors.	Would like to be able to visit other (larger) PICUs to learn/share practice
<b>PI11</b> Band 8 Medium			Feels some trusts are too guided by evidence and guidelines, no flexibility to try other treatments.	
<b>PI12</b> Band 6 Large	Individual experience, what used to using.		Experience of the unit and doctors.	

<b>PI13</b> Band 6 Small		Own practice based on how taught by band 7, so related to their experience and expertise.		
<b>PI14</b> Band 7 Small			Has always worked at same hospital, own practice related to historical practice on unit. Dependent on consultant experiences.	Influenced by treatments used in other areas of hospital. Access to a network.
<b>PI15</b> Band 7 Small	Individual confidence and experience.		Some trusts continue with historical practice. Related to type of patients and what treatments they use at home/in community.	Likes hearing what other centres do, networking at conferences.
<b>PI16</b> Band 7 Medium		Practice consistent across teams related to how have been taught by senior.	Staffing levels. Treatments led by consultant preferences. Ingrained, historical practice.	Sharing of practice between centres important for learning, especially coming from a small centre. Need to facilitate this.

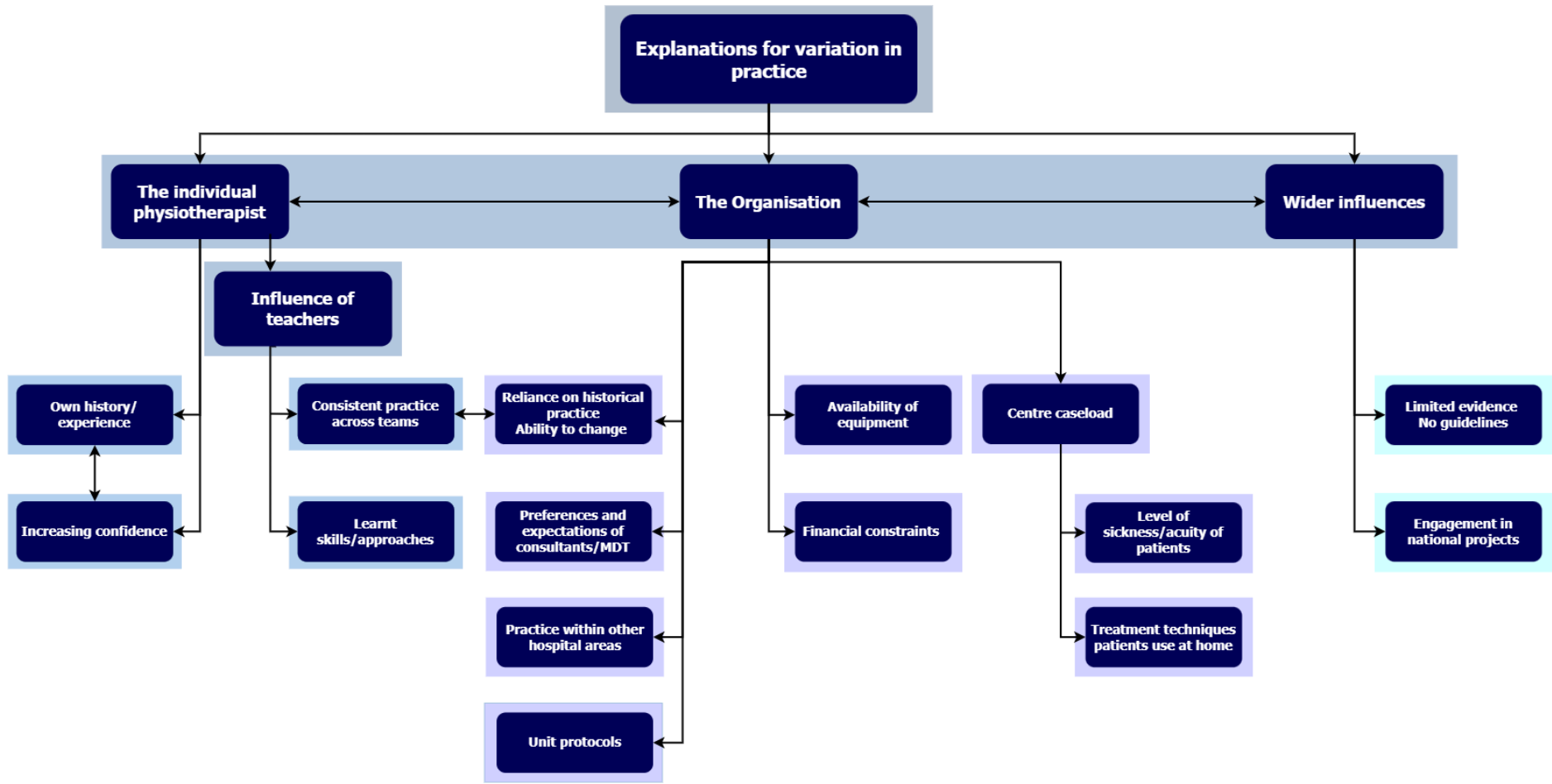


Figure 4.4 Diagrammatic summary of Framework II

The physiotherapists frequently mentioned an individual's experience as a possible explanation for variation in practice, with each physiotherapist relying on treatments that had worked previously and what was familiar to them. This was closely linked to the influence of teachers, relating to treatment selection and similar practice across teams. These themes are illustrated in the following quotes:

*"I think a lot of it comes down to experience as well though, because I think there's certainly some mucolytics that I probably haven't really used that much, so I wouldn't choose to use them immediately, because actually I'm not sure how effective they're really going to be, and I'll go to the things that I'm used to, yes. I think experience comes down to a lot of it." (PI12)*

*"For me, when I came as a five, I hadn't done any respiratory experience. My only placement had been as on CF so, I very much was taught by my band seven and the way that she liked to do things is now the way that I like to do things and now the way that I teach my students or the band fives that come in, and so, I feel like a lot of it's probably, almost done on their experiences and their expertise and what they believe is the best type of practice, which can come from, again I guess, certain papers they've read or journal or potentially from their teaching, when they were a junior member of staff.." (PI13)*

Physiotherapists felt that teachers had greater influence earlier in their careers and as they gained experience and confidence they were able to develop their own practice. One band 6 physiotherapist discussed the challenges of learning from different physiotherapists and finding their own path:

*"I think myself, being quite junior, I'm learning a lot from my senior colleagues, and it can be quite difficult almost to choose your path because you're hearing conflicting views and points, so I guess it's trying to take on and understand, and then make your own decisions." (PI09)*

The second theme was the influence the organisation or specific PICU has on variation. Physiotherapists talked about a reliance on historical practice and a centre's inability to change, leading to variation. This was linked to embedded practice of senior physiotherapists or 'teachers' as previously described, as well as other members of the MDT, as explained below:

*"I know even with our unit, depending on what the consultant is on per week, they've got a preference to when we're talking about-, I'm like, 'Right, let's start the hypertonic saline, and they'd be like, 'Actually, no, I want to try the acetylcysteine,' then I'm like, 'Right, okay then.' So, I think from a consultant medic view, that depends." (PI10)*

This experience was not shared by all the physiotherapists. A contrasting experience was described where new members of staff shared ideas from other centres, which implies moving towards standardisation of practice. One physiotherapist reported that approaches used in other areas of the hospital influenced their practice, as explained in the following quote:

*"I think that's just because we've got lots of adult patients like MNDs and stuff. So, you, sort of, pick things, don't you, from other areas? Sometimes we see things, you know, which they do on some of the MND patients, we think, 'Oh, that might be good for some of our Duchenne's actually, or some of our SMAs and, I don't know, I think it just depends what you've got around, doesn't it?" (PI14)*

This physiotherapist was based in a hospital providing both paediatric and adult services, which may offer explanation for variation between centres that have access to different services. The size of the PICU and the type of patients admitted were also highlighted by the physiotherapists as factors resulting in variation. One physiotherapist commented that units who see patients with repeated admissions may be more inclined to use the patient's home treatments. A physiotherapist from a large PICU in a Children's hospital had a strong opinion that the level of the PICU directly influenced experience and practice, as illustrated in the following quote:

*“I think also it depends on the level of sickness you see because I think in our centre, and it's probably very similar to (place), you see the worst cases of things. Therefore, you appreciate what a stiff chest is when you really do treat a stiff chest. I think if you haven't seen the whole spectrum, you might not appreciate the differences in the two...If you experience that change and feel that change, I think that, yes. I think you develop an even stronger sense of what normal is compared to what normal isn't. I think that then directs your treatment and develops your experience further. So, I think you almost need to spend some time in a specialist centre to really understand the ins and outs of it all. I suppose that could be me being biased or being a bit specialist centrist, but I do think that it has got its perks. I think you see those patients that you normally wouldn't.” (PI03)*

The physiotherapists discussed practical reasons for variation, related to organisation culture. Several physiotherapists talked about differences in protocols between PICUs and how being tied to these may impact practice. Financial constraints imposed by individual hospitals were thought to influence variation. Physiotherapists discussed this in relation to staffing levels, availability of certain mucolytics and access to equipment, described in the following quotes:

*“I think part of that is due to their staffing levels and the time that they have. I don't want to go on too much about the levels thing but actually I think our practice here at (place) would be slightly different if we had more time.” (PI16)*

*“Mucolytic wise, we use a variety, I think some of that to be honest is a bit dictated by our funding in a hospital, so they're very keen for us to use acetylcysteine before we try anything else. We use saline with a lot more patients, not routinely but a lot, normal saline. But whenever we have a toss-up between acetylcysteine and DNase we're always encouraged to go for acetylcysteine first.” (PI02)*

The final theme was around wider or external influences that result in practice variation. The limited evidence base supporting chest physiotherapy was frequently mentioned. The physiotherapists felt the lack of evidence drove the reliance on individual experience, which links back to the theme discussed earlier of variation in practice due to experience. Physiotherapists described how national initiatives and trends can influence practice, as described below:

*“But equally, something like that is such a big project, for say, our ECMO patients and things, like, I think the fact they can see it throughout the whole country, and one of our consultants is particularly interested in that and has seen that, it makes a big difference, yes. It makes them really push for it.” (PI02)*

*“I think trends and what's in at that time, like, someone's had reports of really good experiences for using this mucolytic so let's push this one.” (PI07)*

It was felt that some centres were more likely to collaborate, and this would proliferate variation if all PICUs were not involved. Whilst discussing the topic of variation in practice physiotherapists acknowledged the need for greater physiotherapy collaboration and sharing of experience. This was especially important to physiotherapists from smaller centres, as highlighted in the following quote:

*“Covid's made it difficult to network a bit more, I mean, the great side of it is kind of, these opportunities virtually, so it'll be interesting to hear-, kind of, for me too because you don't hear about different challenges faced by the different units. Particularly for me for having a small team, a small unit, I don't often hear about what's going on and the challenges that other teams are facing, there's a lot to learn off each other.” (PI16)*

Suggestions to facilitate collaboration included the development of a network and visits to other PICUs. The physiotherapists demonstrated a desire to want to learn from each other and improve practice nationally.



#### *4.3.4.3 Factors influencing decision making*

Framework III presents the findings relating to factors which influence physiotherapists' decision making on PICU (Table 4.7).

Table 4.7 Framework III - Factors influencing decision making

Participant	Physiotherapist knowledge	The physiotherapist	Consideration of family	Other health care professionals	External influences
<b>PI01</b> Band 8 Medium	Clear indications of mucus plugging causing issues. Named physiotherapist for long term patients, easier for family.	Requires confidence. Having previous experience of condition/type of patient makes decision making easier. Time for education not protected, not a priority when busy.			Reading literature.
<b>PI02</b> Band 7 Medium	Named physiotherapist leads on complex/longer-term patients for continuity and improved multidisciplinary team communication	Judgement develops over time with increased experience. Education and training is time consuming.			Changed to closed suction for all due to COVID.
<b>PI03</b> Band 7 Large	Have to weigh up the clinical indications. Presence of a pathology that physiotherapy can influence.	Dependent on own experience. The level of 'sickness' a centre sees, need to understand full spectrum. Teaching band 6s is a priority.		Pressure from consultants. If consultant going to do physiotherapy treatment irrespective, it is better for physiotherapist to deliver it.	Unknown/new pathology challenging.

<p><b>PI04</b> Band 6 Large</p>	<p>Need to understand the patient's physiology, what are the indications for physiotherapy.</p>	<p>Uses experience, learns from mistakes. Combines available evidence and underlying physiology of patients. Being short staffed limits opportunities for teaching.</p>	<p>Feels it is important to explain all risks to parents, using correct terminology and what it will look like.</p>		
<p><b>PI05</b> Band 7 Large</p>	<p>The clinical picture, what are the indications to treat. See patients from previous day. If right thing for patient same team will continue care when goes to the ward.</p>	<p>Uses own experience, learning from mistakes. Has learnt to deal with challenging situations. Differences in individual physiotherapists personality, differing levels of risk adversity and 'threshold'. Consider learning needs of team in day-to-day planning. Lots of staff requiring oncall training.</p>	<p>Gives them the option to stay/take a break.</p>	<p>Peer support useful for second opinion. Using multidisciplinary team for de-briefs and reflection.</p>	

<p><b>PI06</b> Band 6 Large</p>	<p>Level of treatment and escalation depends on severity of clinical presentation and indications for physiotherapy. Completes a detailed patient assessment, includes reasons to treat and contraindications, helps you to make decisions.</p>	<p>Increasing experience and confidence, being able to reflect on past experiences. Becoming braver with more experience. Things are not black and white. More confident if have prior knowledge of patient compared to a new patient. If have been treating for an extended period.</p>	<p>Sometimes have to negotiate with parents to be able to treat. But also need to give them opportunity to say no.</p>	<p>Doctors more likely to approach band 7 for joint decision making/treatment than rotational staff. Gets second opinion from physio team.</p>	<p>Uses available evidence.</p>
<p><b>PI07</b> Band 7 Medium</p>		<p>Don't have time/staffing to attend ward-round.</p>	<p>Parents are expert in their child, important to listen to them.</p>		<p>Networking with other centres, sharing practice.</p>

<p><b>PI08</b> Band 7 Large</p>	<p>Using specific patient variables and indicators, rather than just going ahead and treating.</p>	<p>Ability of physio to clinically reason and question. Feels like now more thoughtful and clinical reasoning has improved. Confidence to make decisions, especially when deciding not to treat. People are driven by their experiences and what they are familiar with. Useful to reflect on outcome of decisions, important for ongoing learning and evolution. Role more non-clinical than anticipated, ?due to COVID impact.</p>		<p>Specific practice engrained in older, senior staff.</p>	<p>Reads around conditions to improve understanding.</p>
<p><b>PI09</b> Band 5 Large</p>	<p>How the patient looks if you know them well. Needs to be a clear need for treatment. Same person seeing patient each day.</p>	<p>Experience and increasing confidence allows own clinical reasoning and decisions.</p>	<p>Had to develop communication skills with parents. Parents need preparing for physiotherapy.</p>	<p>Have to negotiate a time for physiotherapy with nursing staff and ward round. Challenging and frustrating. Had to keep patient on caseload as doctor's requested it, physio input not required.</p>	<p>Hasn't experienced 'normal' due to COVID, might be a seasonal impact on stressors or decision making.</p>

<b>PI10</b> Band 7 Small	Always based on patient presentation.	Patient mileage, experience of more unique/complex patients.	Pressure from parents to do everything possible.	Input restricted as consultant not open to physiotherapists suggestions.	
<b>PI11</b> Band 8 Medium	Treat the patient in front of them.	Physiotherapist's ability to clinically reason, based on experience. Role multifaceted, PICU clinical specialist, team lead and lecturer, currently interim allied health lead. Very stressful, lots of demands on time with no funding. Most issues are from non-clinical elements. Brand new band 6 require more input.	Allows parents to choose to stay for physiotherapy, sometimes need to give them permission to leave.		Using available evidence to guide decisions.
<b>PI12</b> Band 6 Large	Consider child's mental health and development, prior to completing an intervention.	Involved in lots of oncall and bank staff training. Also supports band 5 training.	Rarely have issues with parents compared to other members of multidisciplinary team, ?better listeners as physiotherapists, something inherent in our nature.	Easy to get too focussed on situation, helpful to get external opinion.	Impact of COVID on treatment choices, less disconnection from ventilator.

<p><b>PI13</b> Band 6 Small</p>	<p>Keep patients from day before for continuity.</p>	<p>With increased experience and patient mileage, has more confidence, able to question more. Uses own instinct</p>	<p>Gives parents element of control in decision making, improves compliance.</p>	<p>Senior physiotherapist support and guidance.</p>	
<p><b>PI14</b> Band 7 Small</p>		<p>Uses own instincts. Uses experiences with other patients to help decision making.</p>		<p>Uses experience of those who have been around longer.</p>	<p>Benchmarking and discussion with other centres. Important as a small PICU.</p>
<p><b>PI15</b> Band 7 Small</p>	<p>Looks to escalate home regime.</p>	<p>More confident and brave with increased experience.</p>			
<p><b>PI16</b> Band 7 Medium</p>	<p>Needs to be clear benefit, using clinical assessment. Understanding the pathophysiology of the disease.</p>	<p>Uses previous experience, learnt through time and exposure. More non-clinical tasks, than should be. Unable to attend ward round if short staffed. Have to upskill band 5s with no experience, Unable to do as much supervision as would like.</p>			<p>Practice changed to more assessment on ventilator.</p>

The physiotherapists' knowledge was an important theme derived from the data. Most physiotherapists discussed clinical knowledge and understanding being a key factor in decision making. Physiotherapists described completing a thorough assessment to enable them to use clinical reasoning to identify clear indications for treatment, as illustrated in the following quote:

*“And, it's almost coming back to the very basics of what we're taught in physio of actually is there something either on X-Ray, auscultation, ultrasound, clinical examination, is there something the patient can benefit from me intervening. Not just, 'let's give it a go and let's see what comes up’” (P116)*

Additionally, physiotherapists talked about how previous knowledge of, and exposure to, the patient aided decision making. They aimed to ensure continuity of care, seeing the same patient throughout their PICU stay and sometimes beyond. One physiotherapist described how this improved her confidence when making decisions and communicating with the MDT:

*“I think, again, it's just come with experience, so I've been working with this patient for, like, the last six weeks, she's a long stay patient, but I think if it was a new patient, maybe not. Because I know her background inside and out, I know what's normal for her, what's abnormal for her, I was able to make those clear decisions, but, I think, for a new patient I probably would have, maybe, doubted myself a bit more and maybe just probably push towards what do the doctors want, what do the doctors want. Where, in this situation, because I knew her, I knew, kind of, what she needs from a cardiac point of view, what she's like from a chest point of view and what she's like weaned off sedation, I was able to have those confident discussions with the doctors and help, like, inform the nursing staff on what to do.” (P106)*

The second theme was the influence of the individual physiotherapist. The main area discussed related to experience, this was closely linked with the physiotherapist's knowledge described above. Physiotherapists reported making



decisions by drawing on experience gained through patient mileage, and the opportunity to make mistakes, reflect and learn from them.

*“Making mistakes. Experience. The more you see, the more mistakes you make and there's nothing worse than having a buzzer pull and not having any idea why it's happened. Because you feel like a complete idiot. And so I think it's, yes, the more you're up there. For me, I had to learn through doing.” (PI04)*

The physiotherapists associated increased experience with greater confidence to deal with clinical situations. The quote below illustrates how a lack of experience and confidence made the management of the patient challenging:

*“Obviously, it came to PICU, so she was probably a really difficult one for me to, sort of, manage. Number one, because we don't see that type of patient very often and then knowing, or having the confidence to, sort of, provide the best possible care to her.”(PI10)*

Physiotherapists talked about how previous experience allowed them to base decision making on instinct:

*“Yes, and sometimes it's just you get, like, a bit of a gut feeling, don't you? That I think, 'Yes, I think this is going to work for this one,' and you, sort of, go with that, really.” (PI14)*

The personality of the physiotherapist was also highlighted as a factor influencing decision making. One individual mentioned how differing risk behaviours may impact decisions:

*“That does play a part in it. I will use an example, myself and another physio...we are very different in personality and very different in that risk adversity, but that isn't to say either of us are wrong or right but it is just interesting that we would go about it in a different way I guess, with situations like that.”*

Most physiotherapists felt that other demands on their time influenced practice and decision making. The physiotherapists discussed that supervision and teaching

was a large part of their role, with all alluding to the time-consuming nature of this. The more senior physiotherapists reported numerous non-clinical responsibilities. The complex process of balancing patient care and additional tasks is illustrated in the following quotes:

*“you try and do some joint treatments as an education role as well but, you know, when it gets super busy you just have to divvy up and treat.” (PI01)*

*“So to be honest, it's very stressful, but it's not necessarily the volume of patients, that tends to be quite steady. It's the extra crap that goes with everything, that's the thing that really gives me the biggest stress. It's the expectations of the staff on ICU and then the expectations of the medical team leaders across the other areas where they think they have full control over what physio they get, how many physios are around, wherever they are.” (PI11)*

The role of the family in clinical decision making was a further theme. This was acknowledged frequently by the physiotherapists, however differing experiences were presented. Several physiotherapists referred to the parent/family as being the expert and utilising their knowledge and skills to facilitate decision making, demonstrated below:

*“We speak a lot to parents as well because a lot of our patients on PICU come from, like, out of area and there's so many weird and wonderful conditions, isn't there? So, we quite often ask parents if it's a patient that's been in hospital a lot but not necessarily with us, we do tend to ask them, you know, what's worked in the past? Or have you tried this before and what happened?” (PI14)*

One individual highlighted this as a challenge, with the expert care parents expect becoming more difficult to complete in the PICU environment:

*“Some of the parents become really, really skilled at looking after their children but almost-, their children become such a skill to*

*look after that unless you are their parent, you actually can't replicate it.” (P112)*

Despite these differences all physiotherapists agreed that decisions needed to be made collaboratively with the parent/family. Physiotherapists talked about managing expectations, allowing them control over certain decisions, and negotiating, as illustrated below:

*“I mean, there are going to be parents who are difficult. But I suppose, again, it's just about that explanation and talking to them about what we would like to do and maybe giving them some options so they feel like they've got an element of control. So, this is what we want to achieve, this is how it could happen, I would choose this one. Are you happy for me to do it? I suppose if they're more informed and they understand and they feel like they've had a choice or been involved in the decision making then that makes that compliance a little bit easier.” (P107)*

Several physiotherapists commented that communicating with parents/families was a strength of physiotherapists in general when compared to other professions, *“for us, that feels like a bread and butter conversation” (P111)*. However, building effective relationships was seen as a double-edged sword, making decision making more difficult, as described by the physiotherapist in the quote below:

*“It's really difficult when you know the families as well. You know, we've known that patient's mum for four years now and she knows you as well because you've had loads of chats at the bedside. You get to know each other more than what one person who's come in and gone back out again would get to know them. So, then, I don't know, things just sometimes-, they don't get a wee bit woolly, but you've obviously got pressures from the parent who's saying, 'Well, what are we going to do? How are we going to fix this?’” (P112)*

Feeling under additional pressure from the parent/family was also discussed by the band 6 physiotherapists. They talked about having to actively work on and

develop communication skills with carers. This links back to physiotherapist experience, those with greater experience described more confident communication approaches.

A further theme was the influence of other healthcare professionals on decision making. Physiotherapists reported occasionally feeling pressured by consultants to provide treatment which they deemed inappropriate or use treatments based on the consultant's personal preference. These situations are illustrated in the quotes below:

*"If I would've said, 'No, we're not treating that child,' then she would've done it anyway. My perception in that situation, and this could be, I don't think it's arrogance, but it's just value of my profession. I think that if anyone is going to do that to that baby, then we're the best people to do that because we're the ones that are most likely to be, (a) effective, if the effectiveness is required, or (b) know when to stop pushing." (PI03)*

*"I had just kept this patient on my caseload because the doctors had wanted it, but for three days didn't do anything. Went in, made sure Mum and Dad were happy, made sure that he was still getting up into his chair, made sure he was getting regular nebulisers just to keep everything loose. Okay, great, and then I was leaving, do you know, so I could have discharged him on that day, but just because the doctor is like, 'No, I would quite like the physio to still go. We're worried about his chest,' we kept him on." (PI09)*

More positive relationships were described by several physiotherapists, they felt able to make joint decisions with consultants. The topic of collaborative decision making occurred frequently and crossed several of the Frameworks. It will be discussed further in Framework IV (Section 4.3.4.4), which explores physiotherapists autonomy and Framework V (Section 4.3.4.5), sharing responsibility to manage instability and adverse events. Physiotherapists across all banding levels reported using other physiotherapists for guidance with decision making. This was peer support for more experienced physiotherapists and senior

support for band 6/5s. This was common practice and involved sharing of ideas, gaining an external opinion, and reflecting on decisions. As described previously in Framework II (Section 4.3.4.2) physiotherapists faced the challenge of not always being able to access the patient in a timely fashion. This was attributed to other procedures or restrictions imposed by nursing staff. Physiotherapists felt this impacted on decision making around timing and approach to treatment.

The final theme was external influences on decision making. The lack of evidence to support physiotherapy treatments on PICU has already been raised in Framework II. Physiotherapists reported that although limited they did use evidence to inform decision making. This included guiding treatment choice, but also reading around specific diagnoses to improve knowledge. Linked closely to the use of peer support for decision making, physiotherapists from both small and large PICUs reported liaising with other units for guidance. This approach is described in the following quote:

*“I, sort of, do benchmarking or I have our chats with you guys and I've spoken to (person) at (place) quite a bit lately about a patient that I was, sort of, stuck with-, because that's what I struggle with. Because we're so small, it's that if I'm struggling with a patient, who do I go to?” (PI10)*

The impact of COVID19 on decision making was mentioned by several physiotherapists. Physiotherapists described how the airborne nature of COVID19 resulted in practical changes to treatments, which limited treatment options and influenced decision making. An experienced physiotherapist discussed how her decision making had been challenged with this unknown patient group, illustrated in the quote below:

*“I've now got that experience of one, but I feel that would be something to help me and I could give that example because that's, like you say, I didn't have that wealth of knowledge like I do with many other conditions, so, yes that was a challenge for me.” (PI01)*

This further highlights the importance of experience and clinical knowledge to guide decision making, as discussed previously in this Framework.

#### *4.3.4.4 Autonomy as a physiotherapist*

Framework IV explores autonomy as a physiotherapist and is closely linked to clinical decision making presented in Framework III (Section 4.3.4.3). Table 4.8 displays the Framework and three themes.

Table 4.8 Framework IV - Autonomy as a physiotherapist

Participant	Levels of autonomy	Developing autonomy (Facilitators)	Barriers
<p><b>PI01</b> Band 8 Medium</p>	<p>Part of the discussion not told what to do. Has high level of autonomy, otherwise would be able to continue in role. Less autonomy for rotational staff. Occasional disagreements, doctors feel the issue is physiotherapy related, had to keep repeating own opinion which was eventually listened to. Able to provide feedback on such situations.</p>	<p>Joint teaching sessions with multidisciplinary team, being able to be open with them. Understanding each other's roles</p>	<p>Busy consultants, unable to have valuable conversations.</p>
<p><b>PI02</b> Band 7 Medium</p>	<p>Lots of autonomy with certain tasks. Perception of being 'lucky' due to having good relationships with wider team/consultants. Consultant has final say, have responsibility for unit. Wouldn't do something they weren't happy with, need to be respectful. Feels security being on PICU with other team members available.</p>	<p>Having time to build a reputation.</p>	<p>Voice smaller as less physios compared to medics/nurses.</p>

<p><b>PI03</b> Band 7 Large</p>	<p>High levels of autonomy, good relationship with and support from consultants. Never conflict, more clinical discussion.</p>	<p>Being present.</p>	<p>Having a strong personality, being able to stand up for profession. Less experienced may be pushed into things.</p>
<p><b>PI04</b> Band 6 Large</p>	<p>Autonomous within the context of the PICU hierarchy. Final decisions lie with consultant, wouldn't go against them. If disagreement, plays the long game or uses multidisciplinary team.</p>	<p>Attendance at ward rounds.</p>	
<p><b>PI05</b> Band 7 Large</p>	<p>Good level of autonomy, feels respected and listened to by multidisciplinary team. Any disagreements tend to be resolved or a compromise achieved through discussion</p>	<p>Working on unit all the time.</p>	<p>Frustrating for band 6s who rotate, limited time to develop trust/autonomy. Decision making controlled by band 7s.</p>
<p><b>PI06</b> Band 6 Large</p>	<p>Physiotherapy is highly respected. The multidisciplinary team have a lot of faith in physiotherapy.</p>	<p>Ensuring good communication with team.</p>	<p>Some consultants more old-school in thought processes, take longer to agree on treatments.</p>



<p><b>PI07</b> Band 7 Medium</p>	<p>Feels has complete autonomy. Able to discuss with MDT but they wouldn't over rule.</p>	<p>Developing relationships over time.</p>	<p>Personality of consultants is a factor.</p>
<p><b>PI08</b> Band 7 Large</p>	<p>Has complete autonomy in terms of nurses and medics, not influenced by any other factors. Do have a weekly peer clinical discussion regarding longer term patients where make more joint decisions. Describes self as lucky, unit open to change, consultants pro-physiotherapy. Although things are not perfect, still got areas to work on.</p>	<p>Demonstrating clinical ability.</p>	<p>Less autonomy if less experienced.</p>
<p><b>PI09</b> Band 5 Large</p>	<p>Believes physiotherapists are autonomous practitioners, wouldn't be challenged by nursing staff. Doctors sometimes have strong opinions/requests. And from a physiotherapy perspective may not be appropriate. But quicker to just go and check the patient than having to discuss.</p>	<p>Need to involve multidisciplinary team in decisions to ensure buy in.</p>	<p>More difficult if part-time.</p>

<p><b>PI10</b> Band 7 Small</p>	<p>Feels has some autonomy but varies dependent on the consultant. Mostly able to have open discussions and feels like decisions respected. Some consultants want to make the final decision, like ownership. In situations of conflict, led to question own clinical reasoning/confidence</p>	<p>Must prove self to medical team, ask very specific questions and have a solution to the problem.</p>	<p>Physiotherapy seen in a very positive light but sometimes multidisciplinary team don't fully understand role and risks.</p>
<p><b>PI11</b> Band 8 Medium</p>	<p>Feels has autonomy, trusted by consultants. Dependent on which physiotherapist and their experience. In situations of conflict, led to question own clinical reasoning/confidence.</p>	<p>How well known you are, your reputation.</p>	<p>Disadvantage of being rotational, hard to gain doctors trust in short period of time. They approach the band 7 first.</p>
<p><b>PI12</b> Band 6 Large</p>	<p>Occasional struggles with doctors accepting treatment decisions, frustrating. Has been a bit of bullying in past to try and get patients treated, or multidisciplinary team will treat themselves. Feels belittled and not trusted. Varying levels of autonomy.</p>	<p>Being visible on the unit and getting to know multidisciplinary team.</p>	<p>Multidisciplinary team understand physiotherapy role and benefits.</p>

<p><b>PI13</b> Band 6 Small</p>	<p>Feels like has reasonable amount of autonomy, can make decisions. Although some consultants like to dictate physiotherapist input. Need to appreciate consultant responsible for patient. Very good relationships with nursing staff.</p>	<p>Communication style with multidisciplinary team important. Need to build respect.</p>	<p>Differences in consultant personalities.</p>
<p><b>PI14</b> Band 7 Small</p>	<p>Feels lucky as has a lot of autonomy. There's a good multidisciplinary team, all opinions valued. Treatment choices always up to physiotherapist. Very rarely conflicts on PICU more on wards.</p>	<p>Lots of joint projects with consultants and involvement in new doctor teaching.</p>	<p>Less autonomy for band 5/6's.</p>
<p><b>PI15</b> Band 7 Small</p>	<p>Feels lucky, has quite a lot of autonomy and is well respected. Seen as being useful. Doesn't encounter conflict, able to talk through issues.</p>	<p>Having confident conversations with consultants.</p>	<p>Reduced physio cover on PICU resulted in multidisciplinary team needing to input more.</p>
<p><b>PI16</b> Band 7 Medium</p>	<p>Has complete autonomy within own practice. Has issues with multidisciplinary team outside of profession using physiotherapy techniques. Consultants very open to discussion. Although times when disagree and has to stick with own decision.</p>	<p>Joint working with nurses, building relationships, earning respect.</p>	<p>Newer generation has less of a medical model approach, open to working more collaboratively.</p>

Most physiotherapists felt they had a high level of autonomy within their own practice and were not influenced by other members of the MDT. However, several individuals put this into the context of the PICU hierarchy, acknowledging that the consultant had overarching responsibility for the patient. These opposing experiences are highlighted in the following quotes:

*“Certainly myself and (person), I think we're completely autonomous in our practice. It's not influenced by any other factors, you know, medical staff handing over patients for example.... There are certain things that we hear and, not that we disregard them, but we don't think that that's necessarily what we can have a role in so we would tell them so.”(PI08)*

*“I'd say, overall, we are pretty autonomous within a realm of hierarchy. Ultimately, the buck ends with the consultant on service. And so, if you do something that destabilises their patient, it's them that has to mop up your mistake and I think that's where I've learned from the ECLS patients.” (PI04)*

Many described feeling lucky to have such a high level of autonomy and this was compared to the field of adult physiotherapy where this was not thought to be the case. When questioned about their perceived level of autonomy an experienced physiotherapist reported that they would not be able to continue in their role if they did not feel respected, illustrated in the quote below:

*“Amazing amounts, I don't think I'd still be here if I didn't, honestly I couldn't bear it... You know, if I had a doctor telling me I had to do BD physio or something I think I would just combust. I just don't, we don't have to put up with that luckily.” (PI01)*

Whilst exploring autonomy the physiotherapists discussed experiences of disagreements with the MDT. Most reported that these were infrequent and resolved easily through discussion and compromise. A few reported conflicts, where they felt unable to have their own opinion. Even experienced physiotherapists described questioning their confidence and frustration in such situations:

*“There are issue patients where we have constant battles. You do question your own clinical reasoning when somebody's consistently saying to you, you know, 'They need physio. We're not going to do this.' 'Well, I can't do anymore,' you know, and then you think, 'Well, is there something else I can do? Is there something that's more effective? Well, no, actually, we are doing the right thing.’” (P111)*

Another concept raised during the interviews was around the definition of autonomy, especially in relation to other health care professionals completing physiotherapy techniques. The challenges and frustration associated with this are highlighted in the following quote:

*“Within my practice, I think I have complete autonomy, but I guess it's whether you look at autonomy in terms of the physiotherapy practice...Are there examples, circumstances in which I wish staff outside of my team would either wait, or consult with us, or take our word and kind of believe us when we don't think this is the right approach. In practice, it doesn't always happen, and there's definitely moments even recently that I can think of where you just, you sigh and you think back how you'll address the issue. The most important thing is patient safety, kind of, being compromised, essentially... Do I wish that nurses wouldn't do what they call nursio etc? Of course I do.”*  
(P116)

The second theme was how the physiotherapists felt they developed autonomy and what facilitated this. These findings are summarised in Figure 4.5, together with barriers which was the third theme derived from the interview data.

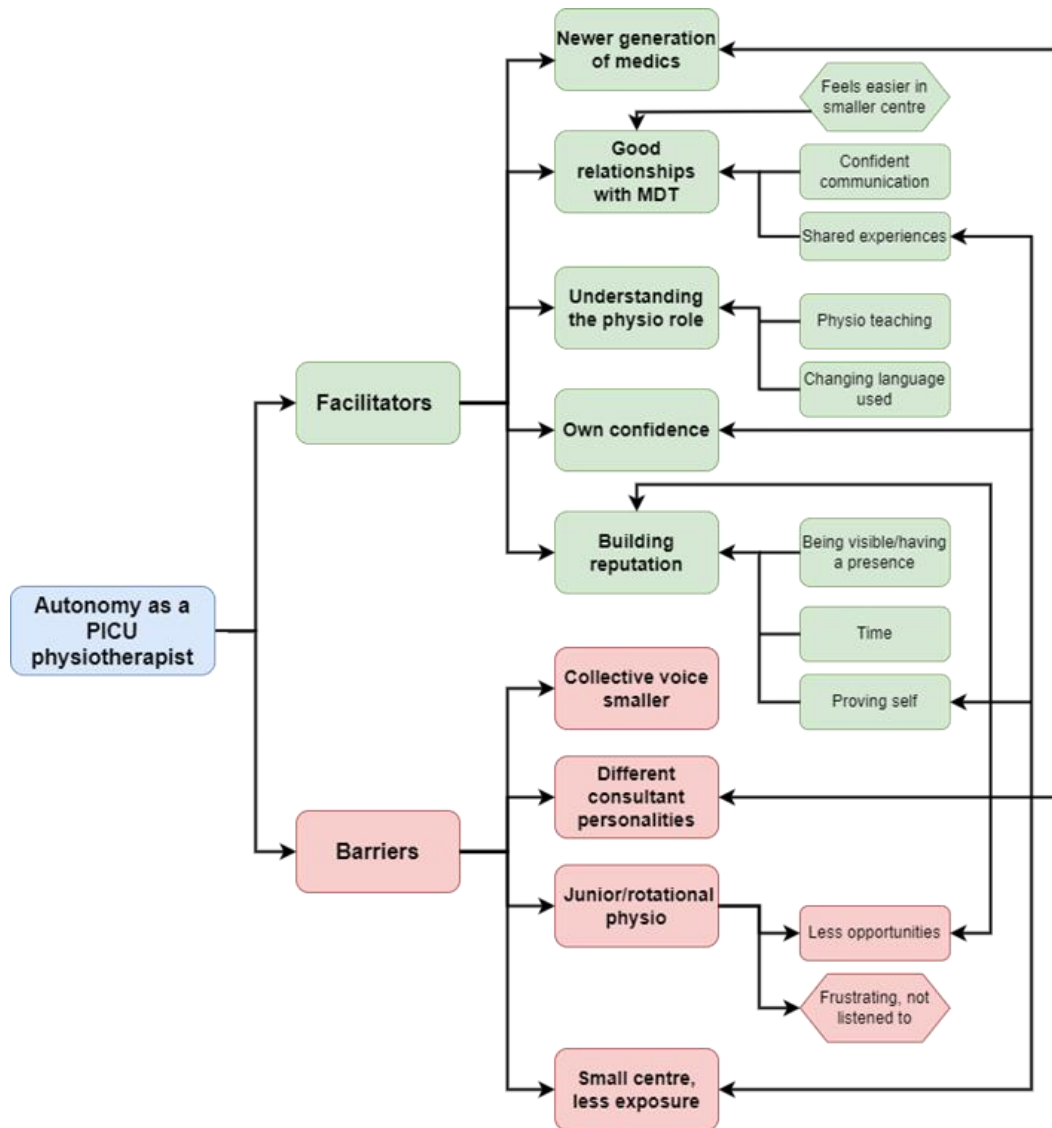


Figure 4.5 Facilitators and barriers to physiotherapists' autonomy (MDT - Multidisciplinary team, Physio – Physiotherapy)

Most physiotherapists commented on the importance of good relationships with the MDT to enable autonomy, based on mutual respect and trust. This linked to effective communication, shared experiences, and helping each other:

*“how you communicate with them, then it is almost a respect thing I guess, they respect you and vice versa, and more autonomy is given. So I think, for example, some bands have been there much longer so I think it has built up more working relationships with the MDT and more experiences.” (PI05)*

*“And it's, like, other things, I think, if we've proned a patient and they need their bedsheets changed then we might de-prone them but get the nursing staff to change sheets as well so, I think, kind of, respect is earned by working together, rather than just delegating jobs or just saying, 'No, I don't have time'.”(PI06)*

Physiotherapist confidence was reported as being an important component in building effective relationships and developing autonomy. This linked to experience, which was a common theme in Frameworks II and III. Physiotherapists from smaller centres reflected that they may have an advantage when building relationships within a smaller team.

Several physiotherapists described the need to build a good reputation on PICU to develop autonomy. The physiotherapists described the importance of being visible and proving their clinical ability, as illustrated below:

*“I think the consultants want to see that you've got the ability and can have that level of clinical discussion before they'll necessarily take what you say as gospel.” (PI03)*

Physiotherapists felt that the MDT having a good understanding of the role of the physiotherapist led to greater autonomy. They wanted them to have knowledge of indications, risks, and contraindications. This was reportedly achieved through promoting the role, education sessions, and also changing the language used to empower physiotherapists, as described in the following quote:

*“I think also we've, kind of, started to change the words that we use as well. Quite often before they would say, 'So, X, Y and Z need chest physio.' We probably sound like a broken record now but we quite often will repeat back, 'Right, so they're for an assessment, they're for an assessment, they're for an assessment?' Put it that way so we're not-, and we're trying to be very obvious and clear with the doctors, if physio is helping or it's not.” (PI12)*

Physiotherapists reported that consultant personality influenced the level of autonomy. This was predominantly related to the age of the consultant. Some

physiotherapists felt they were able to have more autonomy with newer medics, who were more collaborative and 'pro-physio':

*"I think perhaps that a newer generation coming through that are a lot more collaborative and MDT work and there's less of that medical model of, 'Yes, we're doing this because I say so,' and more, you know, 'What do you think about this?'" (PI08)*

Older consultants were often described as being ingrained in historical practice and making independent decisions. A contrasting opinion was highlighted by one physiotherapist who found medical trainees to be less trusting.

Junior or rotational physiotherapists felt they had less autonomy, which was also observed and described by the senior physiotherapists. The nature of their roles meant they had fewer opportunities and time to develop relationships and build rapport:

*"I think now our rotational sixes are coming down, I'm sure it's more difficult for them to say no to a consultant than it would be for me, but I'd like to hope they would still, you know, listen to their point of view, but I feel they might be able to push them into doing something but I think that's just an experience thing."*  
(PI01)

*"I think, because I'm only rotational, it's, like, hard to gain the doctor's, the consultant's trust in such a short amount of time."*  
(PI06)

Less experienced physiotherapists commented that consultants would normally approach Band 7s, leaving them feeling frustrated and undermined. The physiotherapists from the smaller centres reported that they had less exposure to some patient types, which they felt impacted on their confidence and reduced their autonomy.

One physiotherapist discussed autonomy in a more general context. Feeling that, as a professional group, physiotherapists have a smaller collective voice, which may result in less influence and impact:



*“I mean, it's not perfect, it's still, we have the PICU business meeting and I still find it's, particularly with our director now, he's not as good at being, we just get forgotten because there's like three physios on the unit, 140 nurses, however many doctors, so I do still keep having to say, you know, we also have a voice and a view from a different angle than you.” (PI01)*

#### 4.3.4.5 Managing instability and adverse events

The final Framework was based around how physiotherapists manage instability and adverse events, see Table 4.9.

Perceived risk factors for instability and adverse events were highlighted by most physiotherapists. They described three categories: patient types/diagnoses, clinical presentations, and medical support required, see Figure 4.6. There was consensus between the participants regarding these. Most highlighted that it was complex patients who presented with a combination of these factors, rather than just one in isolation, that they would deem higher risk. Several physiotherapists discussed the concept of physiotherapy as a last resort. They were asked to see patients when there were no other options left, these patients were critically ill and often did not tolerate treatment well, illustrated in the example below:

*“so lots of risks associated with treating them, and I think, the consultant was extremely keen because, to be honest with you, reasoning was that actually if we don't do something that probably they're not going to survive anyway, this could be, we need to disconnect, we need to see if the tube is patent, see if there is anything we can clear, to see if we can make any improvements really in that situation..... But I think that, probably the hardest decision because actually in the end the patients actually arrested and died, and that was a big learning curve for me, in terms of, and that is what I talked about kind of, the debrief and the chatting to her afterwards about well should we have done that or not, and feeling like well actually, he is probably going to die anyway.”(PI05)*

Physiotherapists found these situations difficult and unpleasant, with one commenting about feeling like they sped up the process of death.

Table 4.9 Framework V - Managing instability and adverse events

Participant	Risk factors	Preparation and planning	Sharing of responsibility
<b>PI01</b> Band 8 Medium	COVID19	Consultant present. Making sure parents aware of what might happen.	Ensures consultant present, doesn't request this often so taken seriously when does. Lots of discussion with unstable patients, both with multidisciplinary team and parents. Able to provide feedback to medics on situations.
<b>PI02</b> Band 7 Medium	Pneumothoraces		Discussions with consultants, joint decision making.
<b>PI03</b> Band 7 Large	High frequency oscillatory ventilation	Having medics around for cardiovascular support. Families need to be prepared by an experienced clinician.	Treating with another physiotherapist. Having consultant in bedspace for treatment. Discussion with wider team important.
<b>PI04</b> Band 6 Large	COVID, pneumothoraces, high frequency oscillatory ventilation, inhaled nitric oxide, premature, extra corporeal membrane oxygenation	Considers all potential consequences of input prior to treating child. Feels it is very important to explain all risks to parents, using correct terminology and what it will look like. Need to understand the risks and consequences from a medical perspective. Has learnt from a serious	Communicates widely if treating unwell patient.

		incident to understand things in more detail.	
<b>PI05</b> Band 7 Large	Called to see patients when there is nothing else they can do.	Prior to going to treat considers all potential consequences and how would deal with them, when to ask for help. Also important to prepare parents/family fully. Weighs up risk vs benefit. Awareness that may benefit despite additional interventions needed	Joint decision making with consultant, in depth conversations and treating together. Discusses and de-briefs with wider multidisciplinary team.
<b>PI06</b> Band 6 Large		Actions required to stabilise patient prior to treating. Need to be aware of the risks and plan for worst case scenario. What could be the best and worst outcomes. Has an awareness of other clinical systems, not just respiratory. Uses a proforma to do a full assessment of all the systems, includes reasons to treat and contraindications.	If concerns or contraindications will initiate conversations with doctors. Joint decision making with doctors regarding treatment.

<p><b>PI07</b> Band 7 Medium</p>	<p>Haemorrhage</p>	<p>Considers what strategies might minimise or prevent adverse events. Have to be honest with the parents about what could happen during treatment.</p>	<p>Joint decision making and treatments with consultants. Finds it helpful to de-brief and reflect with team, even just informally. Important to be honest, show human. Helps to process events. Acknowledges things can go wrong but need to use it to learn and improve for next time.</p>
<p><b>PI08</b> Band 7 Large</p>	<p>High frequency oscillatory ventilation</p>	<p>Use of clinical reasoning and questioning is important.</p>	
<p><b>PI09</b> Band 5 Large</p>	<p>Extra corporeal membrane oxygenation</p>	<p>Using clinical picture to weigh up pros and cons, seeing how scales balance.</p>	<p>Consultant present at bedside for unstable patients, not to interfere for safety. Still finding these situations difficult and seeking advice from seniors. Not yet making decisions independently.</p>
<p><b>PI10</b> Band 7 Small</p>	<p>Triple inotropes</p>	<p>Ensures consultant in bed space, emergency drugs ready.</p>	
<p><b>PI11</b> Band 8 Medium</p>	<p>Desaturation</p>	<p>Sometimes have to accept unwanted effect for a short period to be more effective and enable greater improvement in long term.</p>	<p>Discussion and involvement with multidisciplinary team.</p>

<b>PI12</b> Band 6 Large	100% Oxygen		Liaising with multidisciplinary team but also important to discuss with parents/carers.
<b>PI13</b> Band 6 Small	Inhaled nitric oxide	Need to plan how will manage instability.	Involve consultants in physiotherapy decisions. Also working collaboratively with parents. Relies on senior physiotherapy support with complex decisions.
<b>PI14</b> Band 7 Small	Ex-premature, chronic lung disease, pulmonary hypertension, inhaled nitric oxide, high frequency oscillatory ventilation.	Preparing the family for effects of physiotherapy. Needs to have bedspace set up and all equipment prepared.	Reflecting back on success of treatment, for future input.
<b>PI15</b> Band 7 Small	Bleeding, oncology, 100% oxygen.	Sets parental expectations prior to treating. Have to weigh up risk vs benefit, consider the context of what aiming to achieve.	Would run more complex decision making through consultants.
<b>PI16</b> Band 7 Medium	If hasn't been disconnected.	Use of pre-recruitment strategies. Awareness of how can reduce instability. Takes a holistic approach, look at all the systems, weighing up the risk. What is the patients main issue, will physiotherapy change their clinical course.	

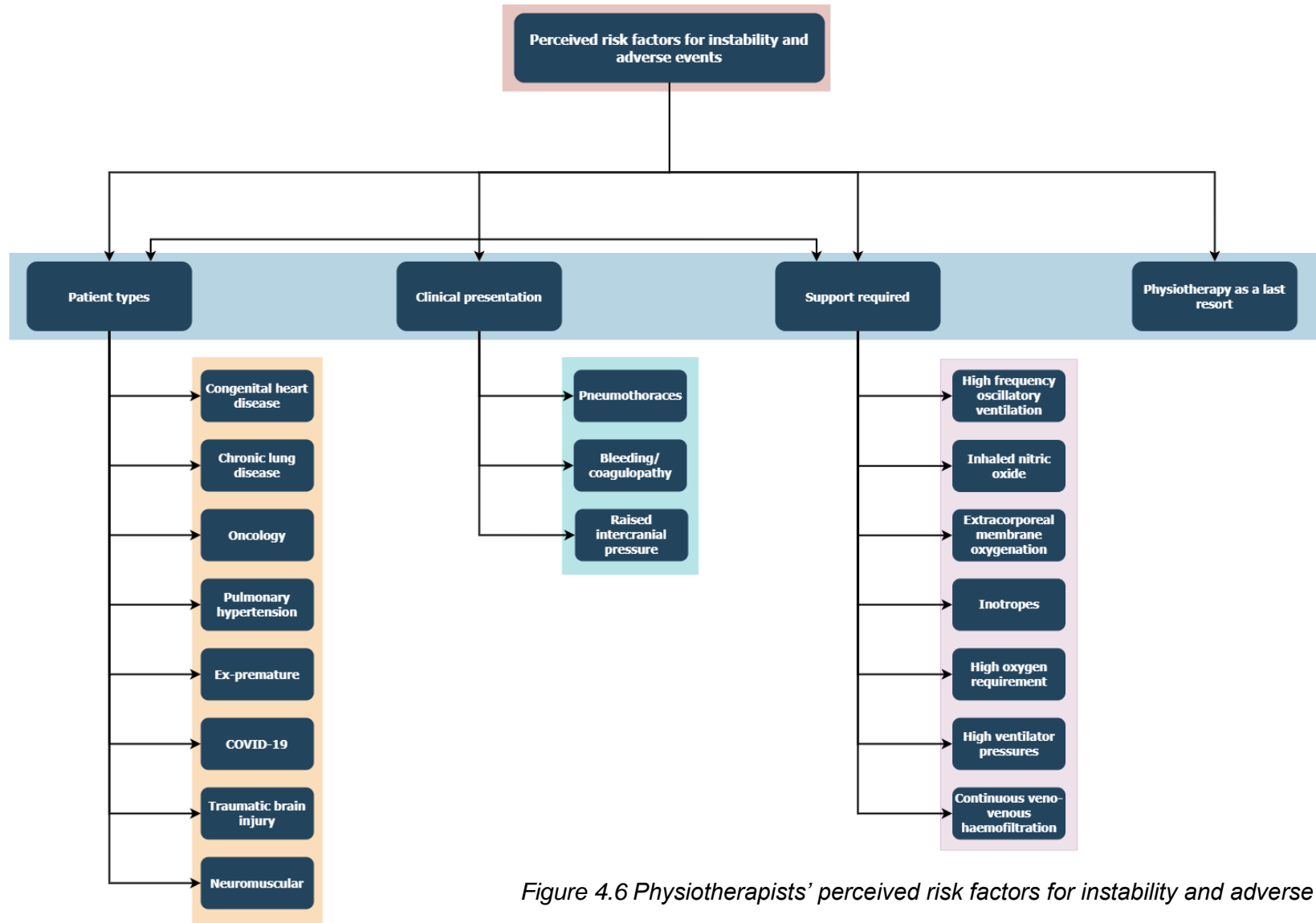


Figure 4.6 Physiotherapists' perceived risk factors for instability and adverse events

Two key themes were generated in relation to managing instability and adverse events: preparation and planning, and sharing of responsibility. Physiotherapists talked about needing to understand and anticipate all potential consequences of treatment, knowing what the worst outcome could be, and plan how they would manage this:

*“In my head, before I even enter into putting on my gloves and gowns and everything on to touch that baby, maybe, making sure I have thought of what can go on in this bed space and what have I got on hand to manage it, and where is my ceiling as a physiotherapist and when do I need to seek help.” (PI05)*

Several practical strategies were discussed, including ensuring the bedspace was set up and all equipment accessible prior to starting, taking a second physiotherapist to treat with, having emergency drugs ready, and ensuring the wider PICU team was informed. Physiotherapists commented that these skills had been developed over time, through learning from mistakes and experience. The physiotherapists described gaining a good understanding of the bigger picture of the child prior to any intervention. This was linked to having all necessary information to weigh up the risks and benefits of treatment.

*“I suppose it's always going to be weighing up benefit versus risk, isn't it really? And I suppose platelets can be low but if you've got no sign of active bleeding and they've got secretions, you know, and X-ray changes, and increasing oxygen requirements and pressures, then maybe we would think, 'Well, we're going to have to do something.’” (PI15)*

One experienced physiotherapist also described occasionally accepting short-term unwanted effects to facilitate a better outcome in the longer term.

The physiotherapists felt strongly that it was important to prepare the parent/family for physiotherapy, especially in situations where the child was critically unwell. They described taking an honest approach and wanted them to understand what physiotherapy would involve and how the child may respond, specifically any



negative effects. One physiotherapist highlighted how their own experience reinforced the importance of this:

*“I explain what I'm going to do and what it will look like and I say, 'There will be lots of alarms.' And I will be honest that they may desaturate, they may drop their heart rate, we may up their medicines. And so I am very honest with what it will look like. I explain what manual techniques are. I explain what suction is. And so they know what's going to happen. I've also had experience of being a patient myself recently and you take in 10% of what they're telling you and so actually that has massively changed my practice from being on the other side.”*  
(PI04)

The importance of the parent/family being prepared sufficiently and by an experienced clinician was also discussed. The quote below illustrates the impact when this was not achieved:

*“The only frustrating thing, that I didn't chat to parents. My junior did. So, I don't think parents were fully informed to the extent of the fact of how bad we thought this was going to go. As predicted, we started treating, they desaturated to 40, we could just about hold them at 40, but couldn't get them any higher. And then blood pressure went, cardiac arrest and subsequently died and parents then said we were murderers.”* (PI03)

Most of the physiotherapists reported that they shared the decision making for complex/unstable patients with the MDT and more specifically the consultants. Physiotherapists described that this approach provided opportunities for debriefing and reflection with the MDT. They felt having joint responsibility prevented any detrimental consequences of treatment lying solely with them:

*“We'll do it together. We accept responsibility for the adverse effects that might happen. We understand that potentially we might have bleeding or we might get, you know, cardiovascular instability and we understand that's your concern but we really*

*feel that we need to try something.' But they wouldn't then just abandon us, they would still, you know, they would be either in there or around and they, again, essentially recognise our concerns but then would take the responsibility for the adverse events that we have maybe identified as a potential problem.”*  
(PI07)

Junior physiotherapists talked about needing senior support in these situations and viewed them as learning opportunities. The parents/family were also frequently mentioned as playing a role in this process:

*“I think we'd also be having lots of discussions with the mum and encouraging the Band 5 to have discussions with the mum to find out what the mum's feelings were about it all.”* (PI12)

Decisions regarding treatment were made collaboratively with the parents, which links to Framework III (Section 4.3.4.3).

#### **4.3.5 Summary**

This section has explored and presented all analysis from the interview data. The key findings that will be discussed in the following section are:

- Variation in physiotherapy practice, specifically the differences in personnel involved in delivering chest physiotherapy.
- The influence of experience on physiotherapists' clinical decision making.
- Decision making as a collaborative process with parents/families and the MDT.
- The complex and multifaceted nature of physiotherapists' decision making.
- The patient, clinical and medical support risk factors for instability and adverse events with chest physiotherapy.
- The use of preparation and planning to manage instability and adverse events.

## **4.4 Discussion**

This section will discuss the key findings, summarised above, in relation to the research questions.

### **4.4.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

This study demonstrated variation in how physiotherapists deliver chest physiotherapy, with opinion divided between providing treatment alone or with another person, and the profession and role of the second person. Physiotherapists who predominantly treated alone felt this approach was more effective. Several physiotherapists who reported treating with another person also shared this opinion and completed all physiotherapy components (MHI and CWV) themselves. This rationale for a single therapist approach is supported by literature exploring the timing of MHI and CWV. The effectiveness of MHI and CWV is based on creating an expiratory flow bias, moving secretions towards central airways through the two-phase gas liquid transport mechanism, described in Section 1.1.2 (Volpe et al., 2020). Studies have demonstrated that optimal timing of CWV in the breath cycle (at the start of expiration) is vital to creating this expiratory flow bias (Marti et al., 2013, Shannon et al., 2010). Shannon et al. (2010) concluded that CWV need to be applied in a well-coordinated manner which is easier to achieve when a single individual is controlling both the MHI and CWV.

An important consideration whilst debating the personnel involved in treatment is the potential detrimental consequence of poorly timed physiotherapy techniques. CWV applied early in the breath cycle have been found to increase peak inspiratory pressure (PIP). The mean difference between early and optimal chest wall vibrations was 8.4 cmH<sub>2</sub>O (95% CI 6.0 to 11cmH<sub>2</sub>O, P< 0.001), with PIP as high as 56cmH<sub>2</sub>O during early CWV (Shannon et al., 2010). High PIP can impair mucociliary clearance and result in lung injury through barotrauma (Diaz and Heller, 2021, Yamashita and Veldhuizen, 2011). This offers further support for physiotherapists' preferences to complete a single person technique.

Despite the considerations discussed above the double treatment, with either a second physiotherapist or a nurse, was popular with physiotherapists interviewed

in this study. The double treatment involves one individual providing MHI whilst another applies CWV. Physiotherapists attributed this approach to improving efficiency and safety. Within PICU prolonged periods of disturbance and disruption can lead to significant fluctuations in stability. This may contribute to further organ failure, and increased morbidity and mortality (Rafter et al., 2015). Therefore, it is a reasonable approach to streamline physiotherapy treatment through involvement of a second person, minimising length of handling and avoiding repeated disconnection and de-recruitment. Similarly, high risk and complex procedures on PICU, e.g., intubation, are frequently time limited and involve checklists to ensure efficiency. The size of the patient also requires consideration when discussing the number of individuals involved in treatment. Logistically two people may be required for treatment when faced with a larger patient.

Whilst patient safety should be a prime concern for physiotherapists working on PICU, the effectiveness of the intervention also requires consideration. Considerations might be whether a double person technique is necessary for more stable, smaller children, with single organ failure, and lower organ dysfunction scores or whether there is a risk of being too cautious to the detriment of the intervention itself. Shannon et al. (2010) reported that the complexity of MHI and CWV timing increases when two people are involved, they are reliant on visual, verbal, and tactile cues. This is not to dismiss the unpredictability of children on PICU and their critical status, but nursing staff and additional support can be easily accessed. It is important to clarify that high-risk children on maximal therapy are a unique group, requiring different approaches. Management strategies for these children will be discussed in Section 4.4.3.

The differences in personnel delivering chest physiotherapy in this study were also related to the size of the PICU and the physiotherapists and nursing workloads. Physiotherapy staffing levels have also been reported to influence treatment length and technique choice in studies involving adult ICUs and acute respiratory care (Matilde et al., 2018, Smith et al., 2007, Van der Lee et al., 2017). Optimal staffing levels on PICU is a widely debated topic and there are clear UK guidelines for minimum nursing and medic to patient ratios (Paediatric Critical Care Society, 2021). Whilst the same document recommends specialist paediatric critical care

physiotherapists, it offers no suggestions for time allocation or workforce size. In this study physiotherapists who predominantly treated with a physiotherapy colleague were from the smaller centres, indicating a higher therapist to patient ratio. In contrast, physiotherapists in very busy units had limited access to a second person of any profession. These findings highlight how variability in service provision influences variability in practice. The complexity of NHS hospital structures may compound this issue. Physiotherapy departments are often situated within Allied Health directorates and are not considered within essential PICU staffing levels or budgets, hence individual PICUs have limited control over posts. Furthermore, without formal staffing standards and limited evidence to support the clinical effectiveness of physiotherapy, it is difficult to gain additional funding.

Rationale for variation in practice was also discussed in more general terms. Reliance on historical practice and difficulties affecting change, within both physiotherapy and the wider MDT, was a common theme in this study. Culture change and changing practice within PICU is challenging and not only requires change in behaviour, but often in organisational processes and technology systems (Tume et al., 2021). Barriers to change in PICU include poor receptivity to change, with individuals preferring what is known and familiar, and a lack of readiness for change, related to time, skills and staffing (Steffen et al., 2021). Similar to the findings in this study, Steffen et al. (2021) reported that more senior healthcare professionals were less receptive to change. An important first step in implementing change is providing strong scientific support (Hopkins et al., 2015, Steffen et al., 2021). The lack of robust evidence supporting chest physiotherapy was frequently discussed in the current study and provided as rationale for the reliance on experience and historical practice, and subsequent variation.

#### **4.4.2 Research question 2: How do physiotherapists make decisions regarding delivery of chest physiotherapy and what other factors influence this decision making?**

The physiotherapists in this study described decision making as a complex process, which evolves over time and includes a combination of linked influencing

factors. Physiotherapists' knowledge and experience, relationships with family/carers and MDT collaboration were important factors.

Level of experience accounted for some differences seen in decision making approaches in this study. Experience has been reported as a key component of physiotherapists' clinical decision making in adult intensive care and other healthcare settings (Connolly et al., 2020, Matilde et al., 2018, McGlinchey and Davenport, 2015). Cardiorespiratory physiotherapists' decision making has been described as a continuum from novice to expert. This relates to development of practice models, retrieval of knowledge, refinement to individual needs, perspective of broader context and management of social relationships (Case et al., 2000, Smith et al., 2010). A study comparing novice, intermediate and expert paediatric therapists also demonstrated differences in decision making strategies (King et al., 2007). Novice therapists relied on literature to guide their treatments whereas experienced therapists were able to customise their approach. The less experienced physiotherapists in the current study described less confidence and autonomy, and communication challenges. These findings are similar to results of a study comparing novice and expert physiotherapists undertaking emergency on-call duties (Dunford et al., 2011). Physiotherapists with less experience reported lower confidence and a requirement for greater support.

The definition of novice varied in the studies discussed, authors used length of experience or self and peer classification. Although band 5 and 6 physiotherapists with limited PICU experience were interviewed in this study they all had a good grounding in general physiotherapy. It is rare that complete novice physiotherapists are expected to work on PICU. However, it is important to consider the increased support required by less experienced physiotherapists and the impact on workforce planning, supervision models and education strategies.

The multifaceted nature of decision making, as described in this study, has been widely documented in both intensive care and physiotherapy (Chipchase and Prentice, 2006, Connolly et al., 2020, Thackray and Roberts, 2017). Several clinical decision making models are discussed in the healthcare literature, offering theoretical bases for these complex interactions. Historically, individually defined models were proposed, the hypo-deductive and intuitive-humanist, these are

explored in Section 1.4.1 (Banning, 2008, Edwards et al., 2004). Several authors have described physiotherapy decision making as involving a combination of these models (Edwards et al., 2004, Thackray and Roberts, 2017). These findings resonate with the results of this study, where experience, knowledge and 'gut feeling' were used. A combined decision making model proposed by Croskerry (2009) may align more with findings from this study. It incorporates pattern recognition and dual-process theory. The model works on the interplay of two systems, system 1 – intuitive and system 2 – analytical. Dependent on the situation, individuals use either or both systems to make decisions. The personality, experience, and education of the individual, together with the context of the decision are included in the model, all of which were discussed by the physiotherapists in the current study.

Despite the value clinical decision making models have in understanding behaviours and informing education, they focus on the individual in the decision making process. Collaborative decision making with families and the MDT was a common theme in this study. Shared decision making is advocated in PICU and involves incorporating family values and preferences into the process (Sánchez-Rubio et al., 2021). It has been described as an essential component of family-centred care, which is recognised as best practice within ICU settings (Davidson et al., 2017, van den Hoogen and Ketelaar, 2022). Parents/carers face significant challenges in the unfamiliar and perceptually threatening environment of the PICU, including communication barriers, loss of the parental role, lack of control and competence (van den Hoogen and Ketelaar, 2022). The physiotherapists in the current study demonstrated good awareness of these issues and shared decision making appeared to be inherent within their practice.

There is no unified model of shared decision making. Forty unique shared decision making models were discovered in a recent systematic review (Bomhof-Roordink et al., 2019). Models ranged from patient-clinician dyads to interprofessional models. The authors identified 53 different elements within the description of the models, these were clustered into 24 components. Prominent components included describing treatment options, tailoring information, and creating choice. Physiotherapists in this study highlighted the importance of educating, allowing

control and engaging families in decisions. These behaviours are in line with the components of the shared decision making models explored by Bomhof-Roordink et al. (2019). Therapists working in paediatric rehabilitation have also described similar approaches to support informed choices (King et al., 2007). Other studies have highlighted the importance of open communication and ensuring parents are fully informed to facilitate shared decision making (October et al., 2014, Sánchez-Rubio et al., 2021). This was also reflected in the findings of the current study, where building relationships and developing effective communication skills with families were frequently discussed. The effectiveness of communication with families and their understanding of the information provided have been reported as a challenge in the application of shared decision making (Bae, 2017, Giuliani et al., 2020).

Further challenges associated with shared decision making were raised in this study, including added pressure, blurring of relationships and the need for complex and sensitive negotiations. The fine balance of family involvement in decision making on adult ICU has also been described by Wubben et al. (2021). Doctors raised concerns about pressure to complete or continue unnecessary treatments. Negotiation between family and healthcare professionals has been described as an essential process to facilitate family-centred care and improve parent/carer participation (Corlett and Twycross, 2006). This review reported that mutual negotiation was limited within nursing care. Although direct comparisons should not be made, due to outdated studies and differences in skills and characteristics of physiotherapists and nurses, the recommendations made to place greater emphasis on negotiation skills are relevant to physiotherapy education. Kon (2010) presented a shared decision continuum, with one end representing patient/parent driven decision making, the opposite end clinician driven decision making, and in the middle many possible approaches. The authors highlight the complexities of shared decision making, discussing that it takes different forms in different situations and hence approaches need to be adaptable.

The influence and inclusion of families was discussed in detail by physiotherapists of all levels of experience in this study. Previous studies report contrasting results. Experienced therapists demonstrated greater appreciation of the family context



and their expectations in a paediatric rehabilitation setting (King et al., 2007). Similarly Embrey et al. (1996) reported novice paediatric physiotherapists to be more activity orientated, compared to experts who displayed greater psychosocial sensitivity. These studies used 'think aloud' methods with pre-recorded assessment and treatment sessions, which may account for the differences with our 'self-reported' practices. The influence of the parent/carer was a strong theme in this study. This factor was less prevalent in studies investigating physiotherapists' decision making with adult patients. Parents/carers play an essential role in care giving and are the main advocates for their child, hence family influence may be more critical to decision making in paediatric settings.

Alongside shared decision making with families, the physiotherapists reported that other healthcare professionals influenced their decision making. Similar findings have been reported by Smith et al. (2008) who described physiotherapists' decision making as a social and collaborative process. The influence of the MDT was frequently viewed positively and effective collaborations were described. Important components were building rapport, mutual respect and high levels of autonomy. Care models that prioritise MDT collaboration and involvement in clinical decision making have been linked to better safety and quality of care (Baggs et al., 1999, Kim et al., 2010). MDT models of care are widely endorsed, and UK standards stipulate that PICUs should have pharmacy, psychology, dietetic, physiotherapy, occupational therapy and speech and language therapy provision (Durbin, 2006, Paediatric Critical Care Society, 2021). Despite this, several physiotherapists in this study described a culture of professional hierarchy which negatively impacted their decision making. The persistence of traditional hierarchies in PICU has been reported to limit nursing and allied health input into decision making and increase moral distress (Larson et al., 2017, Wall et al., 2016). The problems with interprofessional hierarchies were raised by health professionals in a study investigating the management of the deteriorating child (Gawronski et al., 2018). Seniority and perceived competence impacted communication, with the opinions of junior staff disregarded by medics. These findings are in line with the challenges described by some physiotherapists in the current study.

These power dynamics were not experienced by all physiotherapists, which may indicate a changing culture within the PICU community. New healthcare professionals are trained in interdisciplinary settings and an increase in cross discipline roles, such as advanced clinical practitioners and consultant therapists, may be helping to reduce barriers. However, there is scope for improvement. Given the increasing complexity of patients on PICU, the knowledge and skills of all MDT members should be utilised to ensure best practice.

#### **4.4.3 Research question 3: What do physiotherapists perceive to be risk factors for physiological instability and adverse events, and how do they manage these?**

Perceived risk factors for instability and adverse events were consistent between physiotherapists in this study and included a range of patient, clinical and medical therapy components. Although risk factors have not been explicitly investigated in this context, the findings from this study are comparable to the well documented precautions for physiotherapy in PICU (Morrow, 2015, Pryor and Prasad, 2008). Caution is advised for premature infants, those requiring haemodynamic support, pulmonary haemorrhage, and unstable or high ICP. The physiotherapists in this study highlighted ex-prematurity as a potential risk factor for instability and adverse events. Ex-premature infants are a heterogeneous population which may result in uncertainty about the tolerance of physiotherapy treatment. The greater vulnerability of these patients has been described within the literature, together with their higher prevalence of co-morbidities (Frawley, 2017, Glass et al., 2015). Conditions associated with ex-prematurity, including osteopenia and chronic lung disease, can impact physiotherapy treatment options.

The physiotherapists described most concern for patients with multiple risk factors, including a combination of co-morbidities, multi-organ involvement and maximum therapy. Although not specific to physiotherapy interventions, an increased risk of critical incidents on PICU and NICU has also been associated with a combination of patient and clinical related factors (Ligi et al., 2008, Niesse et al., 2011). These included gestational age, male gender, illness severity, and length of mechanical ventilation. Dewan et al. (2020) developed a clinical decision support tool to identify PICU patients at high-risk of clinical deterioration. The tool incorporates 15

criteria encompassing a variety of organ systems, including ventilation, cardiac dysfunction and renal replacement therapy. Multi-component scoring systems are widely used on PICU to measure severity of illness, for example PELOD (Bembea et al., 2022, Leteurtre et al., 2013). The cumulative effect measured by these tools is suggestive of the informal processes described by physiotherapists in this study.

Patients for whom physiotherapy was implemented as a '*last resort*' were also reported as high risk. From the accounts provided, these patients were receiving maximal medical therapy with high organ dysfunction scores, and therefore at an increased risk of morbidity and mortality (Leteurtre et al., 2013). The personal experiences discussed in this study resulted in poor outcomes for the patient. Physiotherapists found these situations challenging and described feelings of stress. There is a wealth of literature exploring nursing and medical experiences of end-of-life care, and similar feelings of high emotional burden, stress and inadequacy are reported (Finotto et al., 2020, Mu et al., 2019, Shorey and Chua, 2022). Several small studies have explored physiotherapy students' experiences of death (Pilmoor, 2021, Powell and Toms, 2016). However, there is a paucity of literature involving qualified or experienced physiotherapists, and no exploration of this phenomenon of treatment as a '*last resort*'. Whilst it should be acknowledged that being present and feeling responsible for a patient's death is a very specific situation relevant to only a small cohort of physiotherapists, it varies significantly from the more familiar experience of being involved with a patient who subsequently dies. This is an important consideration for physiotherapy teams in ICU environments and mechanisms should be in place to support individuals.

Preparation and planning were key strategies identified by physiotherapists to manage high risk patients and minimise instability and adverse events. Preparation of equipment and appropriate personnel, together with the development of an escalation plan were common strategies. Although described in a less formal manner these approaches are similar to procedural and safety checklists and pre-brief strategies routinely used for other high-risk interventions in PICU e.g., intubation. Other areas of physiotherapy implement more formal processes. Risk and safety assessments are commonplace in early mobilisation on PICU, with specific bedside tools available (Choong et al., 2018). The variation

in practice, differences in MDT decision making, and organisational restrictions described previously in this thesis may offer explanation for the more ad hoc approaches described by physiotherapists in this study. Physiotherapists acknowledged that strategies developed over time and with experience. Formalising the processes for higher risk patients may be of benefit for junior, on-call or less confident staff.

#### **4.5 Researcher-participant relationship**

The impact of my clinical role as a paediatric critical care physiotherapist and my experience within this field were key considerations throughout this study. Considering and managing the researcher-participant relationship is essential in qualitative research. This requires the values, assumptions and prejudices of the researcher to be acknowledged, and it is increasingly accepted that the interviewer will not have complete neutrality (Hand, 2003, Ritchie and Lewis, 2013). Ensuring awareness of this influence through reflexivity is recommended to prevent manipulation, reduce bias and achieve rigor (Hand, 2003, Koch and Harrington, 1998). As part of the reflexive process Spencer et al. (2003) highlight the importance of recognising and exploring the theoretical and ideological perspectives and values of the researcher prior to the study. My epistemological position and perspectives have been discussed in Section 2.3.

Reflection prior to data collection enabled strategies to be developed. I explicitly introduced and presented myself within the role as researcher not clinician. The aim of this was to reduce hierarchical imbalance and build equity between me and the participant (Seidman, 2019). This was more challenging with physiotherapists I had met previously, however only one physiotherapist asked me directly about my own practice. Open questions were used and linked to phase 1 results to prevent statements being associated with my personal opinions or experience. This approach is recommended by Seidman (2019) who highlighted the importance of building an appropriate rapport, by erring on the side of formality and avoiding sharing one's own experiences. However, my clinical knowledge provided advantages to the data collection and analysis process, allowing me to understand the context of the physiotherapists' experiences and the clinical presentation of the patients.

Personal reflections were completed after each interview and included self-critique. This is a vital component of interviewing, ensuring a constant awareness of personal influence and bias. Through this self-reflection I was able to refine my interview technique during data collection. It allowed me to acknowledge my own discomfort in exploring more personal and emotional responses attached to experiences/situations and I subsequently became more confident and comfortable probing these areas in more depth. Reflection on certain interviews also reminded me to maintain and reinforce my position as a researcher within the interview. This improved self-awareness allowed me to disconnect more effectively from my own clinical opinions. The process also improved my confidence in my own interviewing style, I was able to see interesting and relevant data being collected.

The Framework analysis method also ensured the results were driven by the data. The preliminary Frameworks were shared with one member of the research team (JW) to check for bias. Following completion of the analysis the transparency of frameworks and themes was assessed by two members of the research team (HS, JW), as previously described in Section 4.3.3.

#### **4.6 Limitations**

The pre-selected PICUs were chosen using a purposive sampling strategy, to ensure they were representative of NHS UK PICUs. Unfortunately, one PICU in East Anglia, South East and Greater London was not recruited. Furthermore, only one participant was recruited from the other PICU in this region. Due to the time constraints of the fellowship and COVID19 delays I was unable to include any additional sites. The sampling bias introduced by this geographical unbalance was further confounded by the over representation of participants from the two largest PICUs involved. Given the small community of PICU physiotherapists in the UK it was deemed important to recruit all physiotherapists who showed interest. The issues of self-selection bias also need to be considered, physiotherapists with less confidence or negative experiences may not have volunteered. There was good representation with regards to banding and gender which aimed to minimise this. Additionally, a wide spectrum of experiences, both positive and negative, were shared during the interviews.

Only one ethnic group (White British) was represented by the physiotherapists in this study. A recent paper reported that the majority of qualified physiotherapists within NHS Trusts and Clinical Commissioning groups in England (at 30<sup>th</sup> September 2021) were classed as white British (87%, 22180/25520), which suggests the participants in this study were representative of the wider physiotherapy community (NHS Digital, 2022). However, the lack of physiotherapists from other ethnic groups needs acknowledging. This absence of diversity introduces bias, with the practices and opinions of physiotherapists from minority groups excluded.

The advantages of completing virtual interviews have been described previously in Section 4.2.1. There are several practical issues and limitations to consider. The ability to build rapport is closely linked to interpreting non-verbal communication. This was more challenging during the interviews with the two physiotherapists without visual software. It was difficult to interpret emotions and there was more talking over each other. However, I was still able to gather data relevant to the research questions and, reassuringly, neither of these interviews were the shortest. One physiotherapist wore a surgical mask, as per trust COVID19 guidelines, however it was still possible to interpret facial expressions, gestures and body language. Interruptions are a well-documented problem with virtual methods, reported to impact flow and data richness (Archibald et al., 2019, Saarijärvi and Bratt, 2021). In this study four interviews had interruptions, however from the field notes and recordings these did not appear to have a significant impact on the discussion or provide distractions. Similarly, despite some interviews being completed in open environments, the physiotherapists were willing to share personal experiences and distractions were minimal.

Generalisability within qualitative research is described as identifying recurrent social processes and also considering deviant cases (Silverman, 2020). This was achieved in this study and hence despite the limitations described above the results of this study are believed to be generalisable to other PICU physiotherapists within the UK.

## **4.7 Conclusion**

This chapter focused on the interview component of phase 2, work package 1. It is the first study to involve interviews with PICU physiotherapists, engaging them within the research process. Variation in physiotherapy practice was evident, specifically related to the personnel involved in delivering chest physiotherapy. Decision making was described as collaborative with the family/carers and multidisciplinary team. Physiotherapists emphasised the importance of experience when making decisions on PICU. Numerous patient, clinical and medical support risk factors for instability and adverse events with chest physiotherapy were identified. Preparation and planning were the main strategies employed by physiotherapists to manage instability and adverse events.

## **5. Work package 1 – Phase 2 Focus groups**

### **5.1 Introduction**

As outlined in Chapter 4, work package 1, phase 2 had multiple components. Chapter 4 presented the methods, results and discussion of the semi-structured interviews. This chapter concentrates on the focus group element of phase 2. The method and rationale are presented, together with data analysis and discussion of the key findings.

#### **5.1.1 Aim**

The overall aim of phase 2 was to provide an in-depth understanding of the decision making that guides delivery of chest physiotherapy in UK PICUs. This component of phase 2 allowed additional exploration of the findings of phase 1 and the semi-structured interviews. Areas which required further exploration were physiotherapists' real-time, bedside decision making and their management of instability and adverse events. These topics have been explored in Chapter 4, but from a more general perspective.

#### **5.1.2 Research questions**

The research questions which related to phase 2 were:

1. What is current chest physiotherapy practice within UK paediatric intensive care units?
2. How do physiotherapists make decisions regarding delivery of chest physiotherapy in UK paediatric intensive care units, and what other factors influence this decision making?
3. What do physiotherapists perceive to be risk factors for physiological instability and adverse events, and how do they manage these?



## **5.2 Methods**

### **5.2.1 Study design**

The second component of phase 2 was a qualitative study, involving focus groups with PICU physiotherapists. As with phase 1 and the interviews this was a cross-sectional study to explore certain phenomena at a single time point. Connolly et al. (2020) used focus groups to explore physiotherapy practice in adult intensive care. Using this method allowed the authors not only to describe practice, but also to explore experiences and the rationale behind decision making. Focus groups can be used following interviews to allow issues to be discussed in more detail, confirm experiences, and help with interpretation of results. Findings from both methods can be integrated to provide a richer understanding of the research problem (Hennink, 2007, Ritchie and Lewis, 2013).

A focus group is a particular method of qualitative research that involves discussing a specific set of issues with a pre-selected group of people (Hennink, 2007). Participants are selected because they have characteristics in common that relate to the research topic (Krueger and Casey, 2015). The main purpose is to identify a range of different views and experiences. Ritchie and Lewis (2013) highlight that additional data are generated by the interaction between participants.

Focus groups can provide a more efficient data collection method than one-to-one interviews, generating a greater breadth and depth of data in a single session (Hennink, 2007). Participants may also feel more comfortable and empowered in a group setting (Hennink, 2007, Sim and Snell, 1996). Hence the inclusion of focus groups in phase 2 aimed to generate data of different quality and depth than previously collected in work package 1. Focus groups have been described as creating a more natural environment where participants are influencing and influenced by others, just as they are in real life (Krueger and Casey, 2015, Ritchie and Lewis, 2013). This was an important consideration in this study, given the practical and clinical topics under discussion. Focus groups utilise the group dynamic to stimulate spontaneous discussion and debate (Hennink, 2007). This was also a key component in this study to allow further exploration of the rationale for differences in practice observed in phase 1 and the interviews.

The challenges associated with focus groups are predominantly related to group management. Compared with one-to-one interviews, data collection is unpredictable and there is a risk of collecting redundant data. The group dynamics need to be effectively managed to avoid individuals dominating the discussion, ensure all voices are heard and discussion remains on topic (Ritchie and Lewis, 2013). To overcome these challenges a carefully selected, skilled moderator was used. Another criticism is that participants may intellectualise or invent responses when in a focus group setting. Additionally self-report bias is a general limitation of qualitative methodology. This problem is minimised when a variety of data collection methods are used and findings triangulated, as was the case in this study (Krueger and Casey, 2015).

As with the phase 2 semi-structured interviews a virtual approach, using video-conferencing software, was adopted due to COVID19 restrictions. The advantages and limitations described in Section 4.2.1 are also pertinent to completing focus groups. An additional challenge specific to conducting focus groups is the management of the group within the virtual environment. The focus group needs to run smoothly, conversation to flow between participants and interruptions to be avoided. As mentioned above a skilled moderator was used, and ground rules and etiquette agreed prior to starting the focus group.

### **5.2.2 Sample**

The sampling strategy described in Section 4.2.2, for the phase 2 interviews, was also used for the focus groups. The same pre-selected nine UK PICUs were used and PICU physiotherapists at each site were invited to take part. The inclusion and exclusion criteria remained consistent across work package 1.

The target sample size was eight physiotherapists, across two focus groups. The suggested number of focus group participants ranges from five to 12 (Bowling, 2009, Krueger and Casey, 2015). Given the virtual nature of the focus group and the additional challenges this provided around group management, a smaller sample was decided upon. Additionally, Krueger and Casey (2015) report that smaller groups provide more opportunity for sharing of ideas. Smaller groups are desirable if participants are likely to be engaged with the subject and have lots to contribute (Ritchie and Lewis, 2013).

Physiotherapists were invited to join one of two focus groups: one involving band 7 and 8 physiotherapists, and one for band 5 and 6. The balance between heterogeneity and homogeneity in group discussion requires careful consideration. Ritchie and Lewis (2013) state that some diversity of the group aids discussion, whereas too much can inhibit it. Two focus groups based on agenda for change banding were thought to provide sufficient shared experience whilst creating a non-threatening environment and preventing hierarchical dynamics. To improve diversity and ensure an open environment, multiple physiotherapists from the same PICU were not included in the same group. Although anonymity between focus group participants is not essential, it has been reported that participants often speak more freely in front of strangers, where there is less fear of repercussions (Ritchie and Lewis, 2013).

#### *5.2.2.1 Inclusion criteria*

Full or part time, rotational or static, qualified physiotherapists working in a UK NHS PICU.

#### *5.2.2.2 Exclusion criteria*

Physiotherapists who only work in paediatric intensive care as part of on-call/emergency overnight or weekend shifts.

### **5.2.3 Recruitment**

An initial invitation to participate in the focus groups was sent with the invitation for the phase 2 interviews. As described in Section 4.2.3, the lead PICU physiotherapist at each site was contacted directly via email. They were invited to participate and asked to disseminate the study invitation (interviews and focus groups) to all physiotherapists who met the inclusion criteria. The invitation included a participant information sheet for the focus groups, with study details, confidentiality and data protection information, funding sources, and study personnel contact details (Appendix 20). Physiotherapists who were interested in taking part were asked to email the researcher directly.

Only physiotherapists who showed an interest in the interviews also showed interest in participating in the focus groups. Therefore, once the interviews had

been completed the physiotherapists who had taken part were approached directly via email. They were re-sent the participant information sheet and given further opportunity to discuss the study. Following this the physiotherapists were asked to provide details regarding their availability and provided with a consent form to complete (Appendix 21).

#### **5.2.4 Consent**

All participants provided written consent prior to the focus group. Participants were free to withdraw at any time prior to the focus group, however once the focus group had been completed they were unable to withdraw their data.

#### **5.2.5 Data collection**

##### *5.2.5.1 The focus groups*

Virtual focus groups were completed using MS Teams. The dates and times of the focus groups were determined by the physiotherapists' availability and arranged to suit all participants. Focus groups were scheduled to last for up to 90 minutes. Physiotherapists were asked to have both visual and audio functions on for the duration of the focus group. They were audio recorded, using a Dictaphone.

##### *5.2.5.2 The focus group moderator*

An academic paediatric cardiorespiratory physiotherapist (SR), external to the research team, was chosen to moderate the focus groups. The moderator plays a vital role in any focus group. Their background and relationship to participants influences group dynamics and requires careful consideration (Smithson, 2008). The researcher's role (ES) as a critical care physiotherapist and pre-existing relationship with some participants was decided to be detrimental to the data collection process. Several authors discuss the advantages of separating the researcher and moderator roles (Côté-Arsenault and Morrison-Beedy, 2005, Morgan, 1998, Sim and Snell, 1996). This approach can improve neutrality and minimise moderator-participant power differential.

The process of selecting an appropriate moderator was challenging. Effective moderators are able to set a comfortable tone, elicit interaction between

participants, and facilitate the discussion (Morgan and Hoffman, 2018). The individual needed to understand the clinical area, but not be 'known' within the field, to minimise moderator-participant power differential. They required experience of facilitating virtual discussions, effective communication skills, and a good understanding of the purpose of the study (Krueger and Casey, 2015). With a background in paediatric cardiorespiratory physiotherapy SR possessed sufficient clinical knowledge but was unlikely to be known within the field of PICU physiotherapy. Given her role in academia she has experience and expertise in teaching and facilitating group discussion. She received a full briefing about the study, and her role as moderator.

Involving a second individual in the moderating process is recommended practice (Morgan and Hoffman, 2018). The lead researcher (ES) was present as an observer during the focus groups but was not visible to the participants and did not interact with them. The researcher completed field notes, capturing emotions, interactions and interesting details, and managed the technology. By having an 'assistant' moderator, SR was able to focus entirely on the participants and discussion.

#### *5.2.5.3 Focus group structure*

As outlined in Section 5.1.1 this study aimed to capture an understanding of practical, real-time, bedside decision making and management of instability and adverse events. An advantage of using focus groups is the ability to use stimulus material to generate discussion and elicit participants' opinions and reactions. Therefore, the focus groups involved a clinical case study. Case studies or vignettes are frequently used in healthcare both within research and education. Vignettes are stories about individuals and situations, shared through text, images or other forms of stimuli (Hughes and Huby, 2002). They are valuable research tools in the study of attitudes, perceptions, and beliefs. Furthermore, they provide an opportunity to model real-life decision making in a context-specific scenario (Riley et al., 2021).

The vignette used in this study included both written information and a simulation video. Written vignettes are most commonly used in research, however video or

visual methods are becoming increasingly popular. It is suggested that they are easier for participants to understand and can offer reliable data as they are seen to more precisely reflect 'real-life' situations (Skilling and Stylianides, 2020). Simulation education is commonplace within PICU and physiotherapy, where real patient encounters are substituted with artificial models, actors or virtual reality patients. Simulation enables the learner to engage in a safe environment, and provides hands-on learning in an immersive environment, with opportunities for repetition, practice and feedback (Harwayne-Gidansky et al., 2020). A video of a simulated patient assessment and treatment was used in this study as this was more readily available and offered fewer challenges related to patient confidentiality, when compared to a real patient video. Within a simulation environment the scenario can also be better controlled to elicit desired discussion or learning.

The content of the vignette was based around the assessment and treatment of a mechanically ventilated child, who demonstrated physiological instability. The diagnosis and presentation represented patients seen frequently on PICU. This ensured the scenario was plausible, relevant and realistic, features discussed as important in effective vignette design (Hughes and Huby, 2004). Basic patient history and clinical presentation were shared with participants in written form as part of the focus group (Appendix 22). The simulation video consisted of two parts: preparation and assessment, and the physiotherapy treatment (video available on request). The simulation video had been developed by a specialist PICU education team and previously used successfully in an educational setting, enhancing its credibility and validity (Hughes and Huby, 2004).

A topic guide was developed for the focus group (Appendix 23). This was in collaboration with the research team (HS, JW) and the moderator (SR), and based on the research questions and findings from phase 1 and the phase 2 interviews. The importance of using a topic guide has previously been highlighted in Section 4.2.5.2. The principles of Ritchie and Lewis (2013) were used to create the topic guide, as displayed in Figure 4.1.

The introduction involved the moderator introducing herself and her role, setting the scene of the focus group and discussing ground rules and etiquette. This stage

also included participant introductions and an 'ice breaker' style question to relax the physiotherapists. Simultaneous dialogue was avoided by using the hands up function on MS Teams. For the second stage, *'the opening topic'*, the written vignette was shared with the participants. Physiotherapists were given five minutes to process the information before the moderator initiated discussion. The questions and discussion in this stage were superficial and knowledge based to gradually ease participants into the focus group. The main element of the focus group involved the simulation video shown in two parts. Discussion was facilitated after each part. Questions were open and required the participants to draw on their individual experiences. The moderator used prompts and probes to facilitate interaction between physiotherapists whilst carefully balancing the discourse to allow everyone to contribute, carefully managing the more dominant characters. The assistant moderator (ES) communicated any non-verbal communication, e.g., nodding/shaking head to SR via an instant messaging system. To end the focus group the participants were given the opportunity to provide any additional comments and thanked for their participation.

Demographic data for each participant had already been collected during the interviews, these included:

- Gender
- Ethnicity
- Geographical region of PICU (as per phase 1)
- Size of PICU
- Agenda for change banding
- Years of PICU experience

### **5.2.6 Data analysis**

The focus group audio-recordings were transcribed verbatim, including conversational fillers such as 'umm' and 'huh' or other such nuances. As with the interviews, the Framework method was used for data analysis. The rationale behind this decision and the process involved are described in detail in Section 4.2.6. NVivo was used as a data management and storage tool, whilst also ensuring transparency and providing a clear audit trail.

Familiarisation was completed for both transcripts, this involved listening to the audio-recordings and reading the transcripts, together with the field notes. Preliminary Frameworks were created using the initial themes and topics documented during familiarisation. The transcripts were then indexed in relation to the Frameworks. NVivo was used to complete the charting process. Case summaries were generated for each Framework and relevant quotes highlighted. The final stage involved mapping the range of responses and interpretation.

### **5.2.7 Data security**

An encrypted Dictaphone was used to audio-record the focus groups and TakeNote, a secure UK transcription service, was used for transcription. Participants were assigned a unique study number and all data pseudonymised. Identifiable data were removed from the transcripts, including names and places. Participants' names and associated study numbers were stored securely and separately to the data, using an NHS password protected computer.

## **5.3 Results**

### **5.3.1 Recruitment**

Eight physiotherapists, from four of the pre-selected PICUs, were recruited to take part in the focus groups. This equated to four band 7/8s in focus group 1 and four band 5/6s in focus group 2. Despite the intention to avoid having physiotherapists who knew each other in the same group, two physiotherapists from the same PICU were recruited to focus group 2. One physiotherapist from focus group 2 withdrew on the morning of the group.

### **5.3.2 Demographics**

Demographics of the physiotherapists are displayed in Table 5.1. These have been summarised to maintain participant anonymity. There was no representation from East Anglia, South East and Greater London or North West, Yorkshire and The Humber.



Table 5.1 Summary of participant characteristics

Demographic	Categories	Number of physiotherapists	
		Focus group 1 Band 7/8 (n=4)	Focus group 2 Band 5/6 (n=3)
<b>Gender</b>	Female	3	3
	Male	1	0
<b>Size of PICU</b>	Large	1	2
	Medium	1	0
	Small	2	1
<b>Geographical region</b>	East Anglia, South East and Greater London	0	0
	Midlands	1	0
	Scotland, Northern Ireland, and North East	1	2
	North West, Yorkshire and The Humber	0	0
	Wales and South West	2	1
<b>Years of PICU experience</b>	Range	1 year – 26 years	6 months – 3 years

### 5.3.3 Data analysis process

Both focus group transcripts were used in the data analysis. From the initial familiarisation stage three preliminary Frameworks, including 13 themes, were generated. The framework topics were developed deductively using the research questions, findings of phase 1 and the phase 2 interviews, and the topic guide. Themes were generated inductively from the focus group data. As with the phase 2 interview analysis, indexing of the transcripts was completed by hand, using a colour coding system. The charting stage of the Framework analysis was completed in NVivo, an example is displayed in Figure 5.1.

Clinical decision making		A: Information gathering	B: Learning from experience
1: FG1	<p>Need to understand patient and situation fully, want to gather as much information as possible. 'Act as detectives'</p> <p>Build up a picture to allow clinical reasoning. Impacts on decisions made.</p> <p>Employ detailed questioning, superficial knowledge not good enough.</p> <p>Want to be able to determine clear indication for treatment.</p> <p>Including background information, very specific clinical details, how handling.</p>	<p>Draw on previous experiences and knowledge to guide decisions. Reflecting and learning.</p> <p>Easier to manage situations if more experienced.</p>	<p>Moderator: Yes, yes, good. So, you're, kind of, thinking in terms of, I suppose, handling as such as well? Yes? So, how they're managing with the nurses treating. P113, you had your hand up and then it's gone down. Did you have something else or are you just putting it down?</p> <p>P113: I do have something else, so I'll just say it now. I was going to say, alongside, kind of, what P109 said then, what have they been trying? Have they tried any nebs? Have they had to do any, like, bagging or saline, that side of stuff.</p> <p>Moderator: Yes, yes, great. Okay and P112?</p> <p>P112: I might also want to know from the nursing staff how they're sounding as well. They could be doing their observations or their auscultation. So, to know are they sounding really tight and crackly or just what they're finding and what their upper lobe sounds like as well.</p> <p>Moderator: Yes, yes, good, good. Yes. You have something else P109? You're on mute, just un-mute yourself, yes.</p>
2: FG2	<p>Build up detailed picture of patient, condition, history and how handling. Gathering information from different sources, specifically other members of MDT.</p> <p>Holistic, wanting to know whole range of information. Explore further, understand full clinical picture.</p> <p>What treatment already completed.</p>	<p>More confidence managing situations with increased experience and exposure.</p> <p>Confidence in own decision making, and ability to communicate this, improves with time and experience.</p>	<p>P109: I think I'd want to know as well if there has been any change recently in their ventilator signs or their oxygen requirement, the pressures that they're on. To see if that, kind of, comes in line with the chest x-ray changes, yes.</p> <p>Moderator: Yes, good, good and you've, kind of, mentioned maybe some of them, but in terms of this specific patient, the information you've been given, are there any red flags in the history that you've been given or in the assessment that are ticking away in your brain that would make you approach this in a certain way? P113, you mentioned a little bit of one already.</p> <p>P113: Yes, just to say, the ex-prem aspect of it, you know, have they got the chronic lung disease picture or have they had any previous respiratory illness history?</p> <p>Moderator: Yes, yes. Anything else from anybody? Any other red flags? Yes, P112?</p> <p>P112: I might also be wondering, the blood pressure might be a wee bit low, and they're not on any inotropes but I'd want to know how it's been trained and has it stayed low or is it a new thing?</p> <p>Moderator: Yes. P109?</p>

Figure 5.1 An example of charting in NVivo

The Frameworks went through several iterations, as analysis stages were repeated and themes refined. The final analysis included four Frameworks with 12 themes, these are outlined below:

#### *Physiotherapy treatment*

- Personnel involved
- Techniques

#### *Clinical decision making*

- Information gathering
- Learning from experience
- Listening to the patient

#### *Instability and adverse events*

- Perceived risk factors
- Monitoring

#### *Managing Instability and adverse events*

- Ensuring efficiency

- Ability to react and adapt
- Accepting some instability
- Involving MDT
- Blame culture

Following completion of the analysis members of the research team (HS, JW) were provided with one of the de-identified transcripts and the Frameworks. They were asked to follow the data from its raw form to the final themes, checking the transparency and credibility of the data analysis. The Frameworks were also verified by the moderator (SR), to ensure data validity.

#### **5.3.4 Final Frameworks**

This section presents and examines the four Frameworks and their individual themes. The Frameworks, which include case summaries for each focus group, are displayed. The themes are illustrated using a combination of direct quotes and diagrams.

##### *5.3.4.1 Physiotherapy treatment*

Table 5.2 displays the physiotherapy treatment Framework. When discussing the specifics of physiotherapy treatment two areas were raised in both focus groups, the personnel involved in treatment and the techniques used.

Table 5.2 Framework I - Physiotherapy treatment

	<b>Personnel involved</b>	<b>Techniques</b>
<b>Focus group 1</b>	<p>All would involve a second person in treatment. Helps with efficiency and safety.</p> <p>Differences in who this person would be, split between another physiotherapist or nurse.</p> <p>Smaller centres reported more likely to be a physiotherapist.</p> <p>Disagreement between what role the second person would take. Three would get the nurse to MHI for treatment, although 2 reported using it themselves for assessment purposes. The other would do all the MHI, more effective.</p> <p>Each had own, definitive opinions.</p>	<p>Different approaches to treatment described.</p> <p>One physiotherapist more hands off, related to type of patient. Most physiotherapists able to see both points of view. One more black and white approach.</p> <p>Positioning, MHI, saline, CWV and suction most frequently described.</p> <p>Gradually build up treatment, assessing how patient tolerating.</p> <p>Consensus between 3 physios.</p> <p>More controversial opinion, don't do many manual techniques. And different techniques used.</p> <p>One centre exclusively used closed suction.</p>
<b>Focus group 2</b>	<p>Nurse would be involved in treatment and would complete MHI.</p>	<p>Inconsistency in some fundamental elements of treatments.</p> <p>Disagreement about what to set bag on. Suction technique used.</p> <p>Agree on not routinely using saline.</p> <p>Differences in approaches, 1 physio more hands on/active treatment.</p> <p>Positioning popular.</p> <p>Able to see both points of view, but provide rationale for own approach.</p> <p>All described measured, step wise approach.</p>

(CWV – Chest wall vibrations, MHI – Manual hyperinflations)

Both groups reported they would usually treat with another individual, their reasoning was to enhance safety and efficiency. Focus group 1 had more discussion around the personnel involved. There was debate around treating with a nurse or another physiotherapist. The physiotherapists from the smaller centres in focus group 1 reported they would most frequently treat with a physiotherapist. This group also had different views regarding the role the second person would take, with the physiotherapists offering strong opinions. This demonstrates variation even within a similar approach. The quote below illustrates this discourse:

*“PI08: So, yes, just makes it so much easier, that the nurses do the bagging, and you're treating the patient.*

*Moderator: Yes, and has that come in in all of the centres? No, PI01 you're shaking your head.*

*PI01: No, I very much feel that we are the best at bagging, and if you're going to be timing your bagging and vibs, and getting a feel for the chest, that's really part of the treatment that I really think is valuable for the physio to be doing. We do it differently than they did, and we would always ask the nurses to suction.*

*Moderator: And PI14?*

*PI14: Yes, we do it as a mixture really. Ideally we would be doing it with two physios, so it would be two physios working together. But failing that, yes. Normally the physio would start the patient on the bag, just to get a feel for them as part of their assessment, but then the nurse would probably bag, but we'd be asking things like, do they feel stiff? The nurses, they get used to the physio, they know what sort of things we want, and the physio would very much be saying, 'Do this for me, I want a quick release.' Or things like that.” (FG1)*

Both groups described a step wise approach to treatment, allowing re-assessment and escalation of input if required. Differences in manual techniques and suction were apparent in both focus groups. This related to the frequency of use and techniques chosen, e.g., chest wall vibrations vs rib springing. The physiotherapists in focus group 2 also discussed different approaches to suction and MHI flow rate, as described in the following quote:

*“PI13: And another point as well, in [place] we do a sterile technique when we are suctioning intubated patients, we have a sterile glove, we don't use just gloves from the boxes, which was just something I picked up on as well.*

Moderator: Yes, yes. Fair point. And what about in terms of, kind of, the preparation for the treatment, is there anything specific?  
 Sorry, PI09, you had a comment, do you want to go with that first of all?

PI09: I was just going to say, just to PI13, so we use just the clean technique rather than the sterile technique down [place], which, I think in adults they use the sterile technique, but in paed's we've just got the clean one. Just for information.” (FG2)

Focus group 2 agreed on some elements of treatment including the use of positioning and not routinely using saline. The similarities and differences described in this section are summarised in Figure 5.2.

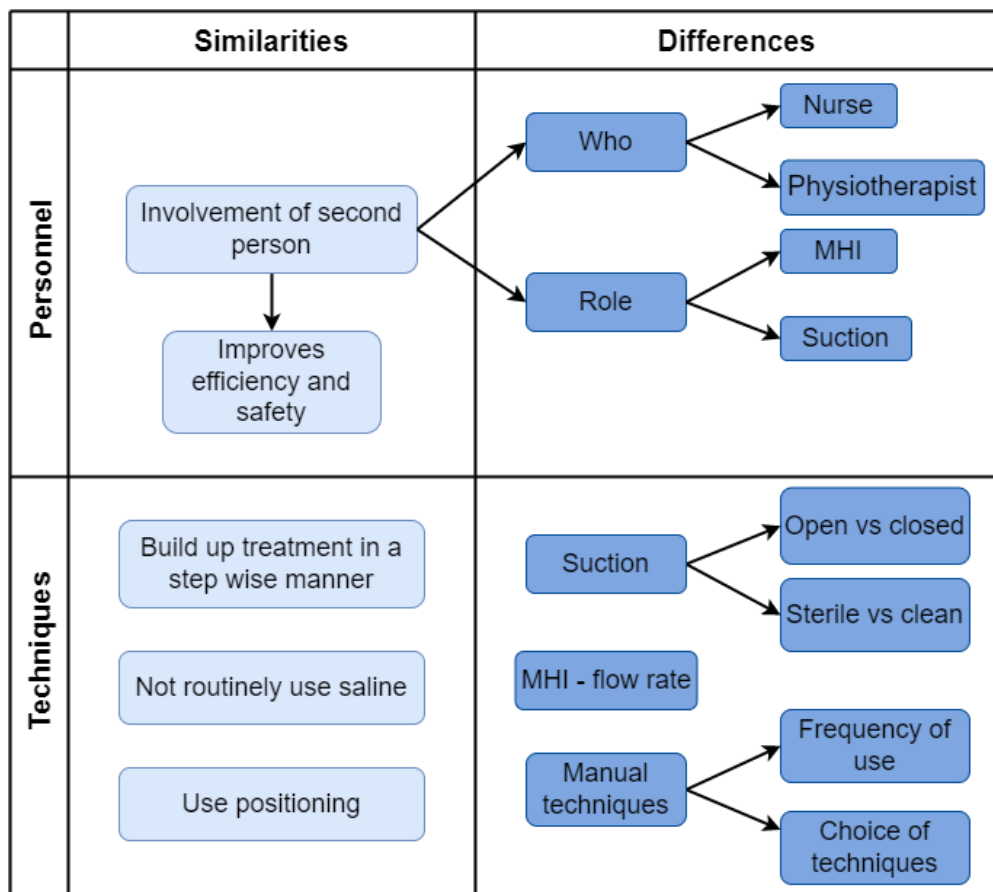


Figure 5.2 Similarities and differences in delivery of chest physiotherapy

The discussion of this theme was very open within focus group 2, the physiotherapists were inquisitive about others' experience and practice. Opinions

were more definitive and perhaps defensive in focus group 1, although there was some acknowledgment of others' reasoning and perspectives.

#### 5.3.4.2 Clinical decision making

Framework II was related to clinical decision making and is displayed in Table 5.3. The themes derived from the data were the processes involved in decision making.

Table 5.3 Framework II - Clinical decision making

	<b>Information gathering</b>	<b>Learning from experience</b>	<b>Listening to the patient</b>
<b>Focus group 1</b>	Need to understand patient and situation fully, want to gather as much information as possible. Build up a picture to allow clinical reasoning. Impacts on decisions made. Employ detailed questioning, superficial knowledge not good enough. Want to be able to determine clear indication for treatment. Including background information, very specific clinical details, how handling.	Draw on previous experiences and knowledge to guide decisions. Reflecting and learning. Easier to manage situations if more experienced.	'Listen' to the patient, having awareness. Using this to inform decision making.
<b>Focus group 2</b>	Build up detailed picture of patient, condition, history and how handling. Gathering information from different sources, other members of multidisciplinary team. Holistic, wanting to know whole range of information. Explore further, understand full clinical picture. What treatment already completed.	More confidence managing situations with increased experience and exposure. Confidence in own decision making, and ability to communicate this, improves with time and experience.	Need to take cues from how patient is behaving and tolerating treatment/handling. Include this in clinical reasoning process.

Both focus groups described the importance of gathering as much information about the patient as possible, including history, clinical presentation, and handling. They reported wanting to develop a detailed picture of the patient. Focus group 1 talked about detailed questioning of nursing staff, and that superficial knowledge

was insufficient. This process also allowed them to determine clear indications for treatment. The following quote illustrates this:

*“I think we're detectives, aren't we, and we just need to find out as much information. I always think I put my detective hat on and try and find out as much as I can about the patient. What are the secretions like, if they're just loose, and white, and they're clearing, then why would we want to get involved? If it's just a bit of patchy lobar collapse that you get in bronchiolitis, then again you might just want to leave, but if that has then progressed to a whole lung collapse, and the CRP's gone up. So, it's all the bits of information that I think will change the way we treat, and certainly in our unit we have definitely got through that we don't do physio on every patient.” (FG1)*

The second theme was listening to the patient and being able to react and adapt. This related to decision making and information processing at the bedside during treatment. Physiotherapists in both groups commented on taking cues from the patient in front of them, how they are behaving, and including this information and interpretation in the clinical reasoning processes.

*“ So, I felt he was, kind of, multitasking when the patient was not really liking things and the patient didn't like the first suction, but he then went ahead and did more treatment when I think the patient was trying to say that, 'Actually I don't like this, I want to be left alone for a bit.’” (FG2)*

Both groups discussed how increased experience facilitates decision making; being able to reflect and use this knowledge for future decisions. Focus group 1 raised that this had been highlighted by COVID19, a new disease. A physiotherapist described the challenges of being unable to rely on previous experience:

*“Yes, I think it's a lot like P108 was saying, from your previous experiences, that you draw from, and that's why for me it was tricky with this baby with COVID that was so young, because I*



*didn't really have much experience to draw from, and I found that really unusual, because I've been doing PICU for about 20-odd years. So, normally I've got quite a lot to draw from. So, that felt different.” (FG1)*

Focus group 2, involving the junior physiotherapists, discussed how experience and exposure also led to increased confidence.

*“And I think the longer that I have spent in this respiratory rotation, and become more confident in my own reasoning, like, sort of, the patient I had last week, I chatted that through to the nurse and I was, like, 'Look what I'm thinking is that I'm going to walk away and do nothing because otherwise we won't know what's working here. So this is our plan, we're going to leave it for 24 hours, we're going to focus on position only and then we are going to reassess when we do the next CXR to see if actually we need to do anything more.' And she was, like, 'Ah okay, that makes sense,' whereas maybe when I was a little bit more new I was more timid and didn't have the confidence to chat that through.” (FG2)*

#### *5.3.4.3 Instability and adverse events*

Perceived risk factors for instability and adverse events, and how physiotherapists monitor instability, were the themes in Framework III (Table 5.4). Both focus groups described two groups of risk factors, patient types and the support required by the patient.

Table 5.4 Framework III - Instability and adverse events

	Perceived risk factors	Monitoring
Focus group 1	<p>A range of patient types, some depended on type of unit or size Generally agreeing</p> <p>Ex-premature Complicated neonatal period Complex history Cardiovascular system instability Head injury Underlying respiratory disease Airway issues High ventilation High frequency oscillatory ventilation Complex presentation, multiple risk factors</p>	<p>Monitoring during treatment and re-assessing Consensus between participants</p> <p>Blood pressure/Heart rate Vital signs Chest movement Manometer Auscultation End tidal carbon dioxide</p>
Focus group 2	<p>Range of patient types. In agreement.</p> <p>Ex-premature Chronic lung disease Bronchiolitis Cardiac patients Unstable neuro patients High ventilation Complex children with ceiling of care. Fine line between helping and harming, with nowhere to escalate to.</p>	<p>Consensus between participants.</p> <p>Heart rate/blood pressure Oxygenation End tidal carbon dioxide Observation of patient Chest expansion Compliance on bag Auscultating throughout treatment</p>

A range of patient types were highlighted, there was agreement within and between the groups. Focus group 1, with the more experienced physiotherapists, discussed the complexity of the patient being linked to the level of risk. This was in the context of the patient’s history or a combination of risk factors. They also offered insight into differences in perceived risk factors between individuals, which included experience due to specialities seen at centres and the centre size, illustrated in the quote below:

*“PI01: I think maybe it's because I work on a mixed cardiac and PICU-based ICU but I'm always looking at cardiovascular instability and amount of inotropes that patients are on, and the position of their line, thinking about with moving, checking that*

*that line and the delivery of the inotropes is going to stay patent during your treatment.*

*Moderator: Yes. PI10?*

*PI10: I guess from us, because we're quite a small PICU, I think when we always get a new head injury, an ICP bolt in and unstable, that's definitely one that I take a breath first before ploughing on with really." (FG1)*

The most experienced physiotherapist within focus group 2 described patients with a ceiling of care as being high risk, they described having nowhere further to go with support if they deteriorate.

When discussing the case study, the physiotherapists described a range of variables used to monitor stability, which included physiological variables and observation and palpation of the patient. There was agreement within and between the groups. Both groups mentioned that they would use a range of measures and continually re-assess the patient during treatment, as illustrated below:

*"Yes, so similar, just watching all their vital signs really, and how they respond. We also always teach people to check the chest movement if they're on the bag, so check that equal expansion, and also you're getting good expansions with the pressures that you're using. I didn't see the manometer there but obviously making sure that you've got the manometer in." (FG1)*

#### *5.3.4.4 Managing instability and adverse events*

Managing instability and adverse events was the topic of the final Framework, see Table 5.5. Four themes were generated which related to specific strategies for managing instability and adverse events, these are summarised in Figure 5.3. A fifth theme has also been included which describes a phenomenon of blame.

Table 5.5 Framework IV - Managing instability and adverse events

	<b>Ensuring efficiency</b>	<b>Ability to react and adapt</b>	<b>Accepting some instability</b>	<b>Involving the multidisciplinary team</b>	<b>Blame culture</b>
<b>Focus group 1</b>	<p>Preparation, ensuring optimised before treating, pre-oxygenation, equipment ready.</p> <p>Being efficient, using other members of staff.</p>	<p>Being able to react to the patient/instability and adapt approach. Change treatment plan. Be flexible.</p> <p>Very strong opinion across all participants.</p>	<p>Weigh up longer term effect, may be worth short period of instability.</p>	<p>Important to have open discussions around whether to treat or not treat.</p> <p>Being involved in team discussions.</p> <p>Reflect on challenging cases together. Joint learning.</p> <p>Experience of nurse (or second physiotherapist) impacts on management.</p>	
<b>Focus group 2</b>	<p>Using nursing staff to improve efficiency of treatment. Better to not have to multitask too much.</p> <p>Preparation important, including pre-oxygenation, sedation bolus ready.</p>	<p>Need to be able to acknowledge instability and when patient not tolerating treatment, and not just continue regardless.</p> <p>Assessing during treatment and adapting input accordingly.</p>	<p>Understand than may make worse before getting better.</p>	<p>Happy to use emergency bell if needed. Feel quite relaxed about it.</p> <p>Can get appropriate help very quickly.</p> <p>Feel more supported/safer with emergency situations on PICU than on ward.</p> <p>More reassurance, less scary.</p> <p>Experience of the nurses can impact on stability/treatment.</p>	<p>Feel physiotherapists blamed for instability, maybe be said in a jokey manner but believe some truth in comments. Sometimes difficult to manage.</p> <p>Attributed to a lack of understanding of role.</p> <p>Differing experiences. Predominantly medical led, nursing to varying degrees.</p>



Figure 5.3 Strategies for managing instability and adverse events (FG1 – Focus group 1, FG2 – Focus group 2, MDT – Multidisciplinary team)

The use of strategies to ensure treatment efficiency were frequently discussed. Physiotherapists described wanting to minimise handling and disruption to the patient, believing this reduced the opportunity for instability. The same practical strategies were described in both focus groups, including preparation of equipment and medications, pre-oxygenation and emergency planning.

A popular opinion within both groups was the need to involve a second person with treatment, this also linked to efficiency. The physiotherapists described preferring to delegate tasks and avoid multi-tasking:

*“Yes, and I guess it's just different, isn't it, how you delegate tasks. So, that would probably be something I would be asking the nurse maybe, to be doing the suction, because it was obvious they didn't like all the disconnecting. We had low sats, and we were faffing around putting them back on the vent, and getting a suction. I probably would have been saying to the*

*nurse, you get a suction ready, because we need to be a bit quicker.” (FG1)*

*“Yes, I agree with everything you said there PI12. I was going to say that the nurse was not helpful at all, just making comments about, 'Oh this is not good.' Well do something about it then. But, yes, we would not disconnect, reconnect, that seems to me absolutely insane to do that.” (FG2)*

There was consensus within and between the groups regarding the importance of recognising instability whilst treating the patient, and then being able to react and adapt the approach. Focus group 1 described this theme in more detail, they talked about ongoing problem solving and being able to change approach early enough to salvage the situation or prevent instability:

*“PI14: And then just after the last cycle, we went back on the vent, even though our sats were really low, which I didn't really get. I would have just put them straight back onto the bag, and I mean, first line for us is always a sustained manual hyperinflation, for things like bradycardias, rather than just keep bagging at the same pressures. It took quite a while for them. I guess they just didn't really change what they were doing in response to what was happening. I would be looking at, why are they still going bradycardic after I've done the suction? I'd be checking the tube position, has something moved? I'd probably be changing their neck position, to see if I extended their neck, would that help. Yes, just lots of things. It made me stressed.*

*Moderator: Yes, okay, PI01?*

*PI01: Yes, I think probably I'm going to echo a bit of what the others said, but the main things to bring it together were yes, the fact that there was no learning from the first brady” (FG1)*

Focus group 2 linked this to using re-assessment during treatment to help recognise such situations.

Linked to acknowledging instability, the third theme was based around having to sometimes accept short-term unwanted effects for a better outcome in the longer term. This was raised by the more experienced physiotherapists in focus group 1 and involved weighing up the risks and benefits of treatment, as illustrated in the following quote:

*“And then after the treatment, I'd want to reassess, and say actually, for all the cons that happened, was that enough really. You have to sort of weigh up really was it worth whatever happened, that period of instability. Because sometimes you do get patients, you know, they're a bit unstable afterwards, or during, but actually fifteen minutes later, you can see a clear improvement in that patient.” (FG1)*

Both groups also discussed involving the MDT to manage instability and adverse events, although this was from different perspectives. Focus group 1 talked about being involved in open discussions with the MDT to guide decisions and management of these patients. Additionally, one physiotherapist highlighted the importance of these discussions as opportunities to reflect and learn from challenging cases. In contrast, participants in focus group 2 talked about their experiences of using the emergency call bell in situations of instability, which was not discussed in group 1. One physiotherapist felt relaxed about using the bell, see quote below, and all described a feeling of being reassured that appropriate help would come quickly.

*“I have had a few emergency buzzers, I think at one point I started to get the name of emergency buzzer puller, not because-, I don't think I was really doing wrong, I think there were just lots of really sick patients, but-, I don't know I weirdly feel quite calm when you have to pull the emergency buzzer. I don't know if that's wrong or not, but I think if you work in PICU a lot you, kind of, get used to having to do it and you get into the way of, kind of, calmly saying to the families, 'Look we just need a bit of extra help here, we're going to pull the buzzer” (FG2)*

They also reflected that they felt safer on PICU than on the wards where support was not as readily available. The theme of involving the MDT also links to ensuring efficiency and involving another person in the treatment. Both groups commented that the experience of the second individual would impact management and the success of the treatment. The physiotherapists indicated that they would prefer to treat with a more experienced nurse or physiotherapist.

When exploring the case study, the physiotherapists in focus group 2 raised a phenomenon of blame. This related to being blamed by the MDT for instability or adverse events. The participants described these comments being made in jest, but all felt there was some element of truth to them. They described how this can be difficult to manage, as illustrated in the following quote:

*“There is definitely a bit of a blame, especially if you're the one who has been in the room a few times, and it's not necessarily you that's caused the situation. Some of our doctors do have a, 'What have you done now? 'What have physio done?' 'It's physio have caused this.' And you're standing there, like, 'This was not physio, do not blame physio.' But I think partly when they say it they're saying it in jest, but there is, like, an underneath tone of, 'What have you done?' Which is sometimes fine to manage, sometimes a bit difficult.” (FG2)*

The physiotherapists attributed this blame to a lack of understanding of the physiotherapy role.

### **5.3.5 Summary**

This section has presented data and interpretations from the focus groups. The key findings are summarised below:

- Physiotherapists preferred to treat with another person, however there was variation in who this was and the role they adopted.
- Differences in physiotherapists' use of manual techniques and suction approach were apparent.
- Important processes involved in decision making included information gathering, learning from experience, and listening to the patient.



- Physiotherapists reported similar perceived risk factors for instability and adverse events. These included patient types (e.g., ex-prematurity, head injury) and the support required by the patient (e.g., high ventilation requirements).
- A range of physiological variables, including heart rate and oxygenation, together with observation and auscultation of the patient were used to monitor stability. There was agreement between the physiotherapists.
- Several practical strategies for managing instability and adverse events were discussed in the focus groups, including ensuring efficiency, preparation, and involvement of the MDT.
- Being able to recognise instability and subsequently reacting and adapting treatment was highlighted, as was the necessity to accept short-term unwanted effects for a better outcome in the longer term, discussed in the context of weighing up risks and benefits.
- More junior physiotherapists identified being blamed by the MDT for episodes of instability and adverse events.

To avoid repetition from previous chapters, the discussion will focus on the following findings that were not identified within phase 1 or the phase 2 interviews:

- The differences described in suction approach used by physiotherapists.
- The use of information gathering and processing in clinical decision making.
- The consensus between physiotherapists regarding how stability is monitored during treatment.
- Weighing up the risks and benefits of treatment and accepting a period of instability.
- The phenomenon of being blamed for instability or adverse events.

#### **5.4 Discussion**

This section will discuss the key findings in relation to the research questions and available literature.

#### **5.4.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

Variation in physiotherapy treatment was evident in this element of the study, this related to manual techniques and approach to suction. Differences in suction were the use of open (OS) or closed suction (CS), and a clean versus sterile glove technique. Open and closed suction systems have been described previously in Section 1.3.1.7. Similar variability in physiotherapists' use of open and closed suction has been described in adult intensive care (Cross, 2001, Ntoumenopoulos et al., 2018). Physiotherapists' suction practices on PICU have not been explored, however, nursing suction practice also demonstrated variability. A recent international survey reported that 57% (252/446) of nursing suction episodes on PICU used a closed system, with 43% (245/446) open (Rad et al., 2021). During OS, variation in approach to sterility was also described by the authors; 49% (119/244) of suction episodes used a sterile technique, 45% (111/244) clean, with no gloves being used for the remaining episodes (6%, 14/244). Given unit culture and shared guidelines these findings may be reflective of physiotherapists' practice.

Despite extensive research into ETT suction in intensive care units, the debate between open and closed suction in children is ongoing. The comparison of open and closed suction in PICU demonstrated equivalent rates of adverse events and no differences in the incidence of ventilator acquired pneumonia (Evans et al., 2014, Morrow et al., 2012). In a paediatric intensive care model using an animal research laboratory, CS was less effective than OS at removing thin and thick secretions in injured lung (Copnell et al., 2007). Specific adverse events related to CS, including suction catheter disruption and ETT occlusion, have also been reported in children (Blohm et al., 2011, Evans et al., 2014). In contrast, greater physiological disruption, to SpO<sub>2</sub> and haemodynamic variables, have been reported with the use of OS compared to CS (Evans et al., 2014, Tume et al., 2017). Choong et al. (2003) demonstrated that OS was associated with a significant loss in lung volume when compared to CS. It appears that closed suction in ventilated children may be safer but less effective than OS. This debate and the conflicting evidence provide explanation for the variation in suction practice observed in this study. Fisk (2018) reported a gap in the literature

investigating ETT suction in older infants and school age children, concluding that further research is required. The lack of evidence and guidelines reinforces practice based on individual or unit preferences, as seen in the current study.

The use of a clean or sterile suction technique is also widely debated in the literature. This, again, supports the variation in preferences shown by physiotherapists in this study. Reviews of paediatric ETT suctioning report that a sterile technique is not necessary (Morrow and Argent, 2008, Tume and Copnell, 2015). An RCT including 486 ventilated children demonstrated no differences in the incidence of nosocomial pneumonia with the repeated use of disposable suction catheters (Scoble et al., 2001). In contrast a sterile approach has been recommended in the recently published AARC suction guidelines (Blakeman et al., 2022). This should be interpreted with caution as the recommendation was based solely on committee experience due to limited evidence and the recommendations provided are predominantly adult focussed. The differences in suggested approaches for adults and children may provide further explanation for variation in practice seen in this study. Physiotherapists' previous experience working with adults and the setting of the PICU within an adult hospital may influence suction approach.

#### **5.4.2 Research question 2: How do physiotherapists make decisions regarding delivery of chest physiotherapy and what other factors influence this decision making?**

Active information gathering and processing was described in both focus groups as an important process in clinical decision making. Physiotherapists in this study reported using a range of sources, including patient notes, charts, imaging and questioning of the bedside nurse. These findings mirror cardiorespiratory physiotherapists' approach to decision making in acute adult care and adult ICU (Connolly et al., 2020, Thackray and Roberts, 2017). In this study the physiotherapists used this process to develop a detailed understanding of the patient and described using clinical reasoning to identifying individual problems and needs. This initial phase of decision making is suggestive of the hypothesis model of clinical decision making, introduced in Section 1.4.1. Key stages include cue recognition and acquisition, and hypothesis generation. This

model is popular within healthcare and described as essential for medical diagnosis (Banning, 2008). Elements of this model appear to be a common strategy across physiotherapy specialities (Connolly et al., 2020, Smith et al., 2008, Thackray and Roberts, 2017). These similarities are expected given the standardised undergraduate training all physiotherapists receive, and the structured approach to assessment and treatment within the profession.

The information gathering and processing described above also continued at the bedside, during intervention. Physiotherapists explained this as listening to, and taking cues from, the patient. These results link to those in Section 5.3.4.4, the management strategies used by physiotherapists for instability and adverse events. Re-assessment was an important feature, together with the need to react and adapt at the bedside. Similar findings of physiotherapists' continual clinical reasoning have been reported in adult ICU. This involved iterative reassessment and intervention modification (Connolly et al., 2020). In acute respiratory care Thackray and Roberts (2017) reported information processing occurred throughout the interaction with the patient.

The experienced physiotherapists in focus group 1 commented on the need to collect good quality information, during the clinical reasoning process. Higgs et al. (2019) also discuss the importance of complete and accurate information, stating that clinical reasoning is only as good as the information upon which it is based. The authors also described the importance of physiotherapists' cognitive and critical thinking skills to assess and analyse information effectively, acknowledging that these skills develop with experience. This may provide rationale as to why quality of information was explicitly mentioned by the more experienced physiotherapists and the subtle differences in discussion between the focus groups in this study.

Physiotherapists in this study reported the necessity to determine a clear indication for treatment. This individualised, patient centred approach has also been reported by physiotherapists in adult ICU (Connolly et al., 2020). It is reflective of the move away from the provision of routine or standard treatments on PICU (Hawkins and Jones, 2015, Morrow, 2015). This is in line with published UK guidelines on provision of adult intensive care services that state "*Targeted airway clearance*

*interventions should only be considered in selected patients when clinically indicated”* (GPICS, 2019). Although this guidance is not specific to paediatrics it is relevant to the PICU population.

#### **5.4.3 Research question 3: What do physiotherapists perceive to be risk factors for physiological instability and adverse events, and how do they manage these?**

There was consensus between physiotherapists in this study regarding the approaches used to monitor stability during chest physiotherapy. They described the use of several physiological variables together with observation of the patient. The physiological outcomes, which included ventilation and cardiovascular parameters, are standard monitoring for ventilated children and used routinely by health professionals on PICU to monitor patient status. Auscultation was a popular monitoring tool in this study. Auscultation is one of the oldest diagnostic techniques and an important part of respiratory examination. It is used to assess airflow through the trachea-bronchial tree and is inexpensive, non-invasive, safe and easy-to-perform (Sarkar et al., 2015). Recently the value of auscultation has been debated, in the context of new bedside assessment tools, including lung ultrasound and electrical impedance tomography. These point of care, lung imaging modalities are becoming increasingly popular in intensive care and physiotherapy (Davies et al., 2019, Hayward and Janssen, 2018, McAlinden et al., 2020). Advantages over conventional tools include improved sensitivity and specificity, together with higher diagnostic accuracy (Cox et al., 2020, Hansell et al., 2021, Lichtenstein et al., 2004). Hansell et al. (2021) reported that lung ultrasound has the potential to more accurately monitor change associated with chest physiotherapy treatments. These tools were not raised in either focus group, suggesting they are not yet established in routine physiotherapy practice on PICU. However, this needs interpreting in the context of the limited geographical representation of the focus groups. Furthermore, lung ultrasound competence requires the support of an approved mentor and is gained through attendance at an accredited course, a series of supervised scans and a triggered assessment. As a relatively new and developing area these resources may not be readily available to PICU physiotherapists.

When exploring the management of instability and adverse events the physiotherapists described accepting short-term unwanted effects for improvement in the longer term. This was discussed in terms of completing a risk versus benefit assessment. Cardiorespiratory physiotherapists working in acute adult care described a similar approach (Smith et al., 2008). They used a risk versus benefit assessment to prioritise the respiratory system, as illustrated in the following quote “*But I guess in reality it has to get done, and it was just a risk versus benefit situation. The patient’s lungs were deteriorating so badly that we did sort of have to forget a little about the neurological side of things*” (Smith et al., 2008). The physiotherapists in the current study discussed using this approach in the context of an unstable patient where the complexity of the decision was greater. This also aligns with the findings of Smith et al. (2008) who reported that decisions perceived to be of greater difficulty involved more deliberation, where risks were balanced against benefits.

Risk versus benefit analysis is a widely utilised concept within healthcare. In areas such as research, pharmacology and surgical intervention, the analysis process is structured and provides definitive support for decision making. Weighing up the risks and benefits of physiotherapy interventions on ICU is more difficult, there are numerous interacting factors, and it relies on the balance of probabilities. The important role of evidence in informing risk versus benefit analysis has been described within physiotherapy (Jewell, 2008). Evidence provides information on both effectiveness and potential harm of treatments. The inconclusive nature of the evidence supporting chest physiotherapy on PICU was highlighted by the physiotherapists in this study. The paucity of literature provides additional challenges when completing a risk versus benefit assessment.

Patient specific risk assessment is an important component of clinical decision making in ICU (Donaldson, 2021). The physiotherapists in the current study described this process informally, outlining a range of risk factors they would use to identify higher risk patients. Determining risk or patient variability is becoming more common on ICU, and the transition to electronic patient records provides a wealth of data for statistical modelling and machine learning. Risk prediction models have been developed for use in PICU related to mortality, clinical

deterioration, and neurological outcome (Dewan et al., 2020, Gupta et al., 2018b, Pollack et al., 2016). Similar work completed in relation to chest physiotherapy would be useful to better classify patients and identify potential risks. Practical risk management strategies were also described by the physiotherapists in this study, with the aim of minimising risks and balancing the scales towards patient benefit.

Seeking the support and guidance of the MDT to manage instability and adverse events was a common theme described by physiotherapists in this study. MDT involvement was viewed positively, and included collaborative discussion and reflection, with practical assistance as required. Smith et al. (2007) also reported that complex or difficult cardiorespiratory physiotherapy decisions, with a higher risk of adverse events, often included utilising the knowledge of other health professionals.

A conflicting finding was disclosed in focus group 2. The physiotherapists shared experience of being blamed for instability or adverse events. Blame culture within the NHS is widely acknowledged and reported to impact patient safety and discourage learning and reflection (Radhakrishna, 2015, Wise, 2018). The importance of moving away from a culture of blame and retribution are key elements of national and international safety guidelines (NHS, 2019, WHO, 2021). The phenomenon of blame is reported to be prevalent among other healthcare professionals (BMA, 2018, Lake et al., 2021). A recently published study used interpretative phenomenology to understand physiotherapists experiences of incivility (Naylor et al., 2022). A subtheme derived from interviews with six physiotherapists of mixed specialities, was *'undermining professional confidence'*. This related to criticism of physiotherapy treatment and is similar to the experiences described in the current study. Naylor et al. (2022) reported that physiotherapists found it difficult to distinguish 'banter' from deliberate harmful comments. The physiotherapists in the current study found these situations challenging. These findings are supported by literature where blame has been associated with negative emotions, including guilt and moral distress (Wall et al., 2016).

The findings of this study suggest that junior physiotherapists experienced blame more frequently. It could be hypothesised that they are more vulnerable to

interprofessional hierarchies and judgment. An alternative perspective is that the more experienced physiotherapists may have greater confidence in their own skills and relationships with the MDT and hence do not experience these same feelings. However, this theory needs to be interpreted with caution. Although the concept of 'being blamed' was not raised by the physiotherapists in focus group 1 this does not definitively mean they do not have similar experiences. Further investigation is warranted to determine the extent of the issue and enable the development of management strategies and support systems.

## **5.5 Limitations**

The aim of a focus group is to gain a range of views and an understanding of experiences, rather than providing wider generalisations. Despite this it is important for the sample to display sufficient variation and be representative of the population being studied (Krueger and Casey, 2015, Silverman, 2020). Although a purposive sample strategy was used for the individual PICUs, there is a risk of self-selection bias related to the individual participants. Data collected may be biased towards more confident or opinionated physiotherapists, and not represent the entire target population (Lavrakas, 2008). The geographical representation of the participants in this study was limited. Physiotherapists from four units in three regions participated, potentially reducing the range of views collected. However, views across all banding levels were obtained, which allowed valuable comparison between the groups.

The focus group participants were recruited from the same pool of physiotherapists used in the phase 2 interviews. Due to time pressures faced during the project this approach allowed ethical approvals to be obtained and data collection to be completed in a timely manner. This recruitment strategy also ensured data and themes were linked within phase 2. However, there are limitations to this approach, including reduced richness of data and risks that an adequate range of experiences and practices were not captured. This bias may have been avoided if the focus group participants had been recruited from other centres.



The size and composition of focus group 2 also requires consideration. One physiotherapist withdrew on the day of the focus group. Due to the limited time frame for data collection and arrangements already in place it was decided to continue with three participants. To confound this problem further two of these physiotherapists were from the same PICU. The plan had been to avoid this, however no other band 5 or 6 physiotherapists volunteered. Although interesting discussion occurred these factors may have limited the diversity of experiences captured in the data. The impact of having two physiotherapists from the same PICU may have influenced the dynamics of the group and discussion. Anonymity is not a necessity in focus groups however the physiotherapists from the same PICU may have felt constrained or inhibited by the presence of their colleague.

The focus groups were skilfully moderated, SR created an open and respectful environment and facilitated equal contributions, preventing any dominant participants. These are essential elements of a successful focus group (Krueger and Casey, 2015). A limitation was the use of a 'hand up' function for participants to speak. Whilst this was considered good virtual meeting etiquette and avoided interruptions, it reduced the direct discussion between participants. The additional data provided by participant interaction has been described as a key advantage of focus group data collection (Hennink, 2007, Ritchie and Lewis, 2013). This was not prevented completely in this study, and participants were able to react and respond to comments of others and provide contrasting opinions. However, face-to-face focus groups may have generated more spontaneous interactions and natural discourse.

A general limitation of qualitative research is that self-reported behaviour may not completely capture what happens in reality. Participants may describe what they 'should do' rather than what they 'would do'. The moderator worked hard to create a relaxed and non-threatening environment to encourage honesty. Furthermore, the use of a video vignette aimed to negate this effect by using a context specific scenario. Hughes and Huby (2004) report that engaging participants with a relevant and realistic vignette can improve the quality of data. The vignette was well received. It provided the participants with a shared experience, and they were more comfortable, animated, and interactive following introduction of part 1 of the

video. An observational design may have allowed more accurate modelling of decision making behaviours. However due to restrictions on face-to-face meetings, as a result of COVID19, this was not feasible.

## **5.6 Conclusion**

This chapter has presented the focus group component of phase 2, work package 1. The use of focus groups involving PICU physiotherapists is unique within the published literature. The inclusion of a case study with simulation video provided an additional novel element. Subtle differences in practice were identified through the focus group data. Important processes involved in decision making included information gathering, learning from experience, and listening to the patient. Physiotherapists reported similar perceived risk factors for instability and adverse events, including patient types and support required. A range of physiological variables, including heart rate and oxygenation, together with observation and auscultation of the patient were used to monitor stability. Experienced physiotherapists highlighted the necessity to accept short-term unwanted effects for a better outcome in the longer term, whilst junior physiotherapists identified being blamed by the MDT for episodes of instability and adverse events.

## **6. Work package 1 – Phase 2 Document analysis**

### **6.1 Introduction**

As outlined previously, phase 2 had three components. Chapter 4 and Chapter 5 presented the methods, results and discussion of the semi-structured interviews and focus groups respectively. This chapter will focus on the final component of phase 2, document analysis. The methods, results and discussion of the key findings will be presented.

#### **6.1.1 Aim**

The need to adhere to unit protocols/guidelines and their potential influence on decision making was raised by physiotherapists in both phase 1 and the phase 2 interviews. In Section 3.3.5.2 the use of protocols was discussed in relation to decisions about the frequency of physiotherapy treatments. Variations in practice were also attributed to the use of protocols in Section 4.3.4.2. These findings highlighted an area requiring further exploration, which led to the inclusion of the following document analysis. This part of the study aimed to:

- Determine the prevalence of protocols/guidelines related to chest physiotherapy in UK PICUs
- Explore any influence these documents may have on physiotherapists' decision making

#### **6.1.2 Research questions**

The project research questions which related to this component of phase 2 were:

1. What is current chest physiotherapy practice within UK paediatric intensive care units?
2. How do physiotherapists make decisions regarding delivery of chest physiotherapy in UK paediatric intensive care units and what other factors influence this decision making?

## **6.2 Methods**

### **6.2.1 Study design**

This component of phase 2 was a qualitative study involving document analysis. Within the research context a 'document' covers a broad range of materials, both text and images. For the purpose of this study the definition, 'textual content not generated by the researcher' was used and organisational documents were the focus (Bowen, 2009). Documents are valuable sources of data and can provide an understanding of social and organisational practices (Bowling, 2009, Coffey, 2014). Document analysis can be used as a supplementary source of data, which is important in triangulation, to corroborate findings and increase comprehensiveness and validity (Bowen, 2009, Miller and Alvarado, 2005). This was relevant in the context of this study, where the results were synthesised with the findings of phase 1 and the phase 2 interviews and focus groups.

Convenience and low cost are advantages of document analysis compared to other research methods. Documents are non-reactive and unaffected by the research process, which minimises concerns related to the researcher's influence or bias that is inherent with other qualitative methods (Bowen, 2009, Bowling, 2009). The availability, accessibility and authenticity of documents requires consideration and can pose challenges during the research process (Bowen, 2009, Bowling, 2009). A systematic approach to document analysis is essential, irrespective of whether a quantitative or qualitative research method is used (Bowling, 2009). Analysis can examine the production, content, and consumption of the documents, aiming to understand the document within its social and textual context (Coffey, 2014, Miller and Alvarado, 2005). For the purposes of this study the analysis focussed on the function and content of the documents. This was deemed most appropriate given the overall aims to explore physiotherapy practice and influence on decision making.

### **6.2.2 Sample and recruitment**

All 27 UK NHS paediatric intensive care units were invited to participate (PICANet, 2021) (Appendix 5). The lead physiotherapist for each PICU was contacted directly via email. This was a purposive approach, with the aim of recruiting all PICUs.

Requests were made for organisational documents that related to physiotherapy assessment or treatment of mechanically ventilated children. Document types could include, but were not limited to, protocols, policies, or guidelines. A reminder email was sent to the lead physiotherapist if no response was received after two weeks.

### **6.2.3 Data collection**

Copies of relevant documents and any additional information were sent directly to the researcher via email. Demographics including geographical region (as per phase 1) and size of PICU (as per phase 2) were recorded for units who responded.

### **6.2.4 Data analysis**

The Framework method was used for data analysis. The importance of using a systematic approach to document analysis was highlighted in Section 6.2.1. Further rationale to support the use of Framework analysis has been discussed in Section 4.2.6.1.

The Framework analysis process involves five interconnected stages: familiarisation, identifying a thematic framework, indexing, charting, and mapping and interpretation (Ritchie and Spencer, 1994). These are described in detail in Section 4.2.6. Familiarisation was completed with all the documents, which involved repeated reading and note taking. Preliminary Frameworks were created using the initial themes and topics generated during familiarisation. The documents were then indexed in relation to the Frameworks and NVivo used to complete the charting process. Case summaries were generated for each Framework and relevant quotes highlighted. The final stage involved interpretation and mapping the similarities and differences within the data.

As with the phase 2 interviews and focus groups, NVivo was used as a data management and storage tool to ensure transparency and provide a clear audit trail.

### 6.2.5 Data security

Each document was assigned a unique document number and all data were pseudonymised. Identifiable data were removed, including names and places. PICU name and associated document number were stored separately and securely using an NHS password protected computer.

## 6.3 Results

### 6.3.1 Recruitment

Email responses were received from 70% (19/27) of UK NHS PICUs. Table 6.1 displays the number of responding sites from each geographical region. Of the PICUs who responded six were classified as large sites, eight medium and five small.

*Table 6.1 Geographical regions of responding paediatric intensive care units*

<b>Geographical Region</b>	<b>Number of sites (%)</b>
East Anglia, South East and Greater London	8/11 (73)
Midlands	3/5 (60)
Scotland, Northern Ireland, and North East	3/5 (60)
North West, Yorkshire and The Humber	4/4 (100)
Wales and South West	1/2 (50)

### 6.3.2 Data analysis process

All documents received were included in the data analysis. Four description categories were created to provide accurate description of the documents: document type, chronology, development, and target audience. Following initial familiarisation, Frameworks were created based on document subject. This was a variation on the classic Framework analysis used previously in this thesis, where individual Frameworks are based on key issues or concepts. However, this

adaptation allowed easier comparison between cases, and is still considered a valid approach to Framework analysis. Themes were consistent across all Frameworks and developed both deductively from the aims of the study, and inductively from the data. As with the previous phase 2 analysis, indexing of the documents was completed by hand and the charting stage of the Framework analysis completed in NVivo. In total 11 Frameworks were created, each including two themes. The Framework subjects and themes are listed below:

### **Frameworks**

- Bronchiolitis
- Directed saline lavage
- High frequency chest wall oscillation (HFCWO)
- Manual assisted cough
- Manual techniques
- Metaneb
- Manual hyperinflations (MHI)
- Manual insufflation/exsufflation (MI-E)
- Non-bronchoscopic bronchoalveolar lavage (NBBAL)
- Ventilator hyperinflations (VHI)
- Mucoactive agents

### **Themes**

- Purpose
- Content

The final Frameworks, including the descriptor categories, are displayed in Appendix 24. During the interpretation and mapping phase Framework summaries for the purpose and content themes were created.

#### **6.3.3 Prevalence of documents**

Of the 19 PICUs who responded, 15 (79%) reported having organisational documents related to chest physiotherapy (6 large, 5 medium, 4 small) and four reported no documents (3 medium, 1 small). In total, the 15 units reported 39

documents, with copies of 29 of these shared with the researcher. Nine PICUs shared all documents, three provided copies of certain documents but not all, and the remaining three PICUs did not share any. The decision to provide copies of the documents to the researcher was at the discretion of the lead physiotherapist. Table 6.2 outlines the subjects of all documents reported (n=39) and summarises the important details of the documents received (n=29).



Table 6.2 Summary of document details

	Subject	Number stated	Number provided	Year created/updated	Type of document	Developed by	Target audience
<b>Disease</b>	Bronchiolitis	1	1	2020	Guideline	Consultant (Physiotherapist involved in development)	All paediatric intensive care unit staff
<b>Treatment techniques</b>	Directed saline lavage	2	1	2019	Guideline	Physiotherapists	Physiotherapists
	High frequency chest wall oscillation	2	2	2018 2012	1* Guideline 1* Guidance document	Physiotherapist Not stated	Physiotherapists Not stated
	Manual assisted cough	2	1	2020	Guideline	Physiotherapists	Physiotherapists
	Manual insufflation/exsufflation	4	3	2013, 2019, 2021	2* Guideline 1* SOP	Physiotherapists	Physiotherapists Other staff/carers
	Manual techniques	2	1	2019	Procedural document	Physiotherapists	Physiotherapists
	Manual hyperinflations	4	4	All 2020	3* Guideline 1* SOP	Physiotherapists (1 reviewed multidisciplinary team)	Physiotherapists 1 nurses & doctors
	Metaneb	2	1	2019	1* SOP	Physiotherapist	Physiotherapists
	Non-bronchoscopic bronchoalveolar lavage	11	8	2015- 2021	7* Guideline 1* SOP	Physiotherapists Physiotherapist & Intensivist Clinical lead, lead nurse, consultant	Physiotherapists Medics & nurses All healthcare professionals involved
	Ventilator hyperinflations	5	4	2020, 2021	3* Guideline 1* Guideline/SOP	Physiotherapists (reviewed by lead consultant/matron)	Physiotherapists Wider team aware
<b>Mucoactives</b>	DNase and Hypertonic saline	4	3	All 2020	3* Guideline	Physiotherapist, Pharmacist, Consultant	Physiotherapist Medics, advanced nurse practitioners. (All staff)

The subject of the documents encompassed three areas: disease, physiotherapy techniques and mucoactive agents. The majority, 86% (25/29), were related to physiotherapy techniques. Non-bronchoscopic bronchoalveolar lavage (NBBAL) was the most common subject (28%, 8/29).

Twenty-five (86%) of the documents were created or updated after 2018. All of these had a designated review period or date, most commonly every 3 years (14/25) but ranging from 2-4 years. Four of the documents received were classified as 'out of date' by the department/unit.

#### **6.3.4 Document type**

Twenty-two of the documents provided were defined as clinical guidelines. Four were standard operating procedures (SOP), with three of these being from the same PICU. The remaining three documents were classified as a guideline/SOP, a guidance document, and a procedural document. The breakdown of document type is displayed in Table 6.2. A standard trust proforma was used in 86% (25/29) of the documents.

#### **6.3.5 Development and target audience**

The majority (76%, 22/29) of the documents were created by physiotherapists for physiotherapists, with 10 of these relevant to other healthcare staff and one also targeted to carers. Five guidelines were developed jointly between physiotherapists and other members of the MDT and designed for a mixed audience. One document did not involve physiotherapists in its development (NBBAL SOP), and it was unclear if it was targeted to physiotherapists. The remaining guideline, which was related to high frequency chest wall oscillation (HFCWO), contained no details regarding the personnel involved in its development or the intended audience. Summary information is displayed in Table 6.2, with individual details presented in the Frameworks in Appendix 24.

#### **6.3.6 Document purpose**

Table 6.3 displays Framework summaries for the documents' purposes. Individual document summaries are presented in the Frameworks in Appendix 24. Nine of the documents were relevant to all paediatric patients within the hospital, six

exclusively to intubated and ventilated patients, and one to both invasively and non-invasively ventilated children. The remaining 12 documents focussed on NBBAL, MHI and directed saline lavage, which are techniques only completed in intubated and mechanically ventilated populations.

*Table 6.3 Framework summaries of document purpose*

<b>Subject</b>	<b>Purpose</b>
<b>Bronchiolitis</b>	Not stated. Intubated and mechanically ventilated children.
<b>Directed saline lavage</b>	Description of the technique. Children with endotracheal tube or tracheostomy.
<b>High frequency chest wall oscillation (HFCWO)</b>	Not stated. All patients on paediatric intensive care.
<b>Manual assisted cough</b>	To ensure safe and consistent use of the technique. All paediatric patients within hospital.
<b>Manual techniques</b>	Appropriate use of technique and to support training. All paediatric patients within hospital.
<b>Metaneb</b>	Improve confidence using device. All paediatric patients within hospital, specific instructions for those intubated and ventilated.
<b>Manual hyperinflations (MHI)</b>	Ensure standardised, consistent technique, to optimise safety. Ensure competence and effectiveness. Intubated and mechanically ventilated children, or those with tracheostomy.
<b>Manual insufflation/exsufflation (MI-E)</b>	Standardised and evidence-based practice. Guidance for safe use. All paediatric patients within hospital.
<b>Non-bronchoscopic bronchoalveolar lavage (NBBAL)</b>	Standardised technique to optimise safety. Support competency. Provide support for procedure. Effective use of technique. Best practice, evidence-based guideline. Ensure technique in line with requirements of ongoing study. Intubated and ventilated patients.
<b>Ventilator hyperinflations (VHI)</b>	Standardise, formalise approach. Ensure best practice and evidence-based. Ensure safety. Intubated and ventilated patients.
<b>Mucoactives</b>	Guideline for use of medication. Ventilated patients, self ventilating patients across hospital.

Several of the documents aimed to facilitate a standardised and consistent approach to the treatment technique. This was linked to ensuring safety and effectiveness, as illustrated in the quotes below:

*“The aim of this document is to provide a standardised outline of the technique of manual hyperinflation for qualified physiotherapists for intubated and ventilated paediatric patients, thus optimising patient safety.” (D13 - MHI)*

*“The purpose of this guideline is to underpin safe and effective delivery of ventilator hyperinflation by qualified children’s physiotherapists trained and deemed competent in the therapeutic use of VHI in the PICU setting.” (D15 - VHI)*

Ensuring best practice through the use of evidence was also frequently included within the purpose of the documents, as shown in the extracts below:

*“It is to ensure all staff have some standard guidelines to follow when undertaking a manual assisted cough, which are, at best, evidence-based and up-to-date.” (D23 – Manual assisted cough)*

*“This Standard Operation Procedure (SOP)/Guideline aims to guide clinical practice according to any evidence and standards that were available at the date that it became effective.” (D22 - VHI)*

Several of the documents were designed to support training and ensure competency in the use of the treatment techniques, as highlighted in the following quotes:

*“This document should be used to support theoretical and practical training for these techniques.” (D14 – Manual techniques)*

*“To support teaching thus enabling staff to become competent to use the NIPPY clearway®. NOTE: This guideline should only be used in conjunction with practical training.” (D2 – MI-E)*

Eight of the documents did not explicitly outline their purpose.

### 6.3.7 Document content

Framework summaries related to the content of the documents are displayed in Table 6.4.

Table 6.4 Framework summaries of document content

Topic	Content
<b>Bronchiolitis</b>	Specific indications for assessment and treatment, requires own clinical reasoning. Guidance for decision making given as treatment options provided. Evidence-based.
<b>Directed saline lavage</b>	Brief indications, safety considerations, step by step guide.
<b>High frequency chest wall oscillation</b>	Indications for use, safety considerations, equipment set up, step by step procedure. Photographs included.
<b>Manual assisted cough</b>	Comprehensive using literature, goals, indications, types of patients. Background physiology. Safety considerations, explanation of technique. Some support for decision making with regards to indications. Evidence-based.
<b>Manual techniques</b>	Brief indications for use, Safety considerations and potential adverse events. Step by step procedure with rationale. Some support for decision making with adaptations to treatment.
<b>Metaneb</b>	Brief indications, safety considerations and potential risks and adverse events. Equipment and step by step procedure. Indications included.
<b>Manual hyperinflations (MHI)</b>	Guidelines – Indications, safety considerations (2 included possible adverse events/risks). Equipment and step by step procedure with rationale and adaptations. Some support for decision making during procedure, treatment adaptations, and management of adverse events. Varied inclusion of evidence. SOP – Very practical, brief comment safety, step by step procedure. Comments to use own clinical reasoning.
<b>Manual insufflation /exsufflation (MI-E)</b>	Guidelines - Introduction to device, indications, safety considerations. Equipment and step by step procedure with photographs. Adaptations to treatment offering some support for decision making. SOP – Indications, brief safety considerations, step by step procedure.
<b>Non-bronchoscopic bronchoalveolar lavage (NBBAL)</b>	Indications, safety considerations. Most included adverse events or risks, varying level of detail and management strategies. Equipment with photographs, step by step procedure. One bedside check list. Varying support for decision making from minimal to extensive including risk assessment and management of adverse events. Varied use of evidence.
<b>Ventilator hyperinflations (VHI)</b>	Very similar documents. Comprehensive and referenced. Introduction to technique, indications. Safety considerations with adverse events/risks. Equipment. Step by step procedure 1 includes flowchart. All provide some support with decision making, adjustments to ensure safety and progression. Inclusion of evidence varied. 1 more of a technical guide (specific to COVID19).
<b>Mucoactives</b>	Background to drug, mechanism of action, dosage. Indications. Step by step procedure. Safety considerations with side effects/risks. Some support for decision making related to indications, adaptations during treatment and monitoring requirements after.

There was a clear difference in the content of the documents, depending on the document type. The SOPs were procedural and practical, and focussed on description and providing a 'how to' guide for completing the technique. Although potential complications and risks were stated, there was no guidance for management of these or support for decision making. Three of the SOPs, all from the same unit, explicitly stated that physiotherapists must use their own clinical reasoning, as illustrated below:

*“The Metaneb system is indicated for mobilisation of secretions, lung expansion therapy and the treatment and prevention of pulmonary atelectasis. The physiotherapist will have used their clinical judgement to reason that the patient requires physiotherapy intervention and that the Metaneb is indicated.” (D7-metaneb)*

The content and detail of the clinical guidelines varied. All documents provided indications and included a step-by-step guide to using the technique or adjunct. Several of the documents used photographs to depict the equipment required and/or how to complete the technique. Contra-indications, complications and risks were included in most of the guidelines. However, the depth of detail provided varied, as demonstrated in the following extracts:

*“Vigorous coughing - Synchronicity with the inspiratory hold needs to be watched in view of generating high intrapulmonary pressures.  
Worsening of Bronchospasm - May cause or worsen bronchospasm due to turbulent flow of air, monitor closely during treatment. Signs of bronchospasm include increased exhalation time, wheeze / prolonged expiration on auscultation, decreasing saturations, worsening compliance on VHI.” (D22 -VHI)*

*“Adverse effects of percussion, vibrations, shakes that therapist should be aware of: ● Breath holding ● Bronchospasm ● Hypoxaemia ● Increased airflow obstruction ● Skin erythema” (D14 – Manual techniques)*

Five of the documents provided additional information on how to manage or avoid unwanted effects of the treatment, offering the reader practical support for decision making. Examples are included below:

*“Hazards / complications of MHI - Barotrauma, pneumothorax (Cruz et al. 2017)*

*Hazard / Complication Action*

*If you notice any signs or symptoms of a potential pneumothorax, stop immediately and contact the medical team. A chest x-ray may be required. Signs and symptoms as above. The positive pressure delivered during MHI should be no more than 20% higher than the peak inspiratory pressure of the ventilator to minimise these risks (Webber, 1993). Always use a manometer to measure the pressures you are delivering (Redfern et al, 2001).” (D25 - MHI)*

*“Procedure - Pre-oxygenate the patient with FiO<sub>2</sub> 1.0 for at least 2 minutes prior to the procedure (There is no need to change ventilator pressures). This does not apply to patients with balanced circulation due to cardiac conditions.*

*Rationale - There is a risk of hypoxia during the procedure. Ensuring good oxygenation prior to the procedure will minimise risk.*

*Increasing SpO<sub>2</sub> in patients with balanced circulation may increase pulmonary blood flow at the expense of systemic and cardiac circulation.” (D20 – NBBAL)*

The more comprehensive documents also included guidance on how to adapt the treatment to improve its effectiveness. Directing practice and providing support for decision making are illustrated by the following extracts:

*“Considerations for use new patients: Starting pressures will vary depending on the individual patient and should be set by a trained clinician. For anxious patients or those who have not used the Clearway previously, consider starting at sub therapeutic settings of 10cmH<sub>2</sub>O/- 10cmH<sub>2</sub>O or less if necessary. For long term ventilated patients: the peak*

*inspiratory pressure (PIP) shown on the individual patient's ventilator can be used to guide start pressures. Typical Maximal pressures for paediatrics 40cmH<sub>2</sub>O/-40cm/H<sub>2</sub>O." (D2 – MI-E)*

*"Consider adding in expiratory vibrations and percussions in time with the breaths. Consider increasing the expiratory hold time to increase the time for expiration alongside manual techniques to increase mucociliary clearance. Also consider decreasing the PEEP to create a larger pressure difference and further aid mucociliary movement." (D26 -VHI)*

Ten of the documents were well referenced and evidence based. A further four included a comprehensive reference list, although these were not integrated into the body of the document. The remaining documents provided minimal or no references to support their content and recommended practice.

#### *6.3.7.1 Technique comparison*

Documents from multiple PICUs were received for six for the Framework topics. The described techniques were compared between documents.

##### *High frequency chest wall oscillation (HFCWO)*

The two guidelines described similar practice with regards to indications for use, contra-indications, precautions, and fitting of the HFCWO garment. Both documents provided recommended starting settings, which were broadly comparable. D4, however, included guidance on treatment length that was not discussed in D27.

##### *Manual insufflation/exsufflation (MI-E)*

Two guidelines and one SOP were provided relating to MI-E. All documents described the same indications, safety considerations and equipment. The SOP was brief and lacked details on modes or pressure settings for treatment. The guidelines provided more information, with D2 offering suggestions for starting and maximum pressures, and D20 recommending the number of treatment cycles



depending on the mode used. Neither document provided guidance on specific treatments settings.

#### *Manual hyperinflations (MHI)*

The three guidelines described similar indications, contraindications, and precautions, whereas the SOP did not include any of these details. The same equipment and three phase treatment technique was outlined in all the documents. Three documents recommended comparable oxygen flow rates for treatment. MHI was described as requiring two individuals in two of the documents (1 SOP/1 guideline), with the SOP indicating that it would be another member of the MDT who completed the MHI during physiotherapy treatment.

#### *Non-bronchoscopic bronchoalveolar lavage (NBBAL)*

All eight NBBAL documents stated the primary indication was diagnostic purposes, with one describing an additional therapeutic use for lobar collapse. They defined similar contra-indications, precautions, and potential adverse events. The equipment described was also comparable between units, allowing for differences in suppliers. Most documents reported a similar technique, which involved manual ventilation of the patient during the NBBAL and the collection of multiple samples. The NBBAL described in the SOP did not include manual ventilation and only one sample was obtained. A further difference observed in the documents was related to the amount of saline used for lavage, which varied from 3ml to 3ml/kg. The use of physiotherapy manual techniques during the NBBAL also differed. Two documents described the use of expiratory chest wall vibrations with MHI during sample collection.

#### *Ventilator hyperinflations*

The four guidelines described similar indications for use, and contraindications and precautions. Three outlined almost identical procedures and provided clear treatment parameters for all modes of ventilation. One difference between these guidelines was the maximum pressure limit, which varied between 35cmH<sub>2</sub>O and 45cmH<sub>2</sub>O. The remaining document described a similar approach but was less detailed.

### *Mucoactives - DNase*

The three documents were similar and described consistent indications, contraindications, and safety considerations. Two of the guidelines included both nebulised and instilled DNase, with the remaining one only reporting on instilled DNase. The procedures were comparable and used the same drug doses. There were differences in the positions used during the procedure, with one document advocating head down positioning and another modified postural drainage positions.

#### **6.3.8 Summary**

The complete results of the document analysis have been presented. The following key findings will be discussed in the next section:

- Most responding centres (79%) had access to organisational documents relevant to chest physiotherapy. Documents most frequently focused on NBBAL, VHI/MHI, MI-E and the use of DNase.
- There was variation in the description of NBBAL, MHI, and MI-E techniques.
- Most documents were clinical guidelines, with the purpose of facilitating evidence-based and standardised practice, whilst ensuring safety.
- Document content varied. Most were procedural guides with a few providing support for decision making during treatment.

#### **6.4 Discussion**

This section will discuss the key findings in relation to the research questions and available literature.

##### **6.4.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

The majority of the organisational documents analysed in this study related to specific physiotherapy techniques or treatment adjuncts. Excluding NBBAL, which is predominantly a diagnostic procedure, they are all recognised treatment options within the profession and well described in the literature. Each technique has been outlined and explained in Section 1.3.1. The topics with the most documents were

NBBAL, MHI, VHI, MI-E and DNase, which may be related to the complexity and/or risk of the interventions, or their popularity and frequency of use.

NBBAL was the most common focus of the documents disclosed in this study. It is a diagnostic procedure used to obtain samples, including epithelial cells, from the lower respiratory tract to determine causative pathogenic organisms (Morrow and Argent, 2001). It involves the insertion of a catheter via the endotracheal tube, followed by the instillation of 0.9% saline which is then aspirated, providing a lavage of the lower respiratory tract (Morrow and Argent, 2006). Reported complications of NBBAL include desaturation, bradycardia, arrhythmia, and pulmonary haemorrhage (Burmester and Mok, 2001, Morrow and Argent, 2001). NBBAL is often completed on critically ill children with high organ dysfunction scores which, coupled with the potential hazards described above, make this a high-risk procedure. The documents were also targeted to a mixed audience, indicating the procedure is completed by a variety of health professionals, necessitating unit wide guidance. This provides further rationale for the higher prevalence of documents on this subject.

Manual and ventilator hyperinflations were also common topics of the documents analysed in this study. This may be due to the technique's popularity within paediatric intensive care. In the systematic review, completed as part of this project, 8/13 studies reported MHI as a component of treatment (Appendix 1). Furthermore MHI with chest wall vibrations was the most commonly used treatment in a retrospective study based in a Canadian PICU (McCord et al., 2013). The VHI documents received in this study were all created within the last two years, indicative of a response to the COVID19 pandemic. Published guidance advised against ventilator disconnection, recommending VHI as a first line treatment for patients with COVID19 (Battaglini et al., 2020, Thomas et al., 2020). National unit collaboration enabled appropriate guidance documents to be created (Mercer, 2020).

In this study the techniques and equipment described within the documents were consistent for VHI, HFCWO and the use of DNase. Greater variation in practice was described for MHI, MI-E and NBBAL. Variation in chest physiotherapy practice is well documented in the adult intensive care setting (Connolly et al., 2020,

Tadyanemhandu and Manie, 2015, Van der Lee et al., 2017). The method used for MHI was uniform between the documents, however recommendations for the personnel involved in delivering MHI and associated manual techniques varied. This is reflective of the single versus double person approach to MHI with CWV debate within the literature (Shannon et al., 2010). Treatment parameters were not provided in either of the documents related to MI-E, suggesting practice is dependent on individual therapists' preferences and experience. Although MI-E is well established in the paediatric neuromuscular population the settings used vary (Chatwin et al., 2018, Hov et al., 2018). There is limited evidence for optimal titration and studies are limited to paediatric lung models (Hov et al., 2020). The lack of published recommendations provides challenges to creating evidenced based guidelines. Additionally, the MI-E documents analysed in this study were not specific to ventilated children. The wide scope of the documents, including various clinical scenarios and respiratory interfaces, presents further challenges to providing specific settings.

The organisational documents related to NBBAL demonstrated the most variation in described procedure. Differences were apparent in personnel involved, number of samples collected, the volume of saline and the application of manual techniques. These inconsistencies are not unexpected given the similar variation in NBBAL procedures reported in the literature. The technique described by Yildiz-Atikan et al. (2015) included the collection of one sample and used fixed volumes of saline depending on the patient's weight; 5ml <15kg and 10ml >15kg. Sachdev et al. (2010) also reported using a fixed volume of saline, although four samples were obtained, and the patient remained on the ventilator during the NBBAL. In contrast a technique using MHI and 1ml/kg of saline up to 10ml for 3 samples has been described (Burmester and Mok, 2001, Morrow and Argent, 2001). This lack of consensus proliferates variation and individual unit-based practices.

#### **6.4.2 Research question 2: How do physiotherapists make decisions regarding provision of chest physiotherapy and what other factors influence this decision making?**

Most of the organisational documents analysed in this study were classified as standard operating procedures or clinical guidelines. SOPs are defined as written

means to instruct employees on how a particular procedure should be carried out, aiming to achieve uniformity (Rao et al., 2011). This definition aligns with the purpose and content of the SOPs analysed in this study. Clinical guidelines are rigorously developed using evidence-based medicine and consist of two components: the evidence summary and detailed instructions for the application of the evidence to patient care (Broughton and Rathbone, 2001, Rao et al., 2011). The inclusion of relevant evidence varied in the guidelines analysed in this study. Several were well referenced and included up-to-date evidence integrated into the procedure description. In contrast, others provided no background literature contradicting their classification as guidelines. This may be due to the lack of robust trials to support chest physiotherapy in ventilated children and instead documents are based on local expert opinion and consensus.

The Institute of Medicine Committee on Clinical Practice (1992) states that guidelines should assist practitioners' decision making about appropriate interventions for specific clinical conditions and/or circumstances. Only one guideline analysed in this study directly related to a specific diagnosis, the others focused on physiotherapy techniques or adjuncts. To use these documents in a clinical setting the physiotherapist needs to clinically reason whether it is an appropriate treatment option and make the decision to access the document. This suggests that these documents are not used to support decisions about choice of treatment. However, several of the guidelines provided support for decision making during treatment. This included how to prevent/react to adverse events and adjusting the treatment to maximise effectiveness. Most of these documents were designed to be read prior to the treatment, raising the question of how much real-time bed side support they provide.

None of the documents collected in this study were classified as a protocol. Protocols provide rules related to a procedure, dictating actions which must be adhered to. In contrast clinical guidelines offer less rigid advice and should be seen as general recommendations (Broughton and Rathbone, 2001, Hewitt-Taylor, 2004). Therefore, when using guidelines, professional autonomy and individual clinical judgement are still necessary.

Within healthcare a variety of document types are reportedly used to improve the quality of care, standardise practice and ensure evidence-based care (Hewitt-Taylor, 2004, Summers and Payakachat, 2006). Woolf et al. (1999) highlight guidelines as only one option for improving the quality of care. The authors describe the use of guidelines as a “magic bullet” for healthcare problems, where more effective solutions are ignored. Several potential harms and limitations are discussed including unrealistic expectations, inflexibility, and naive use. However, there are several examples of the positive impact of PICU guidelines. The results of a pilot study evaluating the implementation of guideline-directed sedation and analgesia management in Australian PICUs was not associated with PICU length of stay (Keogh et al., 2015). However, the authors reported a reduced risk of remaining ventilated in the post-implementation group. Although not statistically significant, a median difference of 21 hours was deemed clinically important. Furthermore, 88.5% of nurses surveyed described improved overall sedation management due to the guideline. The use of a MDT implemented PICU bundle consisting of three protocols: delirium, sedation, and early mobilisation, was effective for improving delirium screening, detection, and treatment, and also associated with decreased delirium prevalence (Simone et al., 2017). Despite success ongoing challenges related to use of guidelines were highlighted in the studies above. A recent systematic review investigated the strategies used to implement clinical practice guidelines (Pereira et al., 2022). Educational intervention, reminders, audit, and feedback were reported as the most effective strategies to promote guideline implementation.

It is important to emphasise the use of clinical expertise in conjunction with guidelines. This has been highlighted as of particular significance in critical care (Hewitt-Taylor, 2004). In this setting patients’ clinical conditions and needs vary significantly and patients may require care that involves several overlapping and potentially conflicting guidelines. This corroborates the findings of this study that clinical guidelines are tools to augment the decision-making process, rather than direct it. Furthermore, the practical, real-time support guidelines/SOPs provide have been questioned by this study. The documents analysed provided minimal support regarding choice of treatments and were not designed for use at the bed side in an evolving clinical situation.

## **6.5 Limitations**

The main limitations of this study are related to the completeness and representativeness of the documents, which are important elements of document analysis (Bowling, 2009). The study failed to recruit eight of the UK PICUs and three of the responding sites who stated that they used documents did not make any of these available to the researcher. Therefore, a complete picture of the use of organisation documents related to chest physiotherapy in ventilated children within the UK cannot be presented. However, the sites who provided documents were representative of all geographical regions and accounted for a range of size of units.

It is also important to acknowledge that the implementation of clinical guidelines into practice is challenging and there is a gap between guidelines and what happens in practice (Correa et al., 2020). Barriers to implementation include a lack of awareness of their existence, poor clarity or high complexity, beliefs that guidelines are too rigid, perceived challenges to professional autonomy and resource constraints (Correa et al., 2020, Keiffer, 2015). This study analysed the intended purpose and content of the organisational documents, but did not explore how frequently they were accessed, the content implemented, and by whom. Therefore, the practices described in this study may not be a true reflection of what happens in practice. Although this study has generated novel data regarding physiotherapy practices and decision making support using document analysis, interpreting these findings in isolation should be approached with caution.

## **6.6 Conclusion**

This chapter has presented the document analysis, which was the final component of phase 2, work package 1. The organisational documents analysed covered disease, physiotherapy techniques and mucoactives. The most popular document topics were NBBAL, VHI/MHI, MI-E and the use of DNase. This study has provided novel data related to the purpose and content of physiotherapy related documents. Data integration, including synthesis and triangulation, of the phase 2 components will be presented in Chapter 8.

## **7. Work package 2**

### **7.1 Introduction**

Work package 1 has been presented in Chapters 3 to 6. Current chest physiotherapy practice was described and clinical decision making explored, together with how physiotherapists manage instability and adverse events. Chapter 1 and the systematic review highlighted the inconclusive evidence to support chest physiotherapy in PICUs and reported gaps in the literature including a lack of representative populations, the effects of multiple physiotherapy treatments, and the impact on long-term outcomes. Given these findings it is crucial to identify which patients are likely to benefit most from chest physiotherapy and in which situations it may present a significant risk. Work package 2 aimed to address the gaps in the literature using a novel approach with rigorous methodology.

In this chapter, the aims and research questions of work package 2 are presented. The method and rationale are described and the results presented. Discussion of the key findings in relation to relevant literature concludes the chapter.

#### **7.1.1 Aim**

The overall aim of this study was to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children.

#### **7.1.2 Research questions**

The research questions which related to work package 2 were:

4. What is the incidence of physiological instability and adverse events associated with chest physiotherapy in ventilated children?
5. What are the risk factors/characteristics of children who display instability and/or adverse events associated with chest physiotherapy?
6. What is the long-term impact on the child of instability and adverse events associated with chest physiotherapy?



## **7.2 Methods**

### **7.2.1 Study design**

This was a retrospective observational study to identify and explore physiological instability and adverse events associated with chest physiotherapy in ventilated children across the paediatric critical care units at Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH).

Observational studies are a valued method in health care research and have several advantages. Retrospective data collection can be time and cost efficient, providing a large amount of data in a short time frame (Healy and Devane, 2011, Hess, 2004). Therefore, this method was deemed a more feasible option compared to prospective data collection. The observational design enabled a pragmatic approach that was well suited to the practical, clinical questions in this study. Pragmatic trials are an emerging concept within health care research, evaluating interventions in real-life conditions, which can increase generalisability (Peters et al., 2022, Randolph, 2016). This approach has been assisted by the digital revolution in healthcare that provides new opportunities to explore complex data sets. In this study access to automated high-resolution monitor and ventilator data, together with electronic patient records (EPRs), enabled a novel approach to observational physiotherapy research.

Information bias is a limitation associated with retrospective design. This relates to the accuracy and comprehensiveness of previously recorded data (Healy and Devane, 2011). Whilst the implementation of EPRs has improved aspects of ICU care, these systems rely on static data entry. A recent study concluded that EPR vital sign documentation was incomplete compared to an automated data aggregation platform, with significant events underrepresented by the EPR (Lowry et al., 2022). The digital and automated methods used in this study improved data accuracy and standardised the data collection process. It is also difficult to control for bias and confounders in retrospective studies (Hess, 2004). The novel approach to data collection used in this study provided access to a wide range of demographic and clinical confounders. Associations, rather than causation, can be inferred from the results of observational studies, which generate data to guide future sample size calculations and clarification of hypotheses (Healy and Devane,

2011, Sedgwick, 2014). These were important goals given the exploratory components of this study and lack of published research in this area.

### **7.2.2 Setting**

This study was completed across the three intensive care units at GOSH. The hospital has the largest critical care facility for children in the UK, including a 17-bedded general paediatric intensive care unit (PICU), an 8-bedded neonatal intensive care unit (NICU) and a 21-bedded cardiac intensive care unit (CICU).

There are approximately 700 admissions to PICU each year and 300 to NICU (PICANet, 2021). The UK Paediatric Intensive Care Audit Network reports PICU and NICU as a single unit, hence these are described together. Emergency admissions account for 60% of patients admitted to PICU/NICU. The remaining admissions are planned, predominantly following high risk surgery. Respiratory diagnoses account for approximately 30% of patients and those with neurological conditions 18%. The units provide advanced ventilatory support, e.g., high frequency oscillatory ventilation, with 75% of patients requiring mechanical ventilation (PICANet, 2021).

CICU admits approximately 700 patients per year, with 80% of these being planned admissions following surgery (PICANet, 2021). Patients following heart or lung transplantation, and those supported on mechanical circulatory support including extra-corporeal membrane oxygenation (ECMO) and ventricular assist devices (VAD) are also cared for on CICU. Approximately 80% of patients on CICU require invasive mechanical ventilation (PICANet, 2021). Advanced ventilatory support is also provided on this unit.

### **7.2.3 Sample**

Patients from PICU, NICU and CICU were included in the study. The retrospective data collection period was 1<sup>st</sup> October 2020 to 30<sup>th</sup> September 2021. This period was chosen to ensure EPIC, a new electronic patient record software introduced at GOSH on 1<sup>st</sup> April 2019, was fully functional and the high-resolution ventilator data which were integrated into the system on 23<sup>rd</sup> September 2020 were available. Completing the data collection over a full year avoided the impact of seasonal variation on the sample. However, data collection took place during the

severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic (COVID19). Key COVID19 events within the data collection period were as follows. A second National lockdown was enforced between 5<sup>th</sup> November 2020 and 2<sup>nd</sup> December 2020. This coincided with the NHS moving to an incident Level 4 on 5<sup>th</sup> November, indicating National co-ordination of resources. A third national lockdown took place between 6<sup>th</sup> January 2021 and 8<sup>th</sup> March 2021. Restrictions on indoor gatherings remained in place until 19<sup>th</sup> July 2021.

The inclusion and exclusion criteria used in this study are displayed in Table 7.1. A specific age category (0-4 years) was selected to improve homogeneity. There are significant anatomical and physiological differences between premature babies, infants and adolescents. Using a wider age range would have introduced challenges when comparing results and drawing conclusions. Children aged 0-4 years also account for the largest proportion of admissions to UK paediatric critical care units. In 2019 67% of critical care admissions in the UK were children under 4 years of age, with 78% (1351/1730) of GOSH ICU admissions in 2019 within this age group (PICANet, 2021).

*Table 7.1 Inclusion and exclusion criteria*

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• Intubated and mechanically ventilated</li> <li>• Receiving chest physiotherapy</li> <li>• 0-4 years of age</li> </ul>	<ul style="list-style-type: none"> <li>• Premature infants*</li> <li>• Patients requiring extracorporeal membrane oxygenation</li> <li>• Patients not for escalation of care or not receiving active treatment</li> </ul>

\*Infants with a corrected gestational age of <37 weeks at the time of the study were excluded.

Data collection was limited to the first four days of physiotherapy to reflect the acute period of the admission and ensure a manageable amount of data.

#### **7.2.4 Sample size**

This was a retrospective study over a fixed period; therefore a prior sample size was not calculated.

#### **7.2.5 Consent**

This project did not require individual patient/parent consent. The GOSH Digital Research, Informatics and Virtual Environments Unit ethics approval 17/LO/0008 "Use of routine GOSH data for research" allowed for use of routine data for research without explicit patient/family consent.

#### **7.2.6 Data sources and collection**

Patients who met the inclusion criteria were identified from physiotherapy records by the primary researcher (ES). Routinely collected data were retrieved from three sources, T<sup>3</sup> Etiometry, electronic patient records and the local Paediatric Intensive Care Audit Network (PICANet) portal.

T<sup>3</sup> Etiometry is a data aggregation and visualization software that collects, visualizes, and stores intensive care data in near real-time. Access to this high-resolution data for every patient is unique to GOSH within the UK. The T<sup>3</sup> system records measurements at a 5-second frequency from patient monitors and ventilators. Electronic patient records are available for all patients at GOSH, through EPIC. This is an integrated suite of healthcare software that includes functions related to patient care and clinical systems, in a single patient record. PICANet is commissioned by NHS England to collect data from PICUs, including admission, interventions and length of stay data.

##### *7.2.6.1 Outcome measures*

###### *Primary outcome measure*

The primary outcome measure in this study was oxygenation, measured using oxygen saturation index (OSI). It is calculated using fraction of inspired oxygen (FiO<sub>2</sub>), mean airway pressure (MAP) and peripheral oxygen saturations (SpO<sub>2</sub>).

$$OSI = (FiO_2 * MAP * 100) \div SpO_2$$

This non-invasive measurement can be readily and continuously calculated. It is a validated measure of respiratory failure and lung injury in ventilated neonatal and paediatric patients (Khemani et al., 2015, Muniraman et al., 2019, Rawat et al., 2015, Thomas et al., 2010b). The composite nature of OSI, including both the patient and level of ventilatory support, provides a more complete picture of oxygenation than SpO<sub>2</sub> alone, which had been an initial option in this study. Oxygenation index (OI), which is calculated using partial pressure of oxygen (PaO<sub>2</sub>) rather than SpO<sub>2</sub>, was an alternative outcome. However, arterial blood gases are completed at specific intervals and not available in a continuous manner. Furthermore, OI requires patients to have an arterial line, reducing the available sample.

The individual components of OSI, FiO<sub>2</sub>, MAP and SpO<sub>2</sub>, were retrieved from T<sup>3</sup>.

Oxygenation has been used previously to describe adverse events associated with physiotherapy, chest and mobilisation, in both paediatric and adult settings (LaRosa et al., 2022, Shannon et al., 2015a, Zeppos et al., 2007). All physiotherapists (n=72) surveyed in work package 1, phase 1 reported using oxygenation (SpO<sub>2</sub>) to monitor patient stability during chest physiotherapy (Section 3.3.6.1). This highlights its clinical relevance and reinforces the choice of oxygenation as the primary outcome measure in this study.

#### *Secondary outcome measures*

Heart rate (HR), measured by electrocardiography and mean arterial blood pressure (MBP), measured invasively by an arterial line were the secondary outcomes in this study. Both variables were collected as high-resolution data from T<sup>3</sup>. As with the primary outcome these were selected in line with published literature investigating the prevalence of adverse events associated with physiotherapy (LaRosa et al., 2022, Shannon et al., 2015a, Zeppos et al., 2007). Furthermore, heart rate and blood pressure were used to monitor stability by physiotherapists who participated in work package 1 phase 1 (Section 3.3.6.1) and the phase 2 focus groups (Section 5.3.4.3), reinforcing their selection as outcome measures.

### *Defining adverse events*

The definitions for quantifying adverse events used in this study were based on a recently published trial investigating the safety of early mobilisation in PICU (LaRosa et al., 2022). Although not specific to chest physiotherapy these definitions were the best available and population specific. Similar definitions have been used in adult studies (Zeppos et al., 2007). The specific physiological adverse event definitions used in this study are outlined below.

- SpO<sub>2</sub> decrease >15%
- FiO<sub>2</sub> increase ≥20%
- Heart rate change >20%
- Blood pressure change >20% (all relative % change)

The smallest change in OSI corresponding to the above criteria was calculated to be 0.3, therefore this was used as the OSI adverse event threshold. OSI has not been used previously in this context and therefore no published criteria exist upon which to base an adverse event definition.

The definitions for heart rate and blood pressure included changes in either direction. It needs to be acknowledged that in some circumstances this could represent a benefit if the patient is presenting with extremes of either physiological variable. The anticipated impact of this was determined to be minor and although a limitation, using these definitions was deemed suitable for the secondary outcome measures.

#### *7.2.6.2 Demographics/risk factors of interest*

Patient demographics, treatment details and clinical factors were collected to provide a description of the sample and allow interrogation of risk factors which may be predictive of instability or adverse events. These were collected from electronic patient records and PICANet. The variables are displayed in Table 7.2. Those included exclusively in response to work package 1 are highlighted in italics.

Table 7.2 Demographic/risk factors collected from electronic patient records/PICANet

Category	Variable	Details
<b>Demographics</b>	Gender	Male/female
	Weight	Kg
	Age	Months
	Diagnosis	
	Patient location	Which intensive care unit
	Type of admission	Emergency or elective
	<i>Gestation at birth (from WP1)</i>	
<b>Chest physiotherapy treatment</b>	Number of days and sessions	
	Time of day of the treatment	Daytime (09:00-17:00) Out of hours (17:00-09:00)
	Techniques	ETT saline instillation Manual/ventilator hyperinflation Manual techniques Directed saline lavage
	ETT suction type	Open or closed
<b>Clinical status</b>	Paediatric logistic organ dysfunction score (0-33)	Validated, clinically meaningful score of the severity of illness in critically ill children (Leteurtre et al., 2013)
	Paediatric Index of Mortality version 3 (PIM3)	A score measuring severity of illness and risk of mortality on admission (Pollack et al., 2016)
<b>Ventilation</b>	Mode of ventilation	Conventional or HFOV
	Use of iNO	
<b>Infection status</b>	<i>COVID19 (from WP1)</i>	

(ETT – Endotracheal tube, HFOV- High frequency oscillatory ventilation, iNO – Inhaled nitric oxide, WP1 – Work package 1)

### 7.2.6.3 Long-term PICU outcomes

A third set of variables was collected to enable the relationship between instability following chest physiotherapy and overall PICU outcome to be evaluated. Whilst these outcomes are still related to the acute PICU stay they are classified as longer-term in relation to the physiotherapy treatment and the immediate outcome

measures used in previous studies (discussed in Section 1.3.2). These were based on the Core Outcome Set for Critical Care Ventilation Trials and data were downloaded from the PICANet portal and electronic patient records (Blackwood et al., 2019): Mortality and Length of invasive ventilation (days).

#### 7.2.6.4 Data collection

Following patient identification, the data described above were retrieved and uploaded into a digital research environment (DRE) by the Great Ormond Street Hospital Digital Research, Informatics and Virtual Environments Unit. The DRE is a secure, cloud-enabled, secondary use data store, which can collect and manage data from both T<sup>3</sup> and electronic patient records (see Figure 7.1). Data managed in the DRE are non-identifiable.

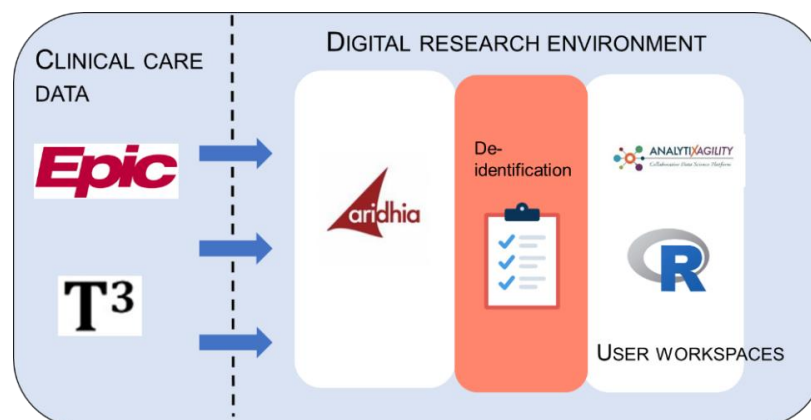


Figure 7.1 Visualisation of the digital research environment

#### 7.2.7 Data analysis

All data were analysed within the digital research environment, using R project ([www.cran.r-project.org](http://www.cran.r-project.org)). The R packages used were tidyverse, ggpubr, beanplot, rstatix and lme4 (Bates et al., 2015, Kampstra, 2008, Kassambara, 2020, Kassambara, 2021, Wickham et al., 2019). A test sample (n=10) was used to develop and write the initial processing and analysis scripts. This approach enabled the script's function to be checked and verified. Within the results section the scripts for OSI analysis are referenced and displayed in the appendices. The remaining scripts used for the analysis are available at (<https://github.com/physioemma/REACH-study.git>).



Physiologically implausible values were removed from the date sets, the limits used are displayed below.

- SpO<sub>2</sub> >100%
- FiO<sub>2</sub> <0.21 & >1.0
- MAP <5cmH<sub>2</sub>O & >35cmH<sub>2</sub>O
- Heart rate >300bpm
- Mean arterial blood pressure <0mmHg and >150mmHg

Pre-ductal SpO<sub>2</sub> only were used for patients who had both pre- and post-ductal monitoring.

#### 7.2.7.1 Time period of analysis

The reference time stamp available for individual physiotherapy treatments was the end time of treatment. This was documented in the electronic patient records. At the time of data collection there was no option to record or document length of physiotherapy treatment within the electronic patient records. A 30-minute treatment window prior to the documented end time was allocated for each physiotherapy session. This decision was based on the results of a local audit of physiotherapy length of treatment across PICU, NICU and CICU (Appendix 25). Twenty-five treatments were included and the median length of treatment was 07:30 minutes (range 03:48 to 23:00 minutes). This provided justification that treatment would have started and ended within the 30-minute period. Allowing for the 30-minute treatment window, the period used for analysis was 30 minutes prior to the start of the treatment window and 60 minutes following the documented end of physiotherapy (Figure 7.2). The specific epochs used for analysis are discussed in the results section.

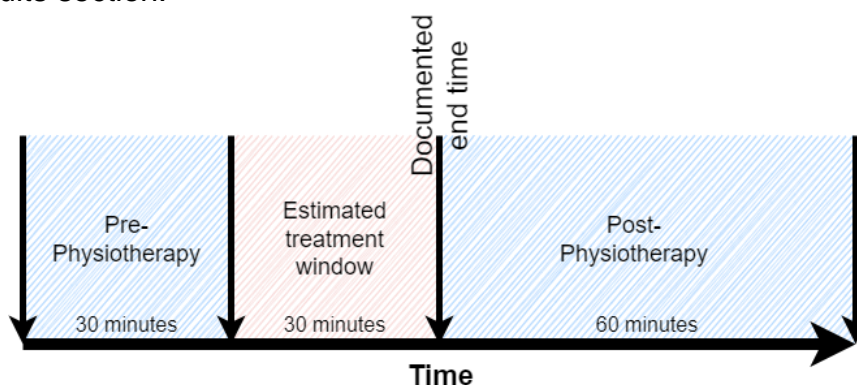


Figure 7.2 Time period used for data analysis

### 7.2.7.2 Overview of data analysis

An overview of the data analysis process is provided below. Analysis was exploratory and iterative hence further description and specific details are included as a narrative throughout the results section. Sample characteristics and demographics, and chest physiotherapy treatment details were described using descriptive statistics, including median and interquartile range, and frequency and percentages respectively. OSI was calculated for the first physiotherapy session. OSI distributions were described according to time in relation to physiotherapy. The number of OSI adverse events post-physiotherapy was calculated using the *a priori* definition (increase  $\geq 0.3$ ). Prevalence and distribution of OSI adverse events following physiotherapy were described and explored. Univariable analysis was completed using Chi-squared, Mann-Whitney or Fishers Exact test. The test chosen was dependent on the level of data, sample size and distribution. Significance level was set at  $p < 0.05$ .

The analysis was repeated for subsequent chest physiotherapy sessions (for the first four days). Univariable analysis was completed to compare patients with and without an adverse event. Chi-squared or Kruskal Wallis test were used dependent on the level of data (means or percentages). Long-term outcomes were compared for patients with and without OSI adverse events using multilevel generalised linear regression.

The analysis of the first physiotherapy session was repeated for the secondary outcomes of heart rate and mean blood pressure.

Missing raw data from T<sup>3</sup> were not imputed and data were left missing. For missing values from EPIC or PICANet 'NA' was used as a replacement value. Due to the retrospective design, missing data due to lack of charting or electronic health record problems could not be minimised.

## 7.3 Results

### 7.3.1 Demographics

Between 1<sup>st</sup> October 2020 and 30 September 2021, 593 admissions met the inclusion criteria. Physiotherapy treatment data for at least the first physiotherapy session were available for 546/593 (92.1%) admissions, therefore these were included in the study. The 546 admissions accounted for 487 patients, with 50 patients having > 1 admission within the 12-month period. Throughout this chapter, unless stated otherwise, the 546 individual admissions will be treated and referred to as individual patients. For each admission patients have different baseline characteristics. Baseline characteristics and outcomes are displayed in Table 7.3.

*Table 7.3 Baseline characteristics and outcomes of the full sample*

<b>Baseline characteristics</b>	
<b>Sex, n (%)</b>	Males 338 (61.9) Females 208 (38.1)
<b>Age in months, median (IQR)</b>	4 (0-10)
<b>Age distribution, n (%)</b>	
< 1 month	138 (25.3)
1-12 months	278 (50.9)
12-24 months	65 (11.9)
24-60 months	65 (11.9)
<b>Weight (Kg), median (IQR)</b>	5.2 (3.5-8.4)
<b>Gestation at birth, weeks, n (%), (n=465)</b>	
≥ 37	345 (74.2)
30 to ≤ 36	91 (19.6)
< 30	29 (6.2)
<b>Unit, n (%)</b>	
CICU	328 (60.1)
PICU	193 (35.3)
NICU	25 (4.6)
<b>Type of admission, n (%)</b>	
Elective	219 (40.1)
Emergency	327 (59.9)
<b>PELOD score, median (IQR) (n=529)</b>	6 (6-8)
<b>SARS-CoV-2, n (%)</b>	6 (1)
<b>Length of ICU stay (days), median (IQR)</b>	6.8 (4-13)
<b>Discharge status, alive, n (%) (n=525)</b>	502 (95.6)

(Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation, PELOD and discharge status, number of children is indicated. PELOD - Pediatric logistic organ dysfunction, ICU – intensive care unit. n=546)

Median age of patients was 4 months (IQR 0-10), with the highest proportion of children being under 12 months of age (416/546, 76.2%). CICU admissions accounted for 328 (60%) patients and in total 327 (60%) were emergency admissions. Figure 7.3 displays a breakdown of admission diagnoses. Over half were cardiovascular (306/546, 56%), with respiratory being the second most frequent diagnosis (86/546, 16%).

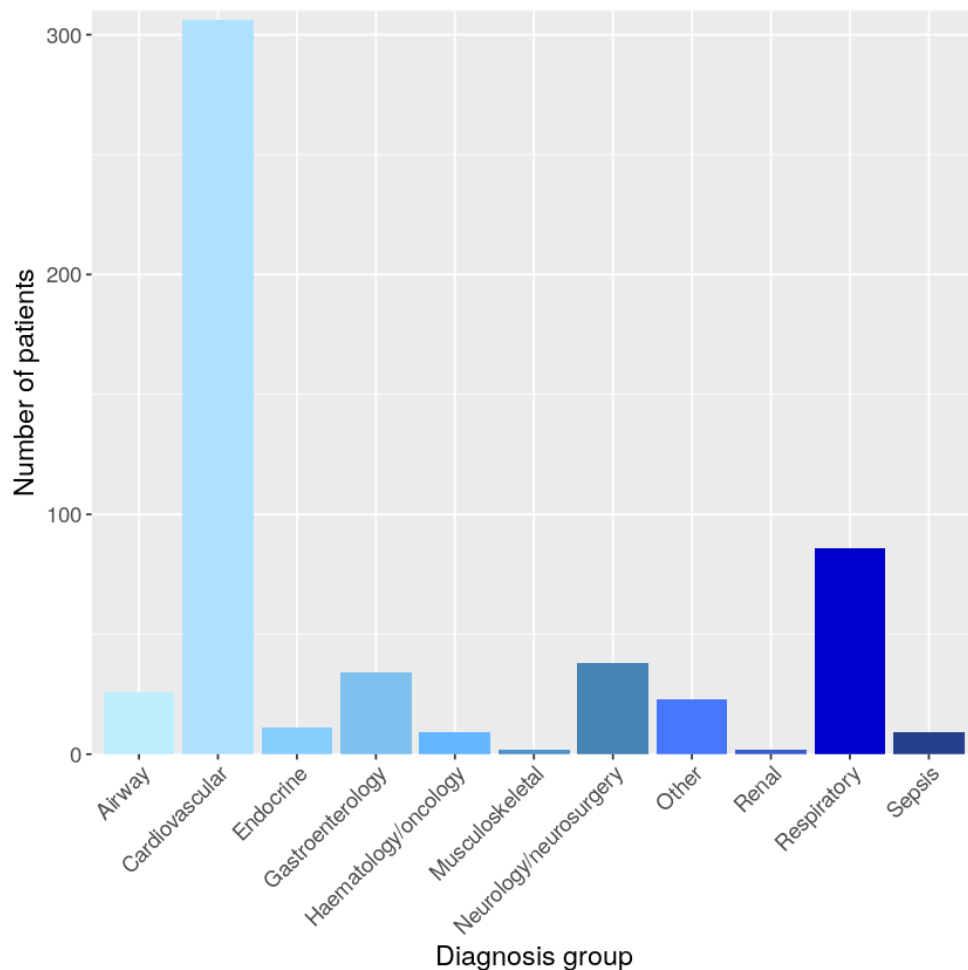


Figure 7.3 Admission diagnosis for all patients

(n=546)

### 7.3.2 Physiotherapy treatment

Cumulatively, the 546 patients underwent 1596 physiotherapy treatments within the first 4 days of physiotherapy. Summary details are shown in Table 7.4. Median number of days of physiotherapy within the first 4 days was 2.5 (IQR 1-4). In 38 patients (7%) the days of physiotherapy were not consecutive. Median number of sessions per patient within the first 4 days was 3 (IQR 1-4), with the maximum number of treatments 11. Median number of treatments per day was 1 (IQR 1-1).

Median time from admission to first physiotherapy treatment was 19.4 hours (IQR 15.5-25.3), with 389 (71%) patients receiving physiotherapy within 24 hours of admission.

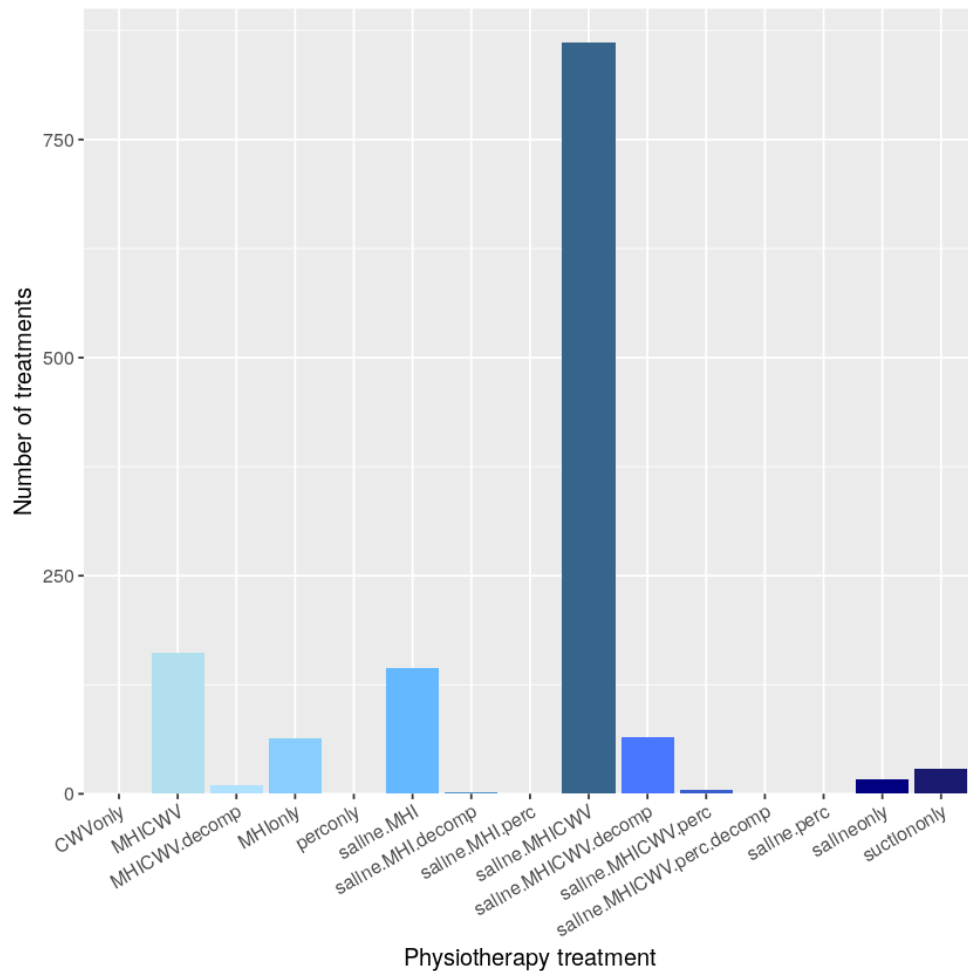
*Table 7.4 Summary table of the number of days of physiotherapy and number of treatments*

<b>Characteristic</b>	
<b>Number of days of physiotherapy in first 4 days, median (IQR)</b>	2.5 (1-4)
<b>Distribution of number of days of physiotherapy in first 4 days, n (%)</b>	
<b>1 day</b>	166 (30.4)
<b>2 days</b>	104 (19)
<b>3 days</b>	94 (17.2)
<b>4 days</b>	182 (33.3)
<b>Number of treatments in first 4 days, median (IQR)</b>	3 (1-4)
<b>Total number of days of physiotherapy whilst intubated and ventilated, median (IQR)</b>	5 (1-6)
<b>Total number of treatments whilst intubated and ventilated, median (IQR)</b>	6 (1-7)

Specific physiotherapy data were available for 1361/1596 (85.3%) treatments. Daytime treatments (09:00-17:00) accounted for 1301/1361 (95.6%) treatments.

The combinations of physiotherapy treatment techniques used are displayed in Figure 7.4. The combination of saline instillation and manual hyperinflations (MHI) with chest wall vibrations (CWV) was the most common treatment (861/1361, 63.3%). MHI with CWV was used in 161 (11.8%) treatments and saline instillation with MHI in 144 (10.6%). Overall MHI was used in 1312 (96.4%) treatments and CWV in 1103 (81%). Saline was used in a total of 1096 (80.4%) treatments. The

saline was placed directly into the endotracheal tube (ETT) in 1072 treatments, with the remaining 24 using a soft catheter for a directed lavage.



*Figure 7.4 Physiotherapy treatments used in first four days of physiotherapy* (CWV - chest wall vibrations, MHI - manual hyperinflations, perc - percussion, decomp – decompression. Treatments=1361)

All treatments included ETT suction. Open ETT suction alone was used in 1260/1361 (92.6%) treatments, closed suction used in 47 (3.5%) and a combined approach used in 20 (1.5%). In the remaining 34 treatments the suction method was not documented.

### 7.3.3 Primary outcome – Oxygen saturation index

#### 7.3.3.1 First physiotherapy treatment

To calculate OSI all available data points for the individual components (SpO<sub>2</sub>, FiO<sub>2</sub> and MAP) were collated for the 30-minute pre-physiotherapy and 60-minute post-physiotherapy periods. Physiologically implausible values for each component were removed, see below:

- SpO<sub>2</sub> >100% (0/627114)
- FiO<sub>2</sub> <0.21 & >1.0 (21/355215, 0.006%)
- MAP <5cmH<sub>2</sub>O & >35cmH<sub>2</sub>O (3638/355215, 0.01%)

Following processing, OSI values for each available 5 second time point were calculated. OSI values within the pre- and post-physiotherapy time periods were available for 251/546 (46%) patients. Twenty-one patients with repeated admissions accounted for 46 of the admissions. High-resolution monitor data from T<sup>3</sup> were more readily available than the high-resolution ventilator data. This resulted in more SpO<sub>2</sub> data available compared to MAP and FiO<sub>2</sub>. OSI could only be calculated for a certain proportion due to missing MAP and FiO<sub>2</sub>. A comparison of the demographic and baseline characteristics of patients with OSI data and those without are displayed in Table 7.5.

Table 7.5 Characteristics of patients with OSI data available and those without

Baseline characteristics	OSI group (n=251)	No OSI group (n=295)	Mann Whitney/ Chi- squared/ Fishers exact
<b>Sex, n (%)</b>	Males 142 (56.6)	Males 196 (66.4)	p=0.023
	Females 109 (43.4)	Females 99 (33.6)	
<b>Age in months, median (IQR)</b>	3 (0-6)	6 (1-17.5)	p<0.00001
<b>Weight (Kg), median (IQR)</b>	4.6 (3.3-6.5)	6.3 (3.8-10.5)	p<0.00001
<b>Gestation at birth, weeks, n (%)</b> ≥ 37 30 to ≤ 36 < 30	175 (78.1) 41 (18.3) 8 (3.6) (n=224)	170 (70.5) 50 (20.7) 21 (8.7) (n=241)	p=0.05
<b>Unit, n (%)</b> CICU PICU NICU	251 (100) 0 0	77 (26.1) 193 (65.4) 25 (8.5)	p=0.013
<b>Type of admission, n (%)</b> Elective Emergency	130 (51.8) 121 (48.2)	89 (30.2) 206 (69.8)	p<0.00001
<b>PELOD score, median (IQR)</b>	7.5 (6-8) (n=242)	6 (5-7) (n=272)	p<0.00001
<b>SARS-CoV-2, n (%)</b>	0	6 (100)	p=0.035
<b>Length of ICU stay (days), median (IQR)</b>	7.6 (4.1-14.9)	5.9 (3.6-10.9)	p=0.004
<b>Discharge status, alive n (%)</b>	246 (98.4) (n=250)	256 (93.1) (n=275)	p=0.042

(Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation, PELOD and discharge status, number of children is indicated. CICU – Cardiac intensive care unit, ICU – Intensive care unit, NICU – Neonatal intensive care unit, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care unit)

The shaded area on the table highlights that all admissions with OSI data were from patients cared for on CICU. Other significant differences in characteristics are



likely due to the differences in caseload between the intensive care units. This unexpected result and the missing data will be discussed later in the chapter (Section 7.5.2). Unless specified all subsequent OSI analysis presented is based on this CICU subgroup.

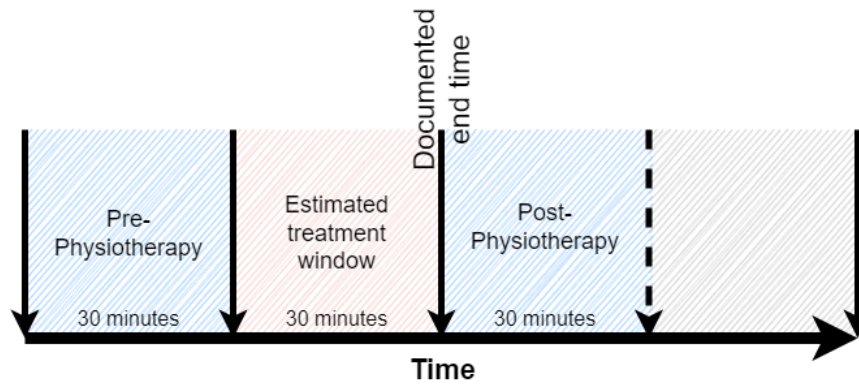
In total 245310 OSI values were calculated for the first physiotherapy treatment. Raw data are displayed in Figure 7.5. For the entire dataset median OSI pre-physiotherapy was 3.7 (IQR 2.8-5.5), with a range of 1.2 to 21.1. Median OSI post-physiotherapy was 3.7 (IQR 2.7-5.4) and ranged from 1.1 to 49.6.



*Figure 7.5 Raw oxygen saturation index values for the first physiotherapy treatment.*

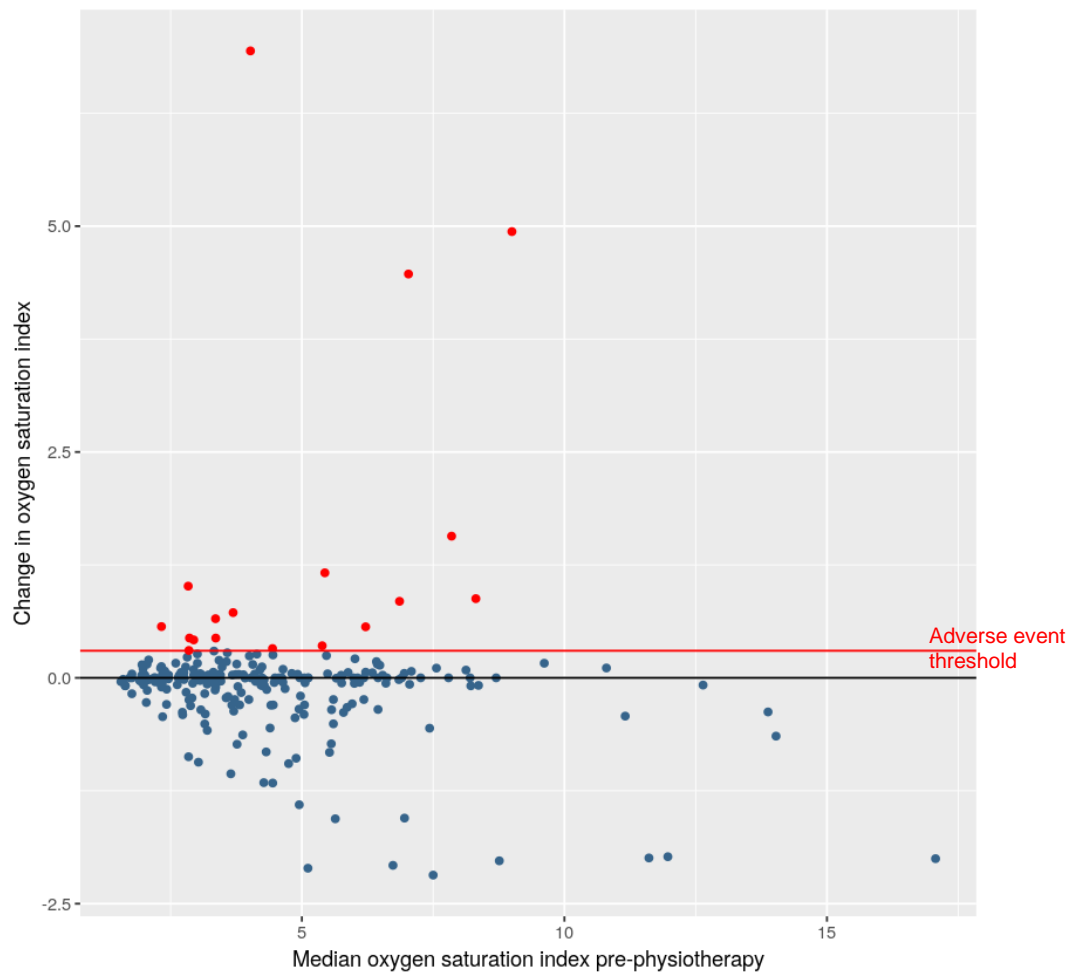
(Each data point is represented by a dot. The estimated treatment window is shown between the two vertical red lines. n=251)

To obtain an initial overview of the data the 30-minute pre-physiotherapy period was compared to 30 minutes post-physiotherapy (Figure 7.6).



*Figure 7.6 Time period used for initial data analysis*

Median OSIs were calculated for each patient for the 30-minute pre-physiotherapy and 30-minute post-physiotherapy period. This enabled a change in median OSI to be calculated for each patient and the proportion of values which crossed the adverse event threshold to be identified (OSI increase  $\geq 0.3$ ) (See appendix 26 for R script). Change in OSI plotted against pre-physiotherapy median is displayed in Figure 7.7.



*Figure 7.7 Change in 30-minute median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median oxygen saturation index. (Patients with an adverse event are highlighted in red. n=251)*

The adverse event rate was 18/251 (7.2%). Adverse events occurred in patients with pre-physiotherapy medians of <10. The plot demonstrates a trend of greater improvements in OSI in patients with higher pre-physiotherapy medians.

Given the high-resolution data available, this 30-minute summary approach was deemed too broad. A decision to explore the data using 5-minute samples was made. 5-minute samples from five distinct periods pre- and post-physiotherapy were used (Figure 7.8).

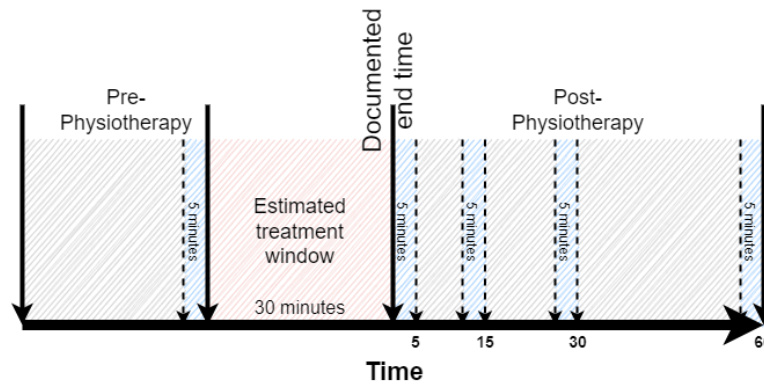
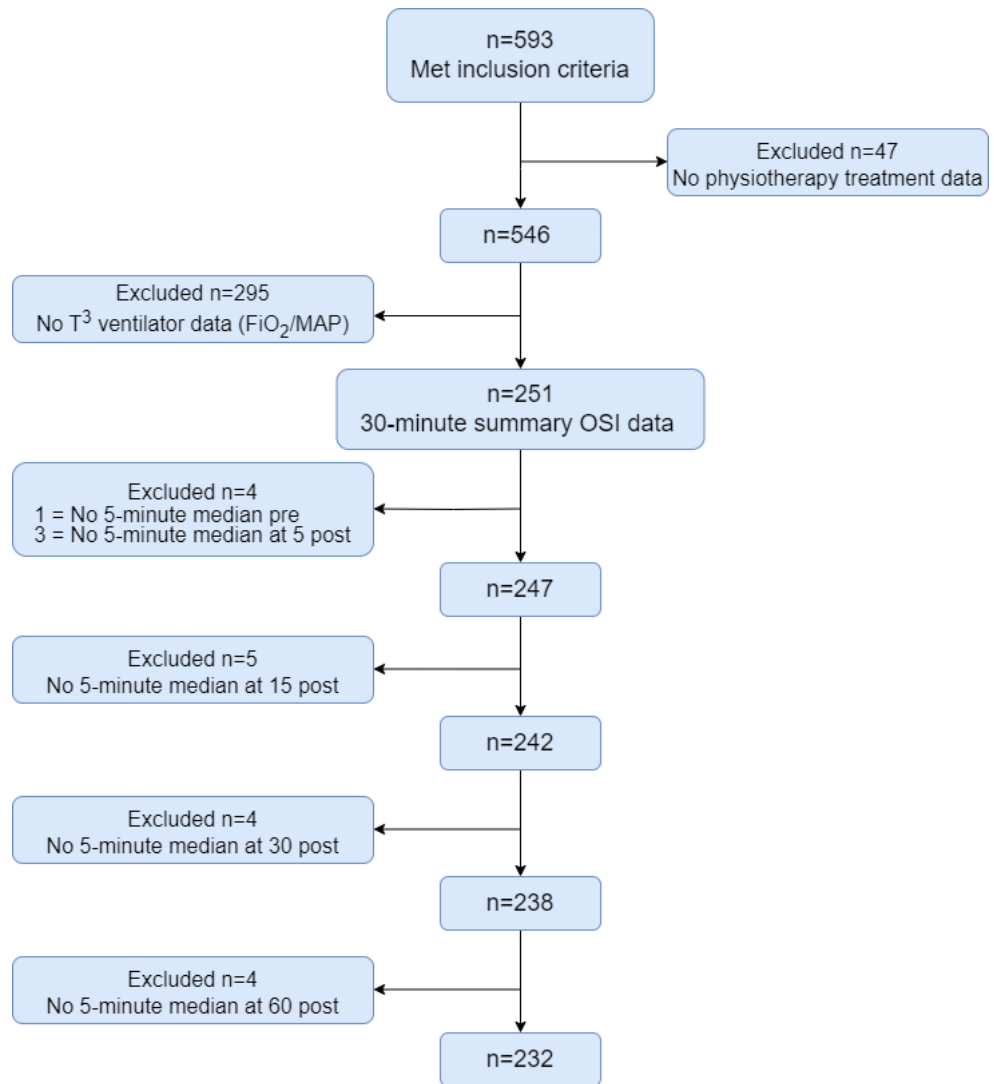


Figure 7.8 Five-minute epochs used for stage 2 data analysis

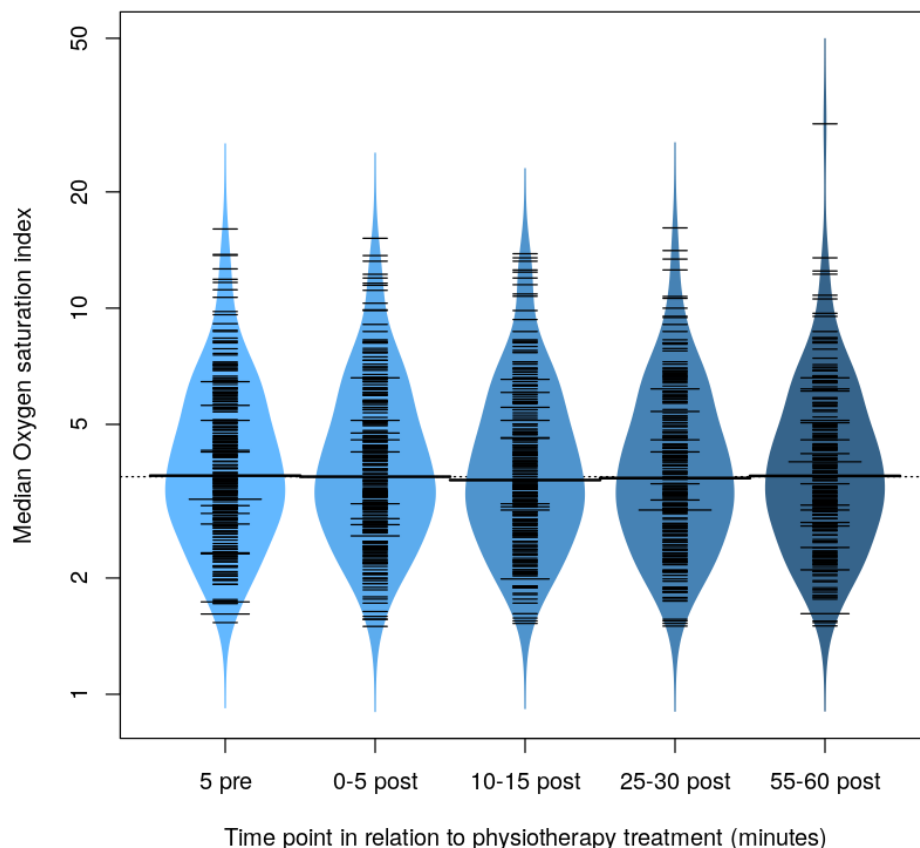
Four post-physiotherapy epochs were selected. This aimed to provide a more sensitive analysis whilst also including data from the entire 60-minute post-physiotherapy period. Three epochs were included within the first 30 minutes to provide good representation of this initial period, when changes were more likely to be attributed to physiotherapy. A 5-minute epoch at 60 minutes was included to allow longer term impact to be explored. A 5-minute epoch was used pre-physiotherapy to ensure uniform durations were compared.

Median OSI was calculated for each 5-minute epoch for each patient (Appendix 27). The flow of patients and data available are shown in Figure 7.9. The amount of OSI data available decreased slightly over the 4 post-physiotherapy time points.



*Figure 7.9 Consort diagram displaying numbers of patients included at the different stages of OSI analysis*  
 (Post refers to post-physiotherapy time point. FiO<sub>2</sub> – Fraction of inspired oxygen, MAP – Mean Airway pressure, OSI – Oxygen saturation index)

The beanplots in Figure 7.10 show the distribution of median OSI in relation to the pre- and post-physiotherapy time periods.



*Figure 7.10 Beanplots of the distribution of median oxygen saturation index (OSI) in relation to pre- and post-physiotherapy time points.*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set, with the thick line for each beanplot representing the median value for the time point. The short horizontal lines within each beanplot represent individual data points. Median oxygen saturation index appears to decrease within the first 15 minutes post-physiotherapy before increasing. n=247)

The beanplots in Figure 7.10 display similar distributions across the time points and show a decrease in median OSI within 15 minutes post-physiotherapy before returning to pre-physiotherapy levels. To explore these differences further, univariable analysis with pairwise comparison was completed using Wilcoxon signed-rank test with Bonferroni adjustment. This test compared median OSI for the entire sample between two time points. The pre-physiotherapy time point was individually compared to all post-physiotherapy time points and the post-physiotherapy time points compared to each other. Bonferroni correction adjusts

probability (p) values to account for the increased risk of a type I error when making multiple statistical comparisons. The results demonstrated a statistically significant decrease in median OSI at 30 minutes (p=0.004) and 60 minutes (p=0.0007) post-physiotherapy (Table 7.6).

*Table 7.6 Wilcoxon signed-rank test with Bonferroni adjustment comparing median oxygen saturation index pre- and post-physiotherapy*

Time point 1	Time point 2	Median of OSI paired differences (IQR)	Wilcoxon signed rank test (p.adjust)
Pre-physiotherapy	5 minutes post	0 (-0.081-0.079)	p=1.0
Pre-physiotherapy	15 minutes post	0 (-0.128-0.070)	p=0.56
Pre-physiotherapy	30 minutes post	-0.004 (-0.272-0.056)	p=0.004*
Pre-physiotherapy	60 minutes post	-0.038 (-0.22-0.074)	p=0.0007**
5 minutes post	15 minutes post	0 (-0.049-0.029)	p=1.0
5 minutes post	30 minutes post	0 (-0.098-0.043)	p=0.015*
5 minutes post	60 minutes post	0 (-0.179-0.076)	p=0.06
15 minutes post	30 minutes post	0 (-0.082-0.037)	p=0.54
15 minutes post	60 minutes post	0 (-0.131-0.082)	p=1.0
30 minutes post	60 minutes post	0 (-0.061-0.079)	p=1.0

(\*p<0.05, \*\*p<0.001. p.adjust – adjusted p-value for multiple comparisons)

To account for confounders, including patient level differences, multi-level generalised linear regression was performed. Median OSI was the dependent variable, time in relation to physiotherapy, weight, admission type and PELOD score were the fixed effect variables and unique patient identifier the random effect variable. This allowed for the evaluation of the median change in OSI at each post-physiotherapy time point, while accounting for weight, admission type, and PELOD as a marker of severity of illness. Inclusion of the individual patient identifier accounted for individual patient effects. Age was not included as it is closely related to weight. Due to the skewed distributions for OSI, weight and PELOD scores, a gamma log-link model was used. See model below.

```
glmer(medianosi ~ time + weight + admission.type +
pelod_score + (1|project_id), data=osi_change9,
family=Gamma(link="log"))
```

Post-physiotherapy time points were associated with small decreases in OSI (Table 7.7). These were statistically significant at 15, 30 and 60 minutes post-physiotherapy, as the 95% confidence intervals do not cross 0. Weight, emergency admission and PELOD score were also significantly associated with OSI. Increased weight was associated with a higher OSI, with OSI greater in emergency admissions compared to elective admissions. A higher PELOD score was associated with higher OSI, e.g., the sicker the child, the higher the OSI is likely to be. As oxygen indices are included within PELOD this was expected.

*Table 7.7 Coefficients for median oxygen saturation index from multi-level generalised linear regression models with post-physiotherapy time points and baseline variables*

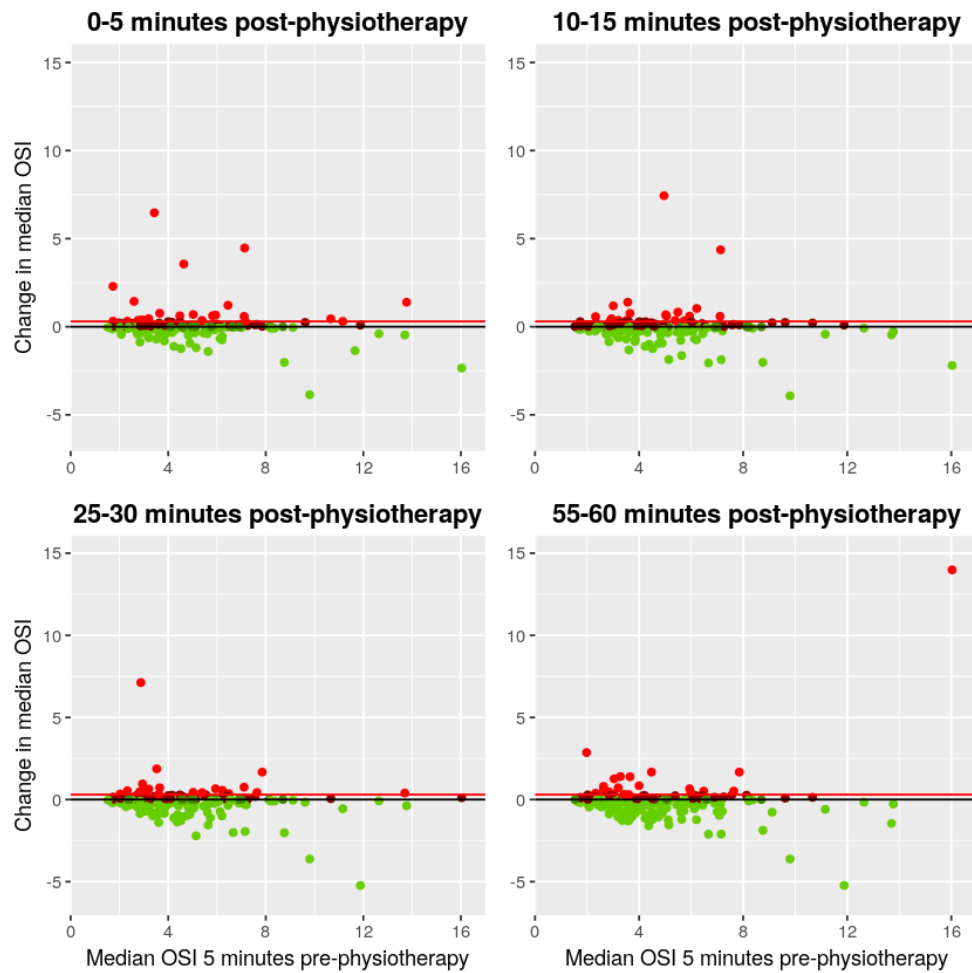
<b>Variable</b>	<b>Linear regression coefficient for OSI</b>	<b>95% Confidence intervals for regression coefficient</b>
5 minutes post-physiotherapy	-1.431e-04	-3.923e-03-3.636e-04
15 minutes post-physiotherapy	-2.018e-02	-2.411e-02-1.626e-02
30 minutes post-physiotherapy	-2.933e-02	-3.304e-02-2.559e-02
60 minutes post-physiotherapy	-3.724e-02	-4.010e-02-3.348e-02
Weight	2.993e-05	1.667e-05-4.319e-05
Emergency admission	1.695e-01	1.655e-01-1.736e-01
PELOD score	4.023e-03	3.201e-04-7.726e-03

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for oxygen saturation index. 95% confidence intervals which do not cross 0 indicate statistical significance. OSI - Oxygen saturation index, PELOD - Pediatric logistic organ dysfunction)

OSI data were explored in relation to the incidence of adverse events. Change in median OSI was calculated between the 5-minute period immediately pre-



physiotherapy and the four epochs post-physiotherapy (5, 15, 30 and 60 minutes) (Figure 7.8). The proportion of patients with an adverse event was determined for each post-physiotherapy time point. The changes in the remaining median OSIs were also quantified, as worse, in-status-quo (ISQ, identical values) or improved. The results are displayed in Figure 7.11 with the individual proportions reported in Table 7.8.



*Figure 7.11 Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median*

(The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green – in-status-quo, green - improved. OSI – oxygen saturation index. n=247)

Table 7.8 Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=247)	23 (9.3)	84 (34)	38 (15.4)	102 (41.3)
15 minutes, n (%) (n=242)	18 (7.4)	76 (31.4)	32 (13.2)	116 (47.9)
30 minutes, n (%) (n=238)	20 (8.4)	70 (29.4)	27 (11.3)	121 (50.8)
60 minutes, n (%) (n=232)	21 (9.1)	67 (28.9)	15 (6.4)	129 (55.6)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo, identical values)

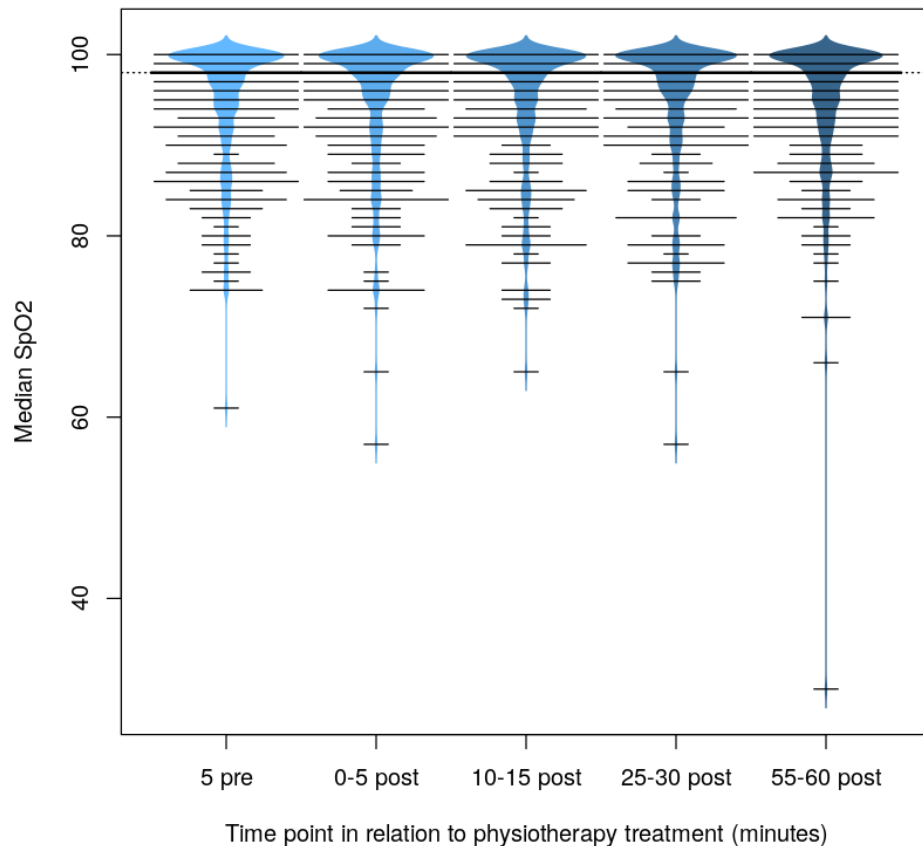
The adverse event rate immediately post-physiotherapy was 9.3% (23/247), this subsequently decreased at 15 and 30 minutes, but returned to 9.1% (21/232) at 60 minutes post-physiotherapy. Most adverse events occurred in patients with a pre-physiotherapy median OSI <8. The number of patients demonstrating improvements in OSI post-physiotherapy increased over the 60-minute period. The greatest improvements were seen in those with higher pre-physiotherapy median OSI. The R script for the analysis of OSI for the first physiotherapy treatment is displayed in Appendix 28.

To provide a more detailed understanding of the changes observed in OSI pre- and post-physiotherapy, the individual components of OSI were examined.

#### *Peripheral oxygen saturation (SpO<sub>2</sub>)*

In total 338258 raw SpO<sub>2</sub> data points were available for patients with OSI data which accounted for 250 patients included in the initial OSI analysis. Overall median SpO<sub>2</sub> pre-physiotherapy was 98% (IQR 93-100), with a range of 31 to 100. Median SpO<sub>2</sub> post-physiotherapy was 98% (IQR 93-100) and ranged from 20 to 100. Median SpO<sub>2</sub> for each patient was calculated for 5-minute epochs pre- and post-physiotherapy (Appendix 29). The distributions of median SpO<sub>2</sub> for the pre-physiotherapy and post-physiotherapy epochs are displayed in Figure 7.12. The

beanplots show very similar distributions and no change in median SpO<sub>2</sub> across the time points.



*Figure 7.12 Beanplots of the distribution of median SpO<sub>2</sub> in relation to pre- and post-physiotherapy time points*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set. The thick black line represents the median value for each time point. The short horizontal lines within each beanplot represent individual data points. Due to an automatic function of the R package, when medians are equal the thick black line representing the median value at each time point is continuous. However, the beanplots should still be interpreted individually. There is no change in median SpO<sub>2</sub> across the time points. SpO<sub>2</sub> – peripheral oxygen saturations. n=250)

Univariate analysis between time points, using a paired Wilcoxon signed-rank test with Bonferroni adjustment, demonstrated no statistically significant differences in SpO<sub>2</sub> between the time points (all comparisons  $p=1.0$ ). A multilevel linear regression model was applied to further explore the differences whilst accounting for confounders. SpO<sub>2</sub> data is skewed by definition and there are no suitable transformations, hence a multilevel linear model was used. Log transformations were used for weight and PELOD score. See model below.

*lmer(medianspo2 ~ time + log(weight) + admission.type + log(pelod\_score) + (1|project\_id), data=spo2\_change9)*

The regression coefficients and 95% confidence intervals are presented in Table 7.9. There were no significant changes in SpO<sub>2</sub> over the post-physiotherapy period. Weight was independently associated with median SpO<sub>2</sub>, although this variable is not relevant to the current study.

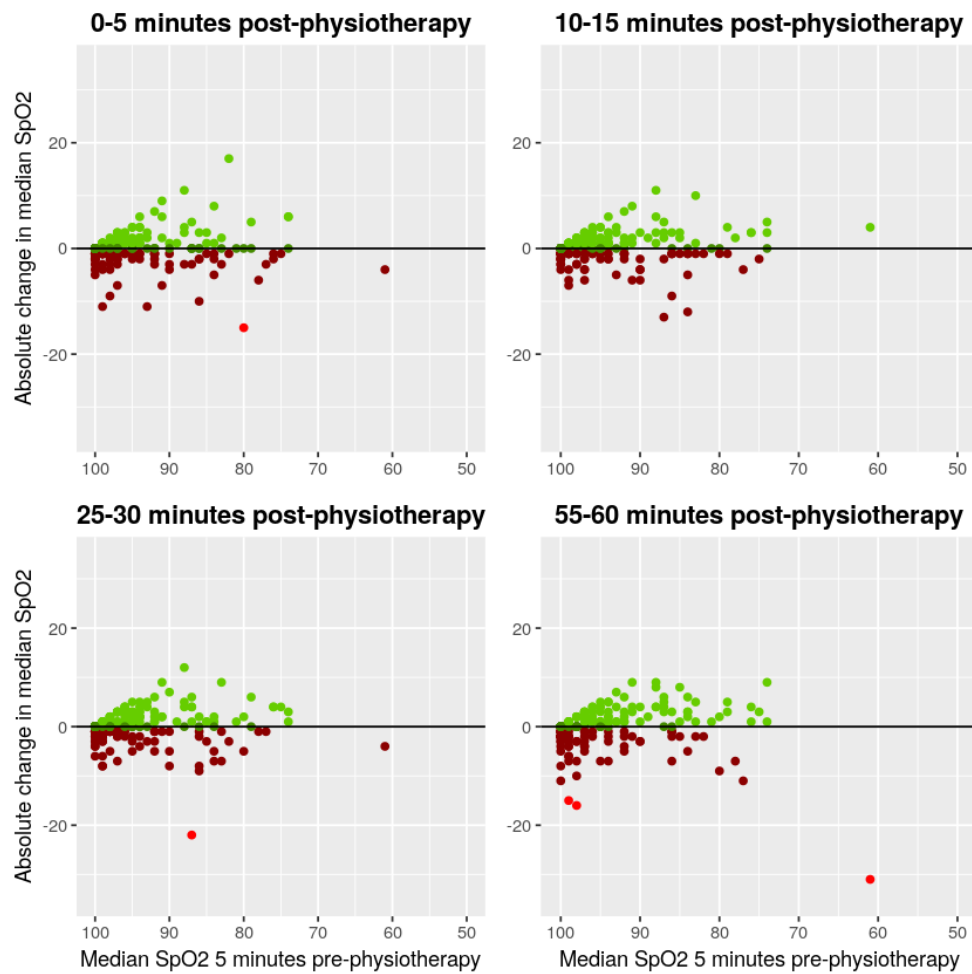
*Table 7.9 Coefficients for median SpO<sub>2</sub> from multi-level linear regression models of post-physiotherapy time points and baseline variables.*

<b>Variable</b>	<b>Linear regression coefficient for SpO<sub>2</sub></b>	<b>95% Confidence intervals for regression coefficient</b>
5 minutes post-physiotherapy	-0.041	-0.443, 0.360
15 minutes post-physiotherapy	0.101	-0.302, 0.503
30 minutes post-physiotherapy	0.003	-0.401, 0.408
60 minutes post-physiotherapy	-0.124	-0.530, 0.282
(log)Weight	2.457	0.393, 4.521
Emergency admission	-0.514	-2.505, 1.477
(log)PELOD score	2.969	-0.800, 6.739

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for peripheral oxygen saturation. 95% confidence intervals which do not cross 0 indicate statistical significance. PELOD - Pediatric logistic organ dysfunction, SpO<sub>2</sub> – peripheral oxygen saturations)

Change in median SpO<sub>2</sub> was determined between the 5-minute period immediately pre-physiotherapy and the four epochs post-physiotherapy, displayed previously in Figure 7.8. The results demonstrated low rates of adverse events (SpO<sub>2</sub> decrease > 15%) (Figure 7.13, Table 7.10). A slight increase in adverse events was seen at the 60-minute time point. An increase in the proportion of

improvements in median SpO<sub>2</sub> was observed over the 60-minute post-physiotherapy period.



*Figure 7.13 Change in median SpO<sub>2</sub> post-physiotherapy plotted against pre-physiotherapy median*

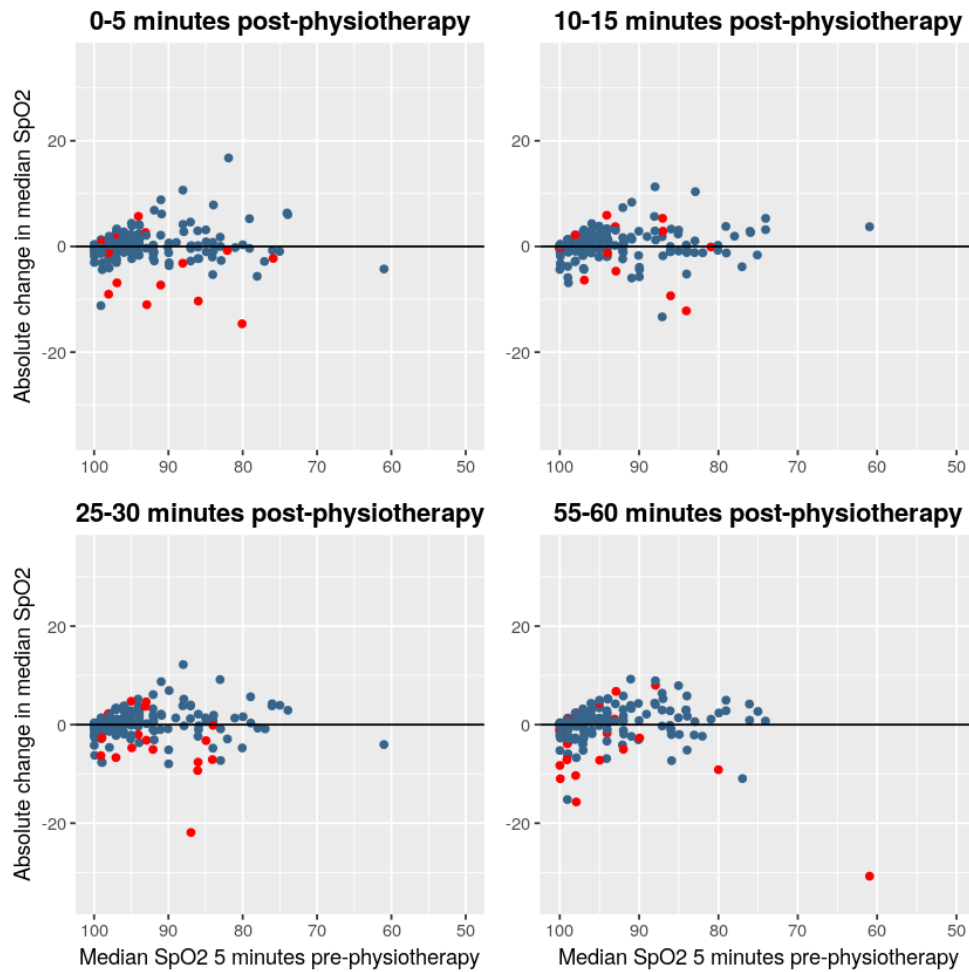
(A jitter function has been applied to enable overlapping points to be more clearly visualised. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with worse SpO<sub>2</sub>, dark green – in-status-quo, green – improved. SpO<sub>2</sub> – peripheral oxygen saturations. n=250)

Table 7.10 Description of change in median SpO<sub>2</sub> post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=250)	1 (0.4)	73 (29.2)	110 (44)	66 (26.4)
15 minutes, n (%) (n=248)	0	68 (27.4)	105 (42.3)	75 (30.2)
30 minutes, n (%) (n=245)	1 (0.4)	73 (29.8)	94 (38.4)	77 (31.4)
60 minutes, n (%) (n=241)	3 (1.2)	66 (27.4)	85 (35.3)	87 (36.1)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo)

Exploring SpO<sub>2</sub> further, Figure 7.14 highlights the patients who were defined as having an OSI adverse event plotted with change in SpO<sub>2</sub>. There were no clear patterns, with OSI adverse events including both increases and decreases in SpO<sub>2</sub>.



*Figure 7.14 Changes in median SpO<sub>2</sub> post-physiotherapy plotted against pre-physiotherapy median SpO<sub>2</sub>. Patients identified as having an OSI adverse event highlighted in red.*

(A jitter function has been applied to enable overlapping points to be more clearly visualised. OSI adverse events included both increases and decreases in SpO<sub>2</sub>. OSI – Oxygen saturation index, SpO<sub>2</sub> – peripheral oxygen saturations. n=247)

SpO<sub>2</sub> values are continuously measured and displayed and usually targeted, compared to FiO<sub>2</sub> and MAP which are set by the user. Additionally, SpO<sub>2</sub> displays greater variability, so signal may be lost when summary values are used. Therefore, a secondary analysis was completed utilising the raw SpO<sub>2</sub> values. Individual adverse event thresholds were calculated for each patient, based on a 15% decrease from the 5-minute pre-physiotherapy median SpO<sub>2</sub>. The frequencies of raw SpO<sub>2</sub> values below the threshold were determined for each patient at the 5-minute epochs post-physiotherapy. These were totalled at each post-physiotherapy epoch to give a cumulative figure for all patients and allow an adverse event rate to be calculated. The results are displayed in Table 7.11.

*Table 7.11 Number of raw SpO<sub>2</sub> values below adverse event threshold for each post-physiotherapy time point*

<b>Post-physiotherapy time point</b>	<b>Raw SpO<sub>2</sub> values below adverse event threshold, n (%)</b>
<b>5 mins</b>	79/14006 (0.6)
<b>15 mins</b>	52/14143 (0.4)
<b>30 mins</b>	51/13933 (0.4)
<b>60 mins</b>	141/13951 (1.0)

(SpO<sub>2</sub> – peripheral oxygen saturations. (n=247))

Low rates of adverse events were evident, with a slight increase at 60 minutes post-physiotherapy. The adverse event rates are comparable to those calculated using median values (Table 7.10), with no significant differences between the two analyses (Fishers exact test p=1).

As highlighted previously high-resolution monitor data from T<sup>3</sup> were more readily available than ventilator data, resulting in a larger sample of SpO<sub>2</sub> data compared to MAP and FiO<sub>2</sub>. This included patients from the initial sample described in Section 7.3.1. Therefore, the SpO<sub>2</sub> analysis was repeated for a subgroup of patients, for whom OSI data had not been available (n=205/295, 69.5%), to act as a sensitivity analysis. The baseline characteristics of this group are described in Table 7.12.

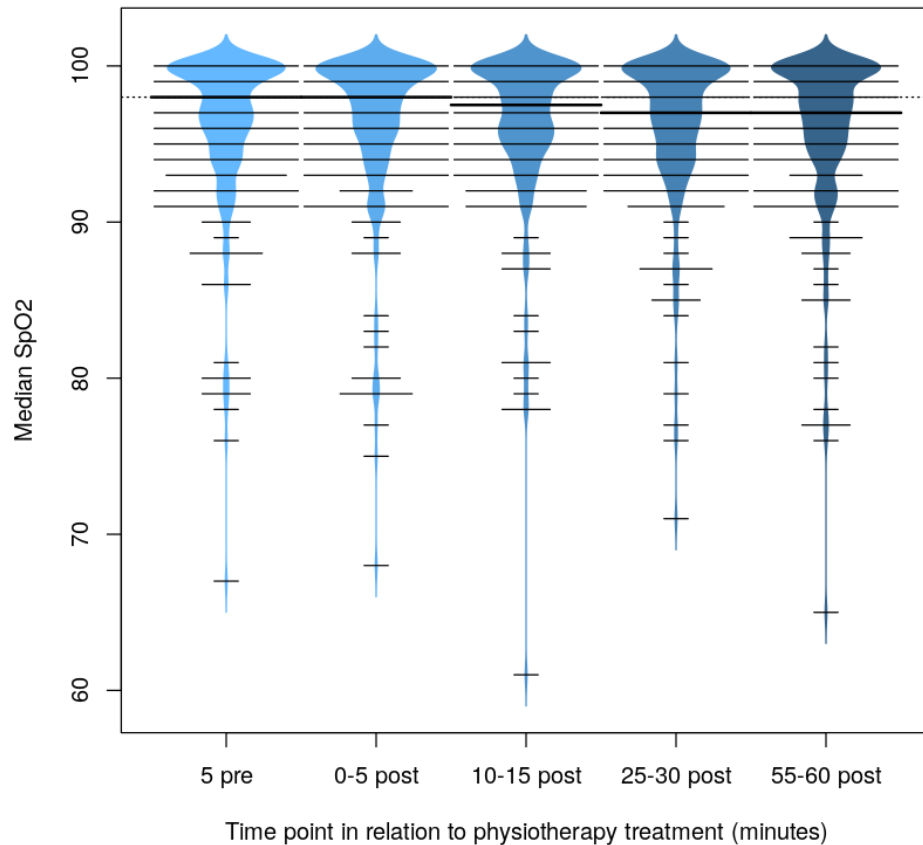


Table 7.12 Baseline characteristics of a subgroup of patients with only SpO<sub>2</sub> data available

<b>Baseline characteristics (n=205)</b>	
<b>Sex, n (%)</b>	Males 129 (62.9)
	Females 76 (37.1)
<b>Age in months, median (IQR)</b>	7 (1-18)
<b>Weight (Kg), median (IQR)</b>	7 (4-11)
<b>Gestation at birth, weeks, n (%), (n=166)</b>	
≥ 37	117 (70.5)
30 to ≤ 36	34 (20.5)
< 30	15 (9.0)
<b>Unit, n (%)</b>	
CICU	53 (25.9)
PICU	143 (69.8)
NICU	9 (4.4)
<b>Type of admission, n (%)</b>	
Elective	66 (32.2)
Emergency	139 (67.8)
<b>PELOD score, median (IQR) (n=188)</b>	6 (5-7)
<b>SARS-CoV-2, n (%)</b>	5 (2.4)
<b>Length of ICU stay (days), median (IQR)</b>	5.9 (3.7-10.8)
<b>Discharge status, alive, n (%) (n=194)</b>	179 (92.3)

(Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation, PELOD and discharge status, number of children is indicated. CICU – Cardiac intensive care unit, ICU – Intensive care unit, NICU – Neonatal intensive care unit, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care unit)

For this group 288856 SpO<sub>2</sub> data values were available. Pre-physiotherapy median SpO<sub>2</sub> was 98% (IQR 94-100, range 45 to 100) and post-physiotherapy median SpO<sub>2</sub> was 97% (IQR 95-100, range 9 to 100). As with the previous analysis median SpO<sub>2</sub> for 5-minute epochs pre- and post-physiotherapy were calculated, displayed in Appendix 30. The beanplots in Figure 7.15 show the distribution of median SpO<sub>2</sub> across the pre- and post-physiotherapy time points.



*Figure 7.15 Beanplots of the distribution of median SpO<sub>2</sub> in relation to pre- and post-physiotherapy time points, for a subgroup with only SpO<sub>2</sub> data available*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set, with the thick line for each beanplot representing the median value for the time point. The short horizontal lines within each beanplot represent individual data points. SpO<sub>2</sub> – peripheral oxygen saturations. n=205)

The distributions are comparable, with the median SpO<sub>2</sub> decreasing at 15- and 30-minutes post-physiotherapy. Pairwise Wilcoxon signed rank test with Bonferroni adjustment, for univariable time point comparison, demonstrated no statistically significant differences (Appendix 31). The multilevel linear regression model was applied, with unit (NICU or PICU) included as an additional fixed effect variable. There were no statistically significant changes in SpO<sub>2</sub> over the post-physiotherapy period (Table 7.13). SpO<sub>2</sub> were lower in emergency admissions compared to elective admissions, which may be linked to the less stable/more unwell nature of patients admitted in an emergency. Additionally, patients on PICU had higher SpO<sub>2</sub> than patients on CICU and NICU. This may be related to the

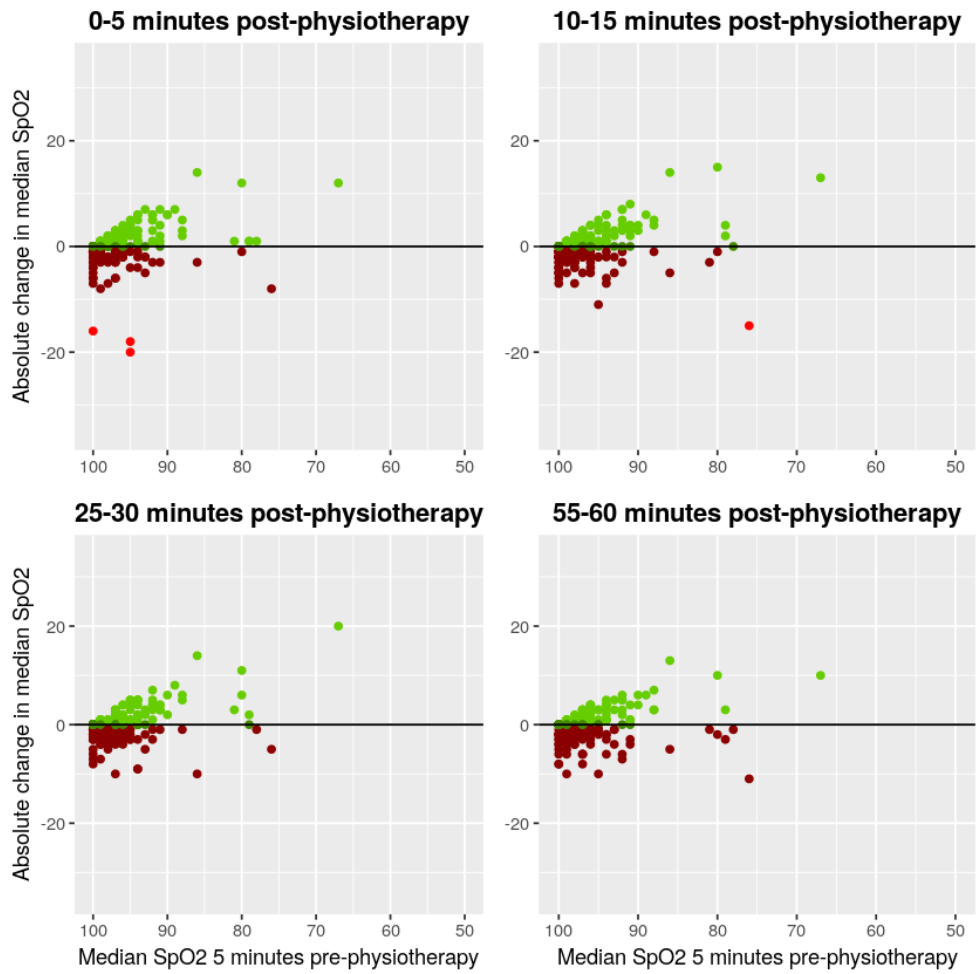
differences in case-mix between units, and the greater number of patients with lower target SpO<sub>2</sub>, mixed circulations, or cyanotic heart defects on CICU and NICU.

*Table 7.13 Coefficients for median SpO<sub>2</sub> from multi-level linear regression models of post-physiotherapy time points and baseline variables, for a subgroup with only SpO<sub>2</sub> data available*

<b>Variable</b>	<b>Linear regression coefficient for SpO<sub>2</sub></b>	<b>95% Confidence intervals for regression coefficient</b>
<b>5 minutes post-physiotherapy</b>	0.053	-0.404, 0.510
<b>15 minutes post-physiotherapy</b>	-0.083	-0.544, 0.377
<b>30 minutes post-physiotherapy</b>	-0.052	-0.514, 0.409
<b>60 minutes post-physiotherapy</b>	-0.289	-0.752, 0.172
<b>(log)Weight</b>	-0.774	-1.977, 0.429
<b>Emergency admission</b>	-1.693	-3.242, -0.145
<b>(log)PELOD score</b>	-1.580	-4.136, 0.974
<b>Unit - NICU</b>	2.257	-1.064, 5.579
<b>Unit - PICU</b>	2.294	0.0692, 3.896

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for peripheral oxygen saturation. 95% confidence intervals which do not cross 0 indicate statistical significance. NICU – Neonatal intensive care, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care, SpO<sub>2</sub> – peripheral oxygen saturations)

Change in median SpO<sub>2</sub> calculated between pre-physiotherapy and post-physiotherapy and incidence of adverse events are shown in Figure 7.14 and Table 7.16. When compared to the initial SpO<sub>2</sub> analysis (Figure 7.12) a similar trend of low rates of SpO<sub>2</sub> adverse events post-physiotherapy was observed. However, in contrast to the improvements in median SpO<sub>2</sub> seen in the initial analysis (Table 7.10), the percentage of patients with improved median SpO<sub>2</sub> decreased over time for this subgroup.



*Figure 7.16 Changes in median SpO<sub>2</sub> for patients without OSI data post-physiotherapy plotted against pre-physiotherapy median*

(A jitter function has been applied to enable overlapping points to be more clearly visualised. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with worse SpO<sub>2</sub>, dark green – in-status-quo, green – improved. SpO<sub>2</sub> – peripheral oxygen saturations. n=205)

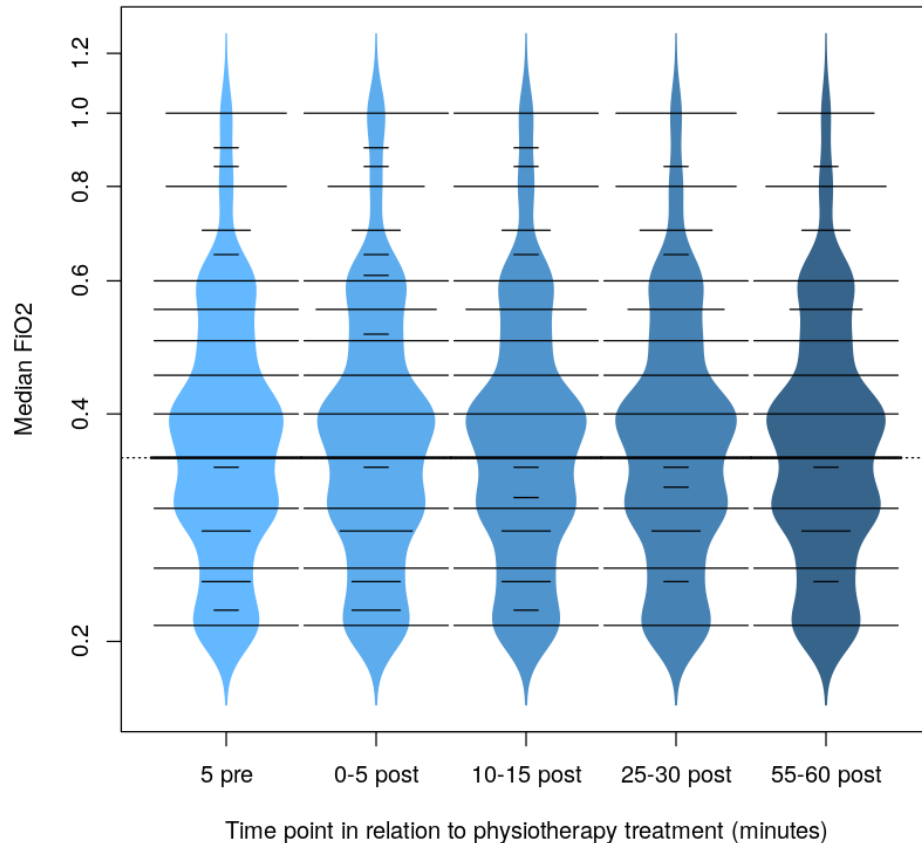
Table 7.14 Description of changes in SpO<sub>2</sub> for patients without OSI data post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=205)	3 (1.5)	58 (28.3)	73 (35.6)	71 (34.6)
15 minutes, n (%) (n=200)	1 (0.5)	73 (36.5)	59 (29.5)	67 (33.5)
30 minutes, n (%) (n=199)	0	71 (35.7)	67 (33.7)	61 (30.7)
60 minutes, n (%) (n=197)	0	74 (37.6)	65 (33.0)	58 (29.4)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo)

#### *Fraction of inspired oxygen (FiO<sub>2</sub>)*

In total 355194 FiO<sub>2</sub> data points were available, which accounted for all 251 patients included in the initial OSI analysis. Overall median FiO<sub>2</sub> pre-physiotherapy and post-physiotherapy were the same at 0.35 (IQR 0.3-0.5, range 0.21 to 1.0). Median FiO<sub>2</sub> was calculated for 5-minute epochs, pre- and post-physiotherapy, for each patient (Appendix 32). The beanplots in Figure 7.17 display similar distributions of median FiO<sub>2</sub> over the 5-minute epochs, with no change in median FiO<sub>2</sub> across the time points.



*Figure 7.17 Beanplots of the distribution of median  $FiO_2$  in relation to pre- and post-physiotherapy time points*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set. The thick black line represents the median value for each time point. The short horizontal lines within each beanplot represent individual data points. Due to an automatic function of the R package, when medians are equal the thick black line representing the median value at each time point is continuous. However, the beanplots should still be interpreted individually. There is no change in median  $FiO_2$  across the time points.  $FiO_2$  – peripheral oxygen saturations. n=251)

Time point comparison was completed using pairwise Wilcoxon signed-rank test with Bonferroni adjustment (Table 7.15). The medians of paired differences and IQRs of the differences were reported as 0. The p values indicate a statistically significant difference between pre-physiotherapy median  $FiO_2$  and median  $FiO_2$  at 60 minutes post-physiotherapy ( $p=0.002$ ), together with a significant difference between immediately post-physiotherapy (5-minutes) and 30 minutes ( $p=0.023$ ) and 60 minutes ( $p=0.0002$ ) post-physiotherapy. The direction of the differences is unknown, however the results indicate a minimal change that is not clinically important.

Table 7.15 Wilcoxon signed-rank test with Bonferroni adjustment comparing median FiO<sub>2</sub> pre- and post-physiotherapy

Time point 1	Time point 2	Median of FiO <sub>2</sub> paired differences (IQR)	Wilcoxon signed rank test (p.adjust)
Pre-physiotherapy	5 minutes post	0 (0-0)	p=1.0
Pre-physiotherapy	15 minutes post	0 (0-0)	p=1.0
Pre-physiotherapy	30 minutes post	0 (0-0)	p=0.078
Pre-physiotherapy	60 minutes post	0 (0-0)	p=0.002*
5 minutes post	15 minutes post	0 (0-0)	p=0.463
5 minutes post	30 minutes post	0 (0-0)	p=0.023*
5 minutes post	60 minutes post	0 (0-0)	p=0.0002**
15 minutes post	30 minutes post	0 (0-0)	p=1.0
15 minutes post	60 minutes post	0 (0-0)	p=0.05
30 minutes post	60 minutes post	0 (0-0)	p=0.173

(\*p<0.05, \*\*p<0.001. p.adjust – adjusted p-value for multiple comparisons)

To explore this further and account for confounders and patient level differences multilevel regression was completed. FiO<sub>2</sub> data were not normally distributed and demonstrated improvement in skewness value with a log transformation. Therefore, the generalised multilevel linear regression model, with gamma link-log was used (described previously for OSI). The regression coefficients and 95% confidence intervals are displayed in Table 7.16. A statistically significant decrease in median FiO<sub>2</sub> is demonstrated between pre-physiotherapy and 30 and 60 minutes post-physiotherapy.

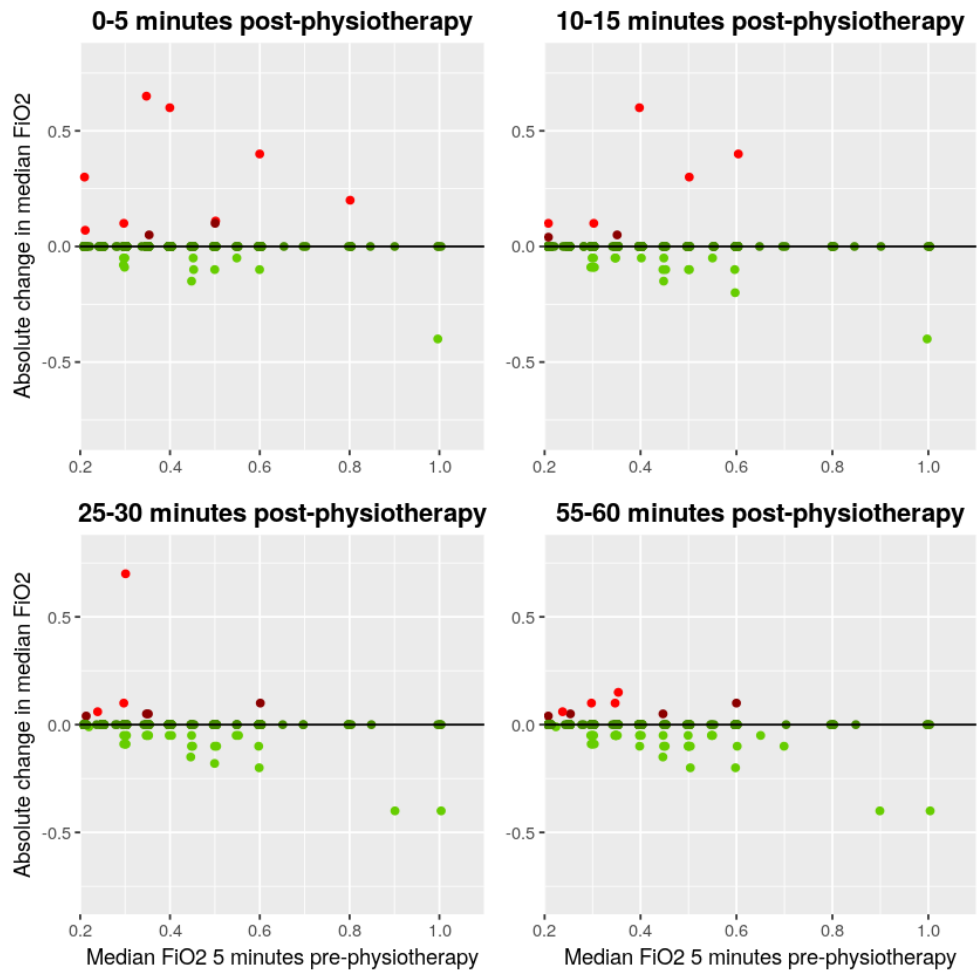
Table 7.16 Coefficients for median  $FiO_2$  from multi-level generalised linear regression models of post-physiotherapy time points and baseline variables

Variable	Linear regression coefficient for $FiO_2$	95% Confidence intervals for regression coefficient
<b>5 minutes post-physiotherapy</b>	7.701e-03	-7.489e-03- 2.2893e-02
<b>15 minutes post-physiotherapy</b>	-9.022e-03	-2.248e-02- 6.231e-03
<b>30 minutes post-physiotherapy</b>	-1.565e-02	-3.093e-02- -3.708e-04
<b>60 minutes post-physiotherapy</b>	-2.618e-02	-4.155e-02- -1.081e-02
<b>Weight</b>	3.624e-05	2.075e-05- 5.173e-05
<b>Emergency admission</b>	9.571e-02	-3.230e-02- 2.237e-01
<b>PELOD score</b>	7.248e-03	-3.529e-02- 4.978e-02

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for fraction of inspired oxygen. 95% confidence intervals which do not cross 0 indicate statistical significance. PELOD - Pediatric logistic organ dysfunction,  $FiO_2$  – Fraction of inspired oxygen.)

Change in median  $FiO_2$  was calculated for the 4 time points post-physiotherapy and the proportion of patients with an adverse event determined ( $FiO_2$  increase >20%). The results are displayed in Figure 7.18 with the individual proportions reported in Table 7.17.





*Figure 7.18 Changes in median  $FiO_2$  post-physiotherapy plotted against pre-physiotherapy median*

(A jitter function has been applied to enable overlapping points to be more clearly visualised. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with worse  $FiO_2$ , dark green – in-status-quo, green – improved.  $FiO_2$  – Fraction of inspired oxygen. n=251)

Table 7.17 Description of changes in median FiO<sub>2</sub> post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=251)	8 (3.2)	2 (0.8)	230 (91.6)	11 (4.4)
15 minutes, n (%) (n=248)	5 (2.0)	2 (0.8)	223 (89.9)	18 (7.3)
30 minutes, n (%) (n=247)	3 (1.2)	4 (1.6)	215 (87.0)	25 (10.1)
60 minutes, n (%) (n=242)	4 (1.7)	4 (1.7)	197 (81.4)	37 (15.3)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo)

The FiO<sub>2</sub> adverse event rate immediately post-physiotherapy was 3.2% (8/251). This decreased at 15 and 30 minutes but increased slightly at the 60-minute time point, although not to the same level as immediately post-physiotherapy. The number of patients demonstrating an improvement in FiO<sub>2</sub> increased over the 60 minutes post-physiotherapy, from 4.4% (11/251) to 15.3% (37/242).

When OSI adverse events (n=247) were plotted with change in FiO<sub>2</sub>, most adverse events were associated with an increase in FiO<sub>2</sub> (Figure 7.19).

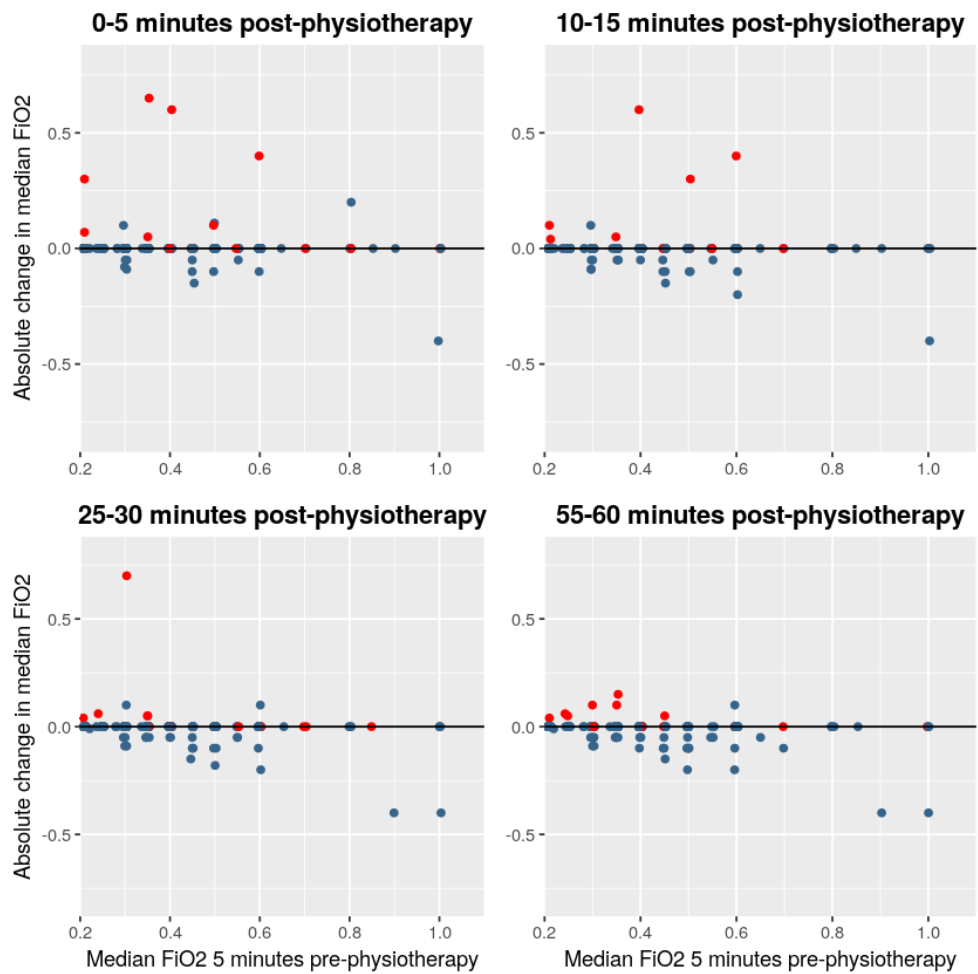


Figure 7.19 Change in median  $FiO_2$  post-physiotherapy plotted against pre-physiotherapy median  $FiO_2$ . Patients identified as having an OSI adverse event highlighted in red.

(A jitter function has been applied to enable overlapping points to be more clearly visualised. Most OSI adverse events included an increase in  $FiO_2$ . OSI – Oxygen saturation index,  $FiO_2$  – Fraction of inspired oxygen. n=247)

A consideration when interpreting these results is the impact of pre-oxygenation. This is a frequently used strategy to manage instability as described in Section 3.3.6.3. To account for this a sensitivity analysis was completed using a 5-minute epoch at 30 minutes pre-physiotherapy rather than the 5-minute epoch immediately prior to the treatment window, as shown in Figure 7.20.

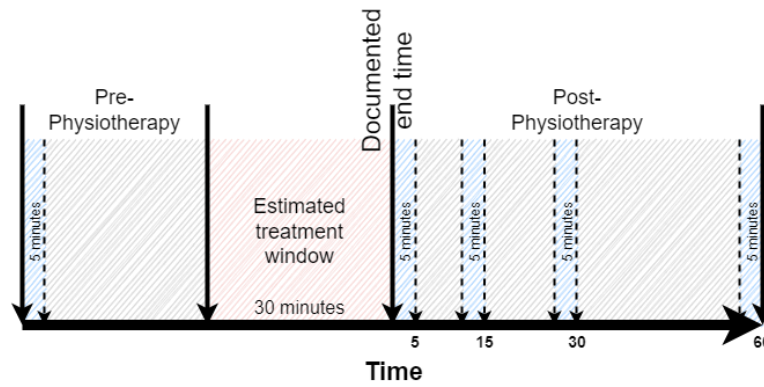
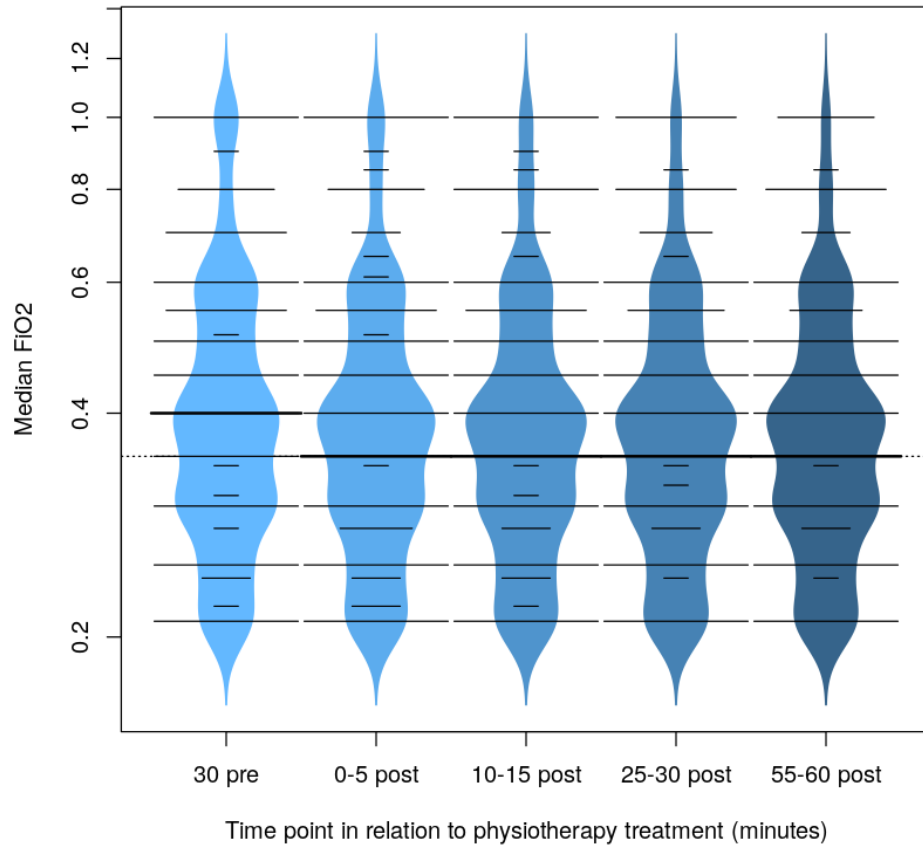


Figure 7.20 Five-minute epochs used for secondary  $FiO_2$  analysis

$FiO_2$  data were available for the 247 patients with OSI data. From Figure 7.21 the distribution of median  $FiO_2$  at each time point is comparable to the distributions demonstrated in the initial  $FiO_2$  analysis (Figure 7.17). Median  $FiO_2$  decreased immediately post-physiotherapy.



*Figure 7.21 Beanplots of the distribution of median  $FiO_2$  in relation to pre- and post-physiotherapy time points (sensitivity analysis)*

(Time periods on the y axis refer to, 30 pre – 30 minutes pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set. The thick black line represents the median value for each time point. The short horizontal lines within each beanplot represent individual data points. Due to an automatic function of the R package, when medians are equal the thick black line representing the median value at each time point is continuous. However, the beanplots should still be interpreted individually. Median  $FiO_2$  decreases at 5 minutes post-physiotherapy.  $FiO_2$  – peripheral oxygen saturations. n=247)

The results of pairwise comparisons using Wilcoxon signed-rank test are displayed in Table 7.18. Whilst the p values indicate a statistically significant difference in median  $FiO_2$  between pre-physiotherapy and 15, 30 and 60 minutes post-physiotherapy, and between 5 minutes and 30 and 60 minutes post-physiotherapy, the median of paired differences and IQRs are 0. Indicating these results are not of clinical significance. The significant p values may relate to differences outside of the middle 50% of the sample, accounting for IQRs of 0. When the multi-level generalised linear regression model was applied, all time periods post-

physiotherapy were independently associated with a decrease in median FiO<sub>2</sub> (Table 7.19), as demonstrated by the 95% confidence intervals not crossing 0.

*Table 7.18 Wilcoxon signed-rank test with Bonferroni adjustment comparing median FiO<sub>2</sub> pre- and post-physiotherapy (sensitivity analysis)*

<b>Time point 1</b>	<b>Time point 2</b>	<b>Median of FiO<sub>2</sub> paired differences (IQR)</b>	<b>Wilcoxon signed rank test (p.adjust)</b>
Pre-physiotherapy	5 minutes post	0 (0-0)	p=0.304
Pre-physiotherapy	15 minutes post	0 (0-0)	p=0.004*
Pre-physiotherapy	30 minutes post	0 (0-0)	p=0.00017**
Pre-physiotherapy	60 minutes post	0 (0-0)	p=0.000003**
5 minutes post	15 minutes post	0 (0-0)	p=0.463
5 minutes post	30 minutes post	0 (0-0)	p=0.02*
5 minutes post	60 minutes post	0 (0-0)	p=0.0002**
15 minutes post	30 minutes post	0 (0-0)	p=1.0
15 minutes post	60 minutes post	0 (0-0)	p=0.05
30 minutes post	60 minutes post	0 (0-0)	p=0.173

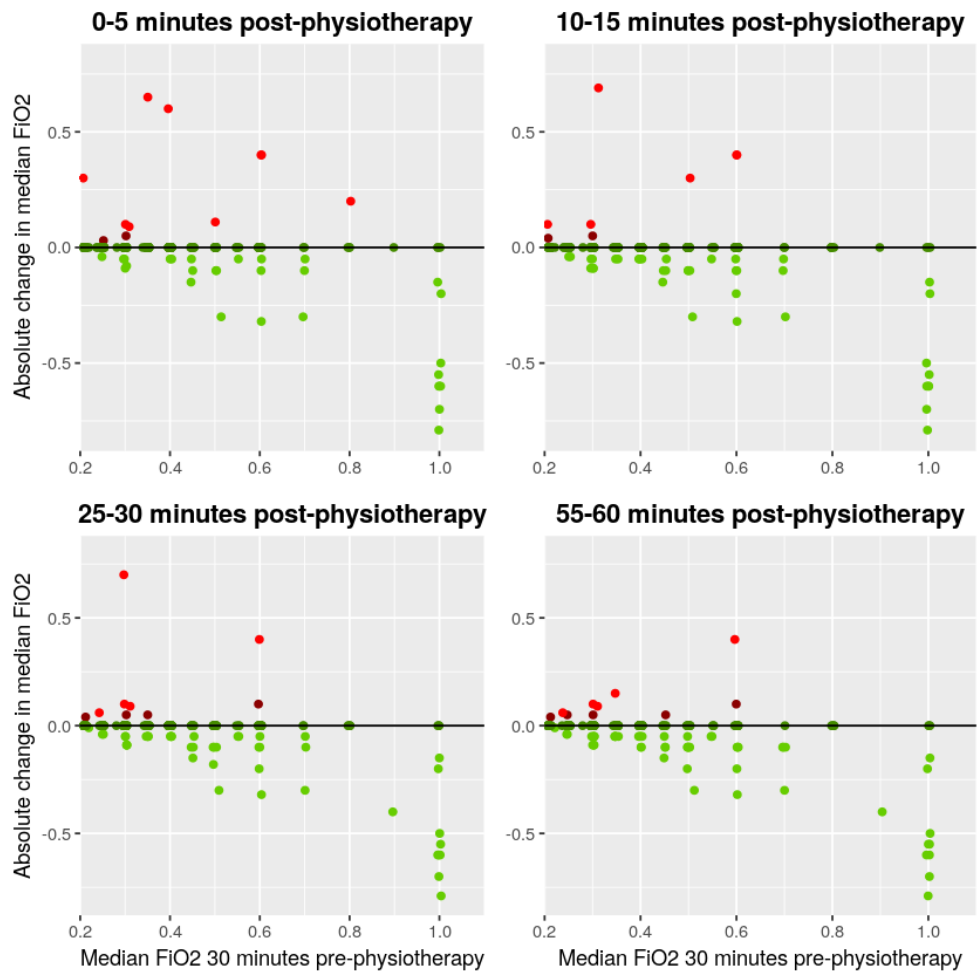
(\*p<0.05, \*\*p<0.001. p.adjust – adjusted p-value for multiple comparisons)

Table 7.19 Coefficients for median  $FiO_2$  from multi-level generalised linear regression models for post-physiotherapy time points and baseline variables (sensitivity analysis)

Variable	Linear regression coefficient for $FiO_2$	95% Confidence intervals for regression coefficient
<b>5 minutes post-physiotherapy</b>	-0.038	-0.059- -0.016
<b>15 minutes post-physiotherapy</b>	-0.055	-0.076- -0.033
<b>30 minutes post-physiotherapy</b>	-0.062	-0.084- -0.040
<b>60 minutes post-physiotherapy</b>	-0.073	-0.095- -0.051
<b>Weight</b>	3.471e-05	1.900e-05- 5.041e-05
<b>Emergency admission</b>	0.098	-0.029- 0.225
<b>PELOD score</b>	0.008	-0.033- 0.050

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for fraction of inspired oxygen. 95% confidence intervals which do not cross 0 indicate statistical significance. PELOD - Pediatric logistic organ dysfunction,  $FiO_2$  – Fraction of inspired oxygen.)

Changes in median  $FiO_2$  between the new pre-physiotherapy and 4 post-physiotherapy time points were calculated. The frequency of adverse events was determined at each time point. The results displayed in Figure 7.22 and Table 7.20 demonstrate a higher  $FiO_2$  adverse event rate immediately post-physiotherapy (9/247, 3.6%), which then decreased over the post-physiotherapy period. The proportion of improved  $FiO_2$  values increased over the 60-minute post-physiotherapy period, 11.7% at 5 minutes post-physiotherapy compared to 22.7% at 60 minutes. These findings are comparable to the initial  $FiO_2$  analysis.



*Figure 7.22 Changes in median  $FiO_2$ , sensitivity analysis, post-physiotherapy plotted against pre-physiotherapy median  $FiO_2$  (sensitivity analysis)*  
 (A jitter function has been applied to enable overlapping points to be more clearly visualised. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with worse  $FiO_2$ , dark green – in-status-quo, green – improved.  $FiO_2$  – Fraction of inspired oxygen. n=247)



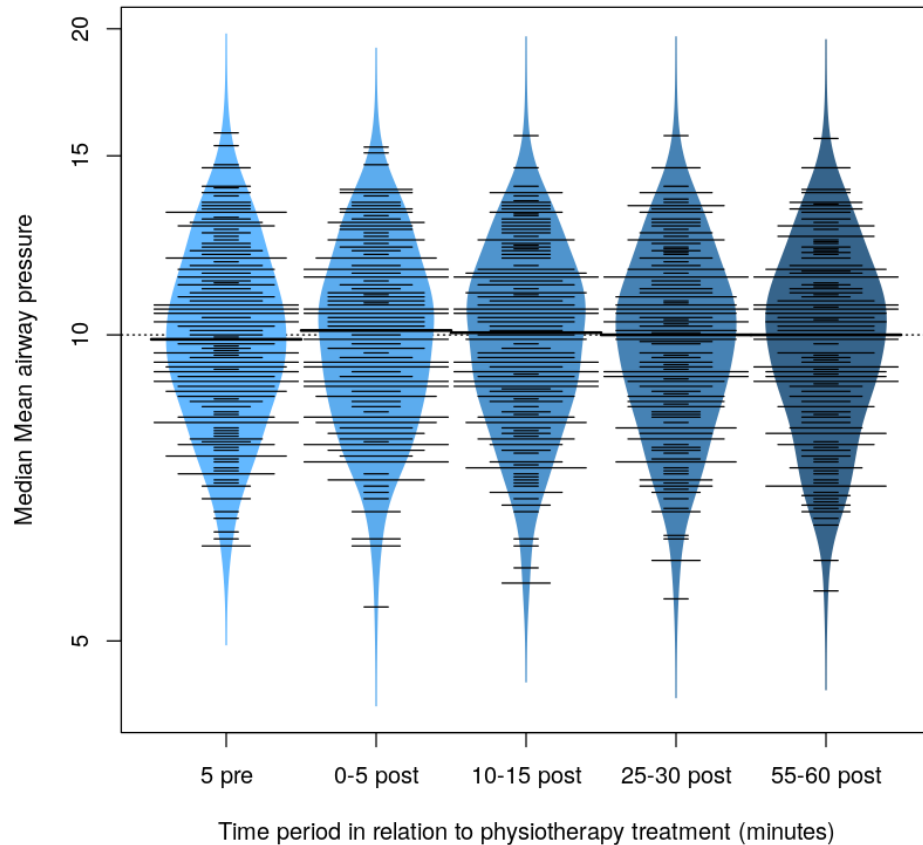
Table 7.20 Description of changes in median FiO<sub>2</sub> post-physiotherapy (sensitivity analysis)

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=247)	9 (3.6)	2 (0.8)	207 (83.8)	29 (11.7)
15 minutes, n (%) (n=244)	6 (2.5)	2 (0.8)	198 (81.2)	38 (15.6)
30 minutes, n (%) (n=243)	5 (2.1)	4 (1.7)	189 (77.8)	45 (18.5)
60 minutes, n (%) (n=238)	5 (2.1)	5 (2.1)	174 (73.1)	54 (22.7)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo)

#### Mean airway pressure (MAP)

Mean airway pressure was the final component of OSI to be examined. In total 351577 MAP data points were available, which included 247 patients. Overall pre-physiotherapy median MAP was 10.1cmH<sub>2</sub>O (IQR 8.7-11.6, range 5 to 20.1). Post-physiotherapy median MAP was 10.2cmH<sub>2</sub>O (IQR 8.7-11.4, range 5 to 22.2). Median MAP was calculated for the 5-minute epochs pre- and post-physiotherapy (Appendix 33). Figure 7.23 displays the distribution of median MAP at the different time points in relation to physiotherapy treatments. The distributions are comparable between the beanplots, with median MAP fluctuating slightly over the post-physiotherapy period.



*Figure 7.23 Beanplots of the distribution of median mean airway pressure in relation to pre- and post-physiotherapy time points*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set, with the thick line for each beanplot representing the median value for the time point. The short horizontal lines within each beanplot represent individual data points. There are small fluctuations in MAP across the time points. MAP – Mean airway pressure. n=247)

Pairwise Wilcoxon signed-rank test demonstrated a significant decrease in median MAP at 30 minutes post-physiotherapy ( $p=0.022$ ) (Table 7.21). MAP data were normally distributed therefore the multi-level linear regression model was applied. There were significant differences in median MAP between pre-physiotherapy and 15, 30 and 60 minutes post-physiotherapy, when adjusted for weight, admission type and PELOD score (Table 7.22). This indicated a decrease in median MAP over these time points.

Table 7.21 Wilcoxon signed-rank test with Bonferroni adjustment comparing median mean airway pressure pre- and post-physiotherapy

Time point 1	Time point 2	Median of MAP paired differences (IQR)	Wilcoxon signed rank test (p.adjust)
Pre-physiotherapy	5 minutes post	0 (-0.1-0.1)	p=1.0
Pre-physiotherapy	15 minutes post	0 (-0.15-0.1)	p=0.679
Pre-physiotherapy	30 minutes post	0 (-0.2-0.1)	p=0.022*
Pre-physiotherapy	60 minutes post	0 (-0.3-0.1)	p=0.06
5 minutes post	15 minutes post	0 (-0.05-0.0)	p=1.0
5 minutes post	30 minutes post	0 (-0.1-0.0)	p=0.112
5 minutes post	60 minutes post	0 (-0.15-0.1)	p=0.928
15 minutes post	30 minutes post	0 (-0.1-0.0)	p=0.162
15 minutes post	60 minutes post	0 (-0.1-0.1)	p=1.0
30 minutes post	60 minutes post	0 (-0.05-0.1)	p=1.0

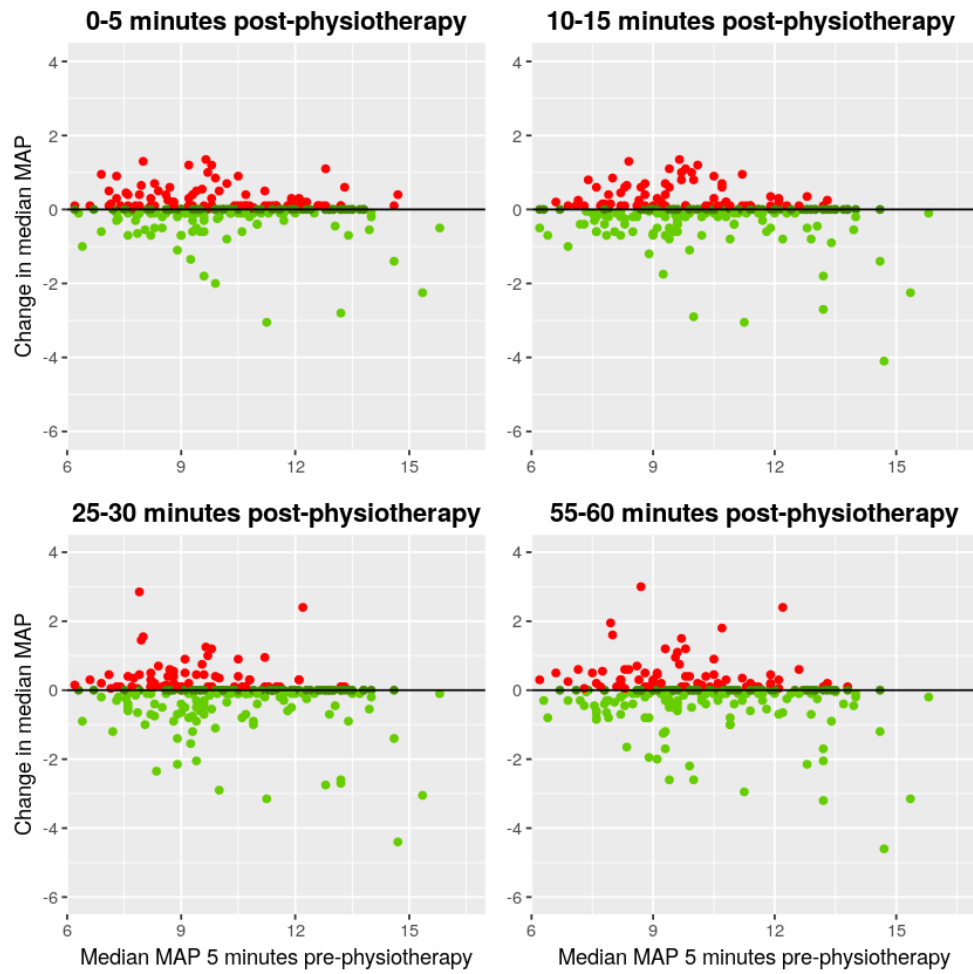
(\*p<0.05. MAP – mean airway pressure, p.adjust – adjusted p-value for multiple comparisons)

Table 7.22 Coefficients for median mean airway pressure from multi-level linear regression models of post-physiotherapy time points and baseline variables

Variable	Linear regression coefficient for MAP	95% Confidence intervals for regression coefficient
<b>5 minutes post-physiotherapy</b>	-0.041	-0.120, 0.038
<b>15 minutes post-physiotherapy</b>	-0.100	-0.179, -0.020
<b>30 minutes post-physiotherapy</b>	-0.156	-0.236, -0.076
<b>60 minutes post-physiotherapy</b>	-0.146	-0.226, -0.065
<b>(log)Weight</b>	-0.052	-0.632, 0.529
<b>Emergency admission</b>	0.550	-0.010, 1.111
<b>(log)PELOD score</b>	0.290	-0.770, 1.349

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for mean airway pressure. 95% confidence intervals which do not cross 0 indicate statistical significance. PELOD - Pediatric logistic organ dysfunction, MAP – Mean airway pressure.)

Given there was no pre-determined adverse event threshold for MAP, analysis involved comparing median MAP between the previously described 5-minute epochs and determining change in terms of an increase, in-status-quo or decrease. The results are displayed in Figure 7.24 and Table 7.23



*Figure 7.24 Changes in median mean airway pressure post-physiotherapy plotted against pre-physiotherapy median MAP*  
 (Red points indicate an increase in MAP, dark green – in-status-quo, green – decrease. MAP – Mean airway pressure. n=247)

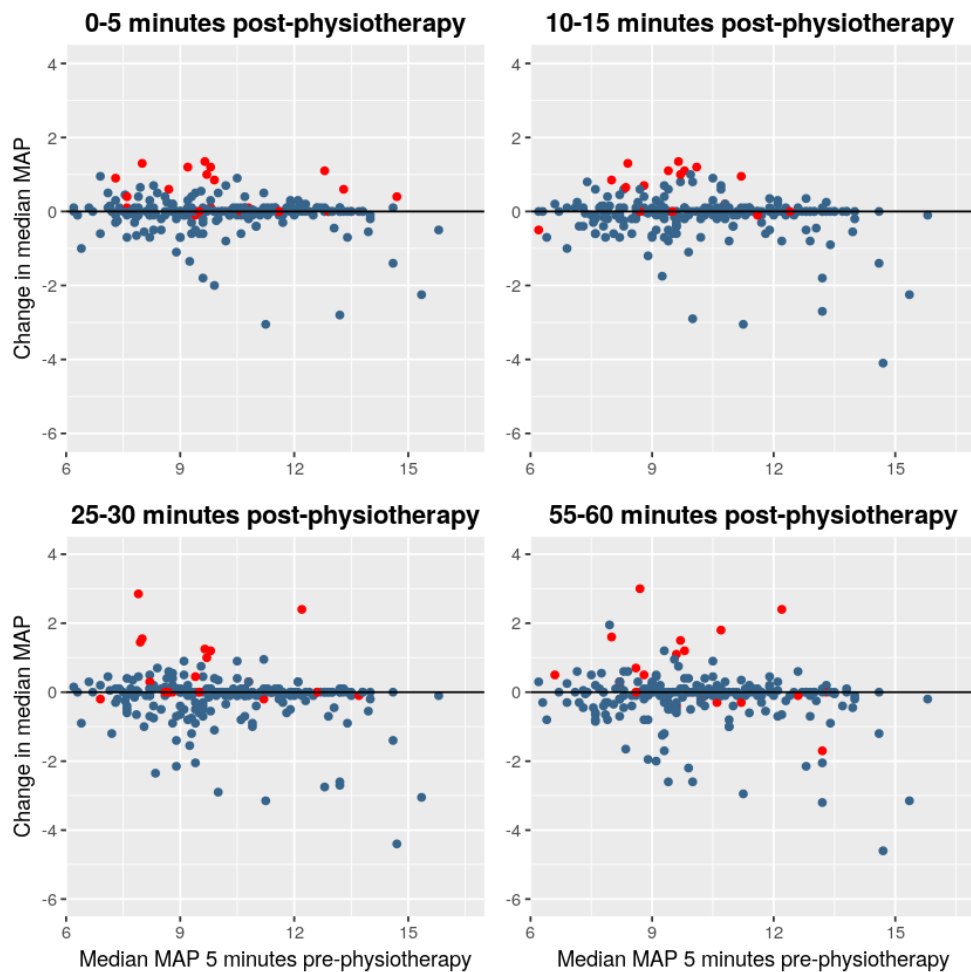
Table 7.23 Description of changes in median mean airway pressure post-physiotherapy

Post-physiotherapy time point	Increase	ISQ	Decrease
5 minutes, n (%) (n=247)	81 (32.8)	93 (37.7)	73 (29.6)
15 minutes, n (%) (n=242)	68 (28.1)	86 (35.5)	88 (36.3)
30 minutes, n (%) (n=238)	63 (26.5)	77 (32.3)	98 (41.2)
60 minutes, n (%) (n=232)	70 (30.1)	60 (25.9)	201 (44)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo)

The proportion of patients with an increase in median MAP was higher immediately post-physiotherapy (81/247, 32.8%), this reduced over 30 minutes (63/238, 26.5%) but demonstrated an increase at 60 minutes. Decreases in median MAP increased over the 60-minute post-physiotherapy period. The largest reductions were seen in patients with higher pre-physiotherapy median MAP.

Exploring mean airway pressure further, Figure 7.25 highlights the patients who were defined as having an OSI adverse event plotted with change in MAP. Most adverse events were associated with an increase in MAP.



*Figure 7.25 Change in median mean airway pressure post-physiotherapy plotted against pre-physiotherapy MAP. Patients identified as having an OSI adverse event highlighted in red.*

(Most OSI adverse events involved an increase in MAP. OSI – Oxygen saturation index, MAP – Mean airway pressure. n=247)

The final stage of the OSI analysis for the first physiotherapy treatment was to understand the factors associated with having an adverse event post-physiotherapy. In total 82 separate OSI adverse events were identified within the 4 epochs post-physiotherapy (Table 7.8). This accounted for 53/247 individual patients (21.5%). Patients were divided into two groups, those who had an adverse event in the 60 minutes following the first physiotherapy treatment (n=53) and those without (n=194). Univariate analysis was performed to compare characteristics of the two groups. There were no detectable differences between the groups in terms of baseline characteristics, diagnoses or physiotherapy treatments (Tables 7.24-7.26). The adverse event group had a higher proportion

of males and were slightly younger and smaller (not statistically significant). A slightly higher proportion of patients with an adverse event were admitted as an emergency and PELOD scores in the adverse event group were slightly lower (not statistically significant). Refer to Appendix 34 and 35 for the R script for this analysis.

*Table 7.24 A comparison of baseline characteristics of patients with an adverse event and those without*

<b>Baseline characteristics</b>	<b>Adverse event group (n=53)</b>	<b>No adverse event group (n=194)</b>	<b>Mann Whitney/Chi-squared/Fishers</b>
<b>Sex, n (%)</b>	Males 33 (62.2)	Males 107 (55.2)	p=0.44
<b>Age in months, median (IQR)</b>	2 (0-7)	3 (0-5.8)	p=0.71
<b>Weight (Kg), median (IQR)</b>	4.2 (3.5-6.9)	4.7 (3.3-6.4)	p=0.69
<b>Gestation at birth, weeks, n (%)</b> ≥ 37 30 to ≤ 36 < 30	38 (82.6) 7 (15.2) 1 (2.2) (n=46)	133 (76.4) 34 (17.5) 7 (4.0) (n=174)	p=0.75
<b>Type of admission, n (%)</b> Elective Emergency	22 (41.5) 31 (58.5)	106 (54.6) 88 (45.4)	p=0.12
<b>PELOD score, median (IQR)</b>	6 (6-8) (n=50)	8 (6-8) (n=188)	p=0.18
<b>SARS-CoV-2, n (%)</b>	0	0	
<b>Use of inhaled nitric oxide, n (%)</b>	5 (9.4)	11 (5.6)	p=0.35
<b>Time of day, n (%)</b>	Day time 52 (98.1)	Day time 191 (98.5)	p=1.0

(Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. For characteristics with missing data the sample number is included as n= within the cell, PELOD - Pediatric logistic organ dysfunction.)



Table 7.25 A comparison of diagnosis of patients with an adverse event and those without

Diagnosis	Adverse event group (n=53)	No adverse event group (n=194)
<b>Congenital cardiac disease, n (%)</b>	41 (77.4)	158 (81.4)
<b>Cardiac other, n (%)</b>	3 (5.7)	9 (4.6)
<b>Heart failure, n (%)</b>	1 (1.9)	9 (4.6)
<b>Airway, n (%)</b>	3 (5.7)	6 (3.1)
<b>Meconium aspiration syndrome, n (%)</b>	0	2 (1.0)
<b>Respiratory other, n (%)</b>	2 (3.8)	1 (0.5)
<b>Respiratory failure, n (%)</b>	0	3 (1.5)
<b>Other, n (%)</b>	3 (5.7)	6 (3.1)

(Fishers exact test, p=0.41)

Table 7.26 A comparison of chest physiotherapy treatments used with those patients with an adverse event and those without

Treatment	Adverse event group (n=53)	No adverse event group (n=194)
<b>Saline, MHI with CWV, n (%)</b>	30 (56.6)	134 (69.1)
<b>MHI with CWV, n (%)</b>	9 (17)	30 (31.9)
<b>Saline and MHI, n (%)</b>	10 (18.9)	19 (9.8)
<b>MHI only, n (%)</b>	2 (3.8)	4 (2.1)
<b>Suction only, n (%)</b>	0	3 (1.5)
<b>MHI with CWV, and decompression, n (%)</b>	0	2 (1.0)
<b>Saline, MHI with CWV, and decompression, n (%)</b>	1 (1.9)	1 (0.5)
<b>Saline only, n (%)</b>	1 (1.9)	1 (0.5)

(Fishers exact test, p=0.25. CWV – chest wall vibrations, MHI – manual hyperinflations)

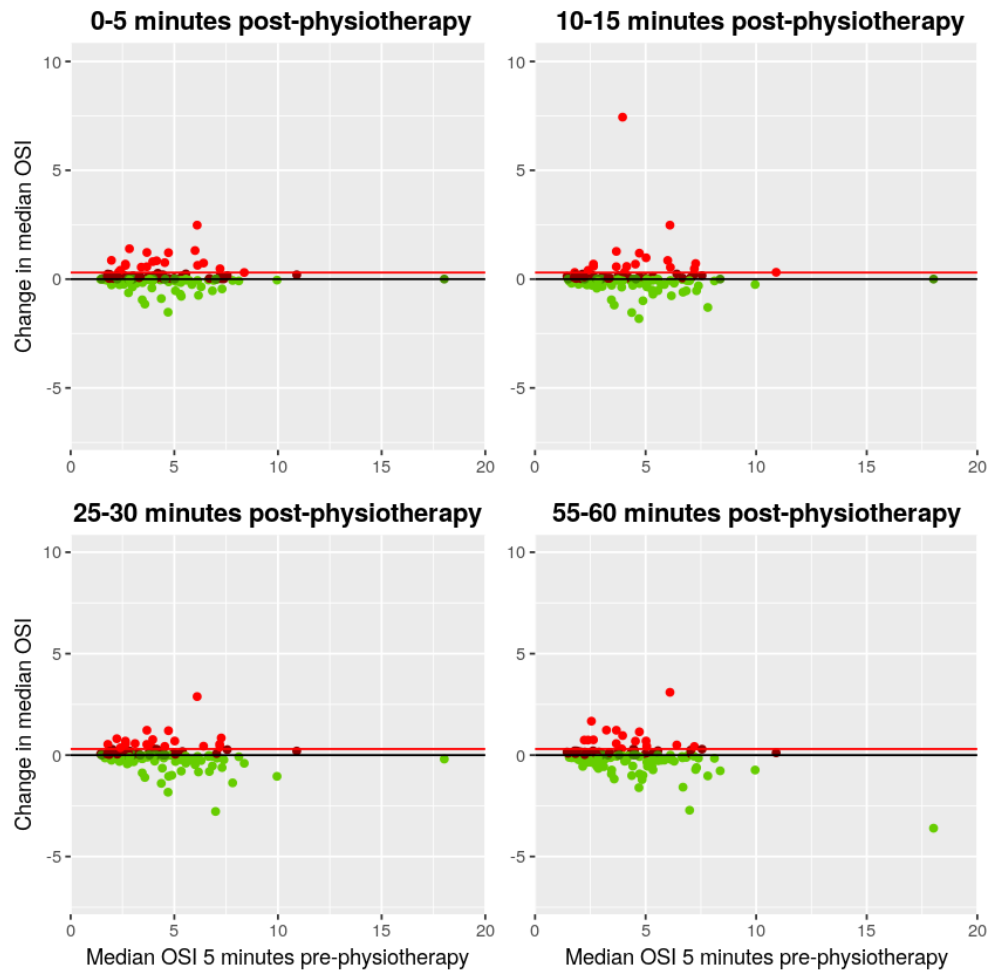
The impact of repeated admissions on prevalence of adverse events associated with the first physiotherapy treatment was also explored. As discussed previously

21 patients had repeated admissions, which accounted for 46 of the total 247 admissions. The number of first admissions was calculated as 222, with 25 repeat admissions. Adverse event rates were comparable, 48/222 (21.6%) for first admissions compared to 5/25 (20.0%) if it was a repeated admission.

### *7.3.3.2 Multiple physiotherapy treatments*

The changes in OSI pre- and post-physiotherapy for the first physiotherapy treatment have been explored in detail. The next phase of analysis involved exploring the changes in OSI in subsequent physiotherapy treatments. Data were collected for the first four days of physiotherapy. OSI values were calculated for the subsequent treatment sessions. Of the 247 patients included in the first treatment analysis, 225 had some OSI data for multiple days of physiotherapy. This accounted for 421 physiotherapy treatments.

Median OSI was calculated for the 5-minute epochs described in Figure 7.8 for the first session of physiotherapy on days 2-4. Changes in median OSI between the pre-physiotherapy and 4 post-physiotherapy time points were determined and the frequency of adverse events calculated for each time point post-physiotherapy. The results related to day 2 are displayed in Figure 7.26 and Table 7.27, with Appendix 36 displaying the results of day 3 and 4.



*Figure 7.26 Day 2 treatment 1 - Changes in median OSI post-physiotherapy plotted against pre-physiotherapy median OSI*  
 (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - ISQ, green - improved. OSI – oxygen saturation index. n=150)

Table 7.27 Day 2 treatment 1 - Description of changes in median OSI post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=150)	19 (12.7)	48 (32)	15 (10)	68 (45.3)
15 minutes, n (%) (n=148)	18 (12.2)	44 (29.7)	15 (10.1)	73 (49.3)
30 minutes, n (%) (n=146)	18 (12.3)	38 (26)	11 (7.5)	79 (54.1)
60 minutes, n (%) (n=144)	16 (11.1)	38 (26.4)	11 (7.6)	79 (54.9)

(Number of patients included at each time point are indicated in brackets. ISQ – in-status-quo)

The adverse event rates over days 2 to 4 were variable, with the lowest rates on day 3 of physiotherapy. On days 2 and 3 the adverse event rate was higher immediately post-physiotherapy, before improving. An increase in the proportion of improved OSI values over the 60-minute period was evident on all days. Day 2 treatment 1 demonstrated the largest improvement 68/150 (45.3) to 79/144 (54.9).

Data were available for the second physiotherapy treatments on day 1 to 4. The change in OSI analysis was repeated and is displayed in Appendix 37. However, the sample sizes are small and it is difficult to provide any useful interpretations. Data for third treatments on days 2 and 3 were only available for 2 patients and 1 patient respectively, and hence not included in the analysis.

The next stage of the multiple treatment analysis was to compare patients with OSI adverse events and those without. A treatment was classified as having an adverse event if median OSI crossed the threshold at one or more post-physiotherapy time points. Three subgroups were created, patients with no adverse events (129/225, 57.3%), patients who had one treatment with an adverse event (78/225, 34.7%), and those with 2 or more treatments with an adverse event (18/225, 8.0%). Univariable analysis was completed to compare the baseline characteristics of the groups (Table 7.28). Type of admission demonstrated a statistically significant difference between the groups with 94.4% of patients  $\geq 2$

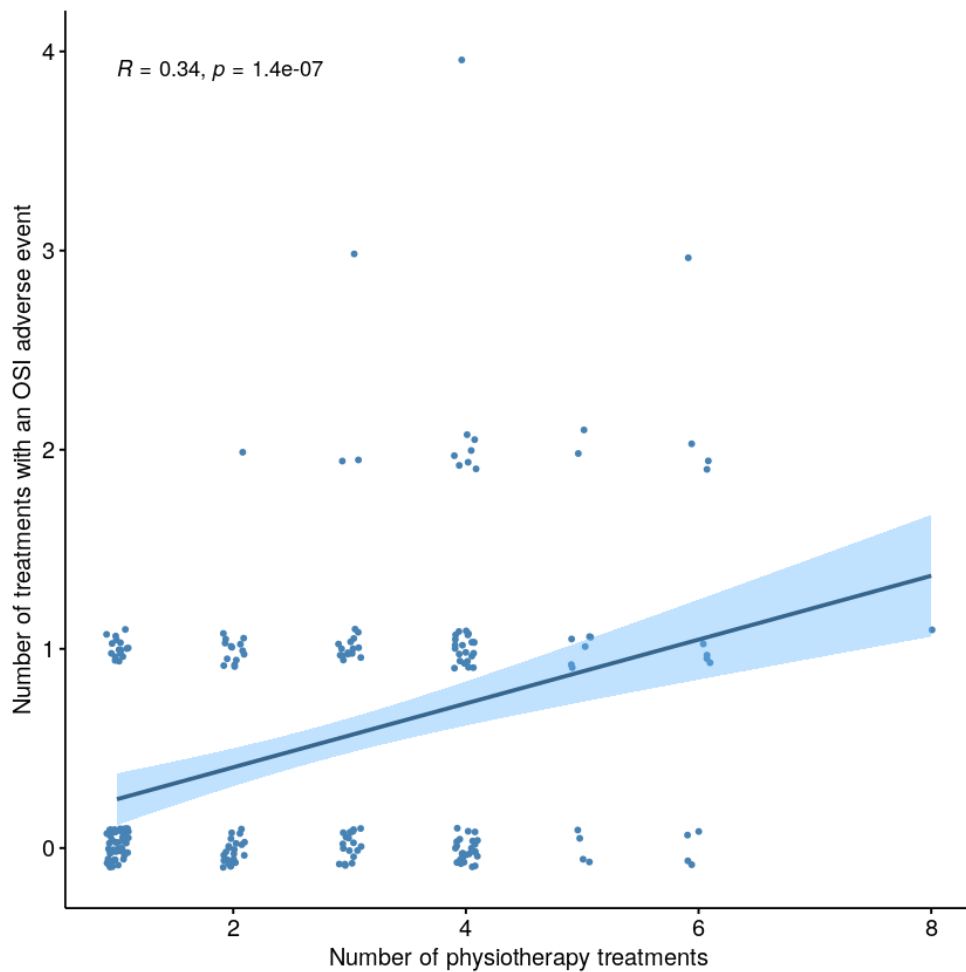
adverse events being emergency admissions, compared to 51.1% and 42.1% for patients with 1 and no adverse events respectively.

*Table 7.28 A comparison of baseline characteristics between patients with no, 1, or more than 2 treatments with adverse events in first 4 days of physiotherapy*

Baseline characteristics	≥ 2 adverse events (n=18)	1 adverse event (n=78)	No adverse events (n=129)	Chi-square d/ Kruskal wallis
Male gender, n (%)	11 (61.1)	48 (61.5)	67 (51.9)	p=0.36
Age in months, median (IQR)	2 (0.25-3)	3 (0-8)	3 (1-6)	p=0.61
Weight (Kg), median (IQR)	4.2 (3.6-6.1)	4.3 (3.4-7.0)	4.7 (3.2-6.4)	p=0.74
Gestation at birth, weeks, n (%)				p=0.58
≥ 37	16 (88.9)	51 (76.1)	86 (76.1)	
30 to ≤ 36	1 (5.6)	13 (19.4)	23 (20.4)	
< 30	1 (5.6)	3 (4.5) (n=67)	4 (3.5) (n=113)	
Type of admission, n (%)				p<0.001 **
Elective	1 (5.6)	40 (51.3)	79 (61.2)	
Emergency	17 (94.4)	38 (48.7)	50 (38.8)	
PELOD score, median (IQR) (n=217)	7 (6-8) (n=17)	7 (6-8) (n=74)	8 (6-8) (n=126)	p=0.49

(\*\* p<0.001, PELOD – Pediatric logistic organ dysfunction)

The relationship between number of physiotherapy treatments within the first 4 days of physiotherapy and number of treatment sessions with an adverse event was explored. The scatterplot displayed in Figure 7.27 demonstrates a significant, but weak, positive correlation (R=0.34, p=1.419e-07, 95% CI 0.22 to 0.45). This indicates that receiving more physiotherapy treatments was weakly associated with more adverse events.



*Figure 7.27 Scatterplot displaying the correlation between number of physiotherapy treatments and number of OSI adverse events*  
 (A jitter function has been applied to the data to show overlapping data points more clearly. The plot demonstrates a weak positive correlation. OSI – Oxygen saturation index)

### 7.3.4 Long term outcomes and oxygen saturation index

The relationship between OSI adverse events following physiotherapy and long-term outcomes, length of ventilation and mortality, were explored. Data for the 225 patients, described in Section 7.3.3.3, were used.

Overall median length of ventilation was 4 days (IQR 2-9). A multilevel generalised linear regression model was completed to investigate the association between any adverse event post-physiotherapy in the first four days of physiotherapy (as a binary variable) and length of ventilation. Length of ventilation was the dependent variable, adverse event, weight, PIM3 score and physiotherapy session were fixed effect variables, with unique patient identifier as a random effect. Due to the

skewed distributions of length of ventilation, weight and PIM3 scores, a gamma log-link model was used, with a simple translation of the length of ventilation variable to account for values of 0. The model used is displayed below and the results in Table 7.29.

```
glmer((lov+0.0001)~AE + weight + pim3 + physio_session +
(1|project_id), data=osi_lov2, family=Gamma(link="log"))
```

Table 7.29 Coefficients for length of ventilation from multi-level generalised linear regression models for occurrence of an adverse event and baseline variables

Variable	Linear regression coefficient for LOV	95% Confidence intervals for regression coefficient
<b>Adverse event</b>	-4.657e-10	-1.963e-06- 1.961e-06
<b>Weight</b>	-9.443e-05	-1.085e-04- -8.033e-05
<b>PIM3</b>	6.742	6.7416- 6.7417
<b>Physiotherapy session</b>	-2.337e-10	-1.783e-06- 1.782e-06

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for length of ventilation. 95% confidence intervals which do not cross 0 indicate statistical significance. LOV – Length of ventilation)

The results demonstrate that an adverse event following physiotherapy was not significantly associated with length of ventilation when adjusted for weight, PIM3 and in which physiotherapy session the adverse event occurred. Lower patient weight and a higher PIM3 score were significantly associated with a longer length of ventilation, although these results are not pertinent to this study.

A second analysis was completed to investigate the impact of the total number of adverse events on length of ventilation. The multilevel linear regression model used is displayed below. Number of adverse events was classified as 0, 1 or more than 2.

```
glm((lov+0.0001)~NumAE.y + weight + pim3 +
number_of_physiotherapy_treatments, data=osi_demo6,
family=Gamma(link="log"))
```

The results in Table 7.30 indicate that a greater number of adverse events was not significantly associated with length of ventilation. Total number of physiotherapy treatments was associated with a longer length of ventilation, which is to be expected.

*Table 7.30 Coefficients for length of ventilation from multi-level generalised linear regression models for number of adverse events and baseline variables*

<b>Variable</b>	<b>Linear regression coefficient for LOV</b>	<b>95% Confidence intervals for regression coefficient</b>
<b>1 Adverse event</b>	-3.428e-02	-5.314e-01, 5.182e-01
<b>≥ 2 Adverse events</b>	2.264e-02	-8.326e-01, 1.044e+00
<b>Weight</b>	-2.273e-05	-8.595e-05, 4.806e-05
<b>PIM3</b>	4.123e+00	-1.476e+00, 1.112e+01
<b>Number of physiotherapy treatments</b>	5.165e-01	3.445e-01, 6.950e-01

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for length of ventilation. 95% confidence intervals which do not cross 0 indicate statistical significance. LOV – Length of ventilation)

Mortality was determined by PICU discharge status. In total 221/225 patients (98.2%) were discharged alive. There were no significant differences in mortality between patients with no adverse events (126/129, 97.7%), 1 adverse event (77/78, 98.7%) or ≥ 2 adverse events (18/18, 100%) following physiotherapy (Fishers exact test, p=1.0). The R script for this analysis is displayed in Appendix 38.



### 7.3.5 Secondary outcomes

#### 7.3.5.1 Heart rate

Changes in heart rate were investigated for the first physiotherapy treatment. Of the 546 patients identified as meeting study criteria in section 7.3.1, 463 patients had heart rate data for the time period under analysis. Thirty-eight of these were removed as they had cardiac pacing at the time of first physiotherapy treatment. This was identified using electronic patient records. The baseline characteristics of the patients included in heart rate analysis are displayed in Table 7.31. The individual diagnoses of patients are presented in Figure 7.28. Patients with a cardiovascular diagnosis accounted for 57.4% (244/425), with respiratory diagnosis being the second most common (66/425, 15.5%).

Table 7.31 Baseline and demographic characteristic of patients with heart rate data

<b>Baseline characteristics (n=425)</b>	
<b>Sex, n (%)</b>	Males 251 (59.1)
	Females 174 (40.9)
<b>Age in months, median (IQR)</b>	3 (0-10)
<b>Weight (Kg), median (IQR)</b>	5.1 (3.4-8.3)
<b>Gestation at birth, weeks, n (%) (n=365)</b>	
≥ 37	274 (75.1)
30 to ≤ 36	69 (18.9)
< 30	22 (6.0)
<b>Unit, n (%)</b>	
CICU	269 (63.3)
PICU	146 (34.4)
NICU	10 (2.4)
<b>Type of admission, n (%)</b>	
Elective	162 (38.1)
Emergency	263 (61.9)
<b>PELOD score, median (IQR) (n=406)</b>	6 (6-8)
<b>SARS-CoV-2, n (%) (n=419)</b>	6 (1.4)
<b>Length of ICU stay (days), median (IQR)</b>	6.8 (3.9-13.5)

(Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation, PELOD and SARS-CoV-2, number of children is indicated. CICU – Cardiac intensive care unit, ICU – Intensive care unit, NICU – Neonatal intensive care unit, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care unit)

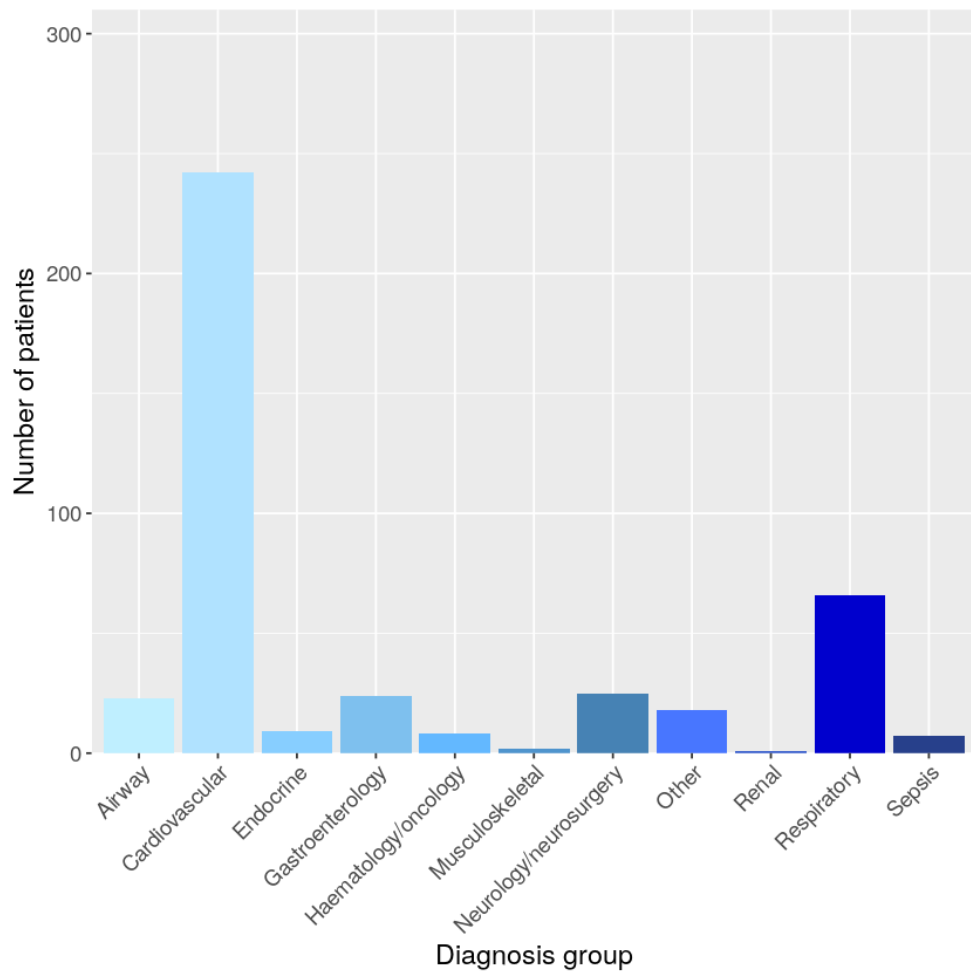
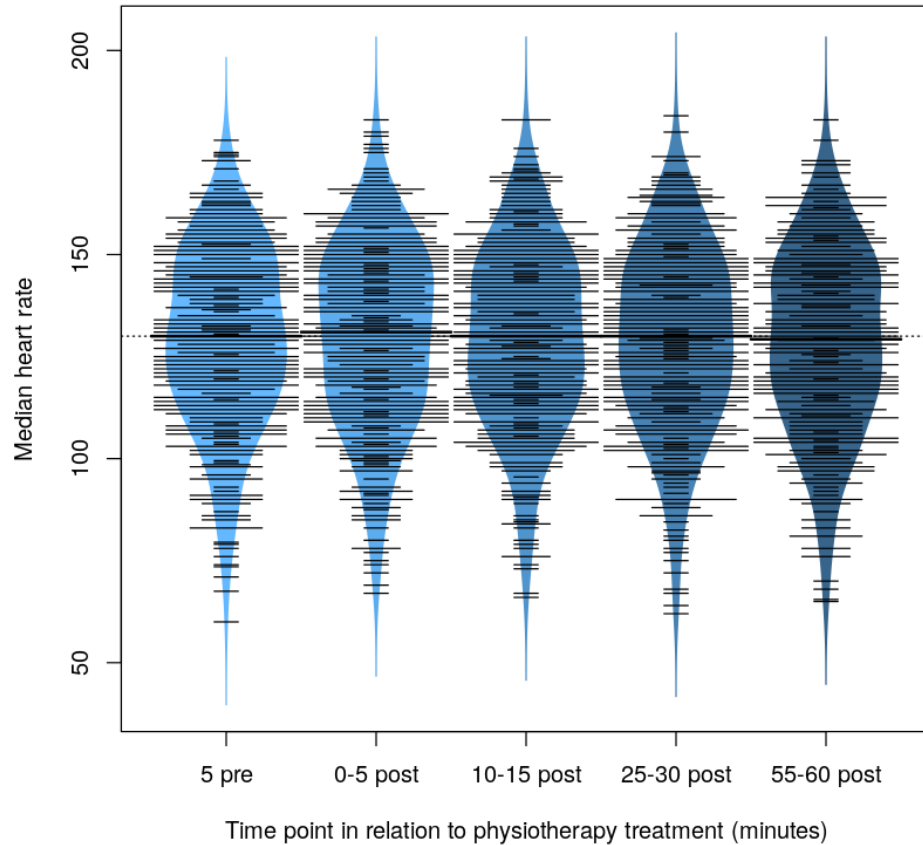


Figure 7.28 Breakdown of diagnoses for patients with heart rate data (n=425)

There were no physiologically implausible heart rate values, > 300bpm, within the dataset. In total 602903 data values were available. Pre-physiotherapy summary median was 131bpm (IQR 115-146, range 0-281) and post-physiotherapy median 129bpm (IQR 113-146, range 0-253).

5-minute medians were calculated for the pre- and post-physiotherapy periods (Appendix 39). The beanplots in Figure 7.29, show comparable distributions of median heart rates across the pre- and post-physiotherapy time points. The thick black line, representing the sample median, displays a slight decrease in heart rate over the 60 minutes post-physiotherapy.



*Figure 7.29 Beanplots of the distribution of median heart rate in relation to pre- and post-physiotherapy time points*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set, with the thick line for each beanplot representing the median value for the time point. The short horizontal lines within each beanplot represent individual data points. There is a slight decrease in heart rate across the time points. n=425)

Pairwise Wilcoxon signed-rank test with Bonferroni adjustment demonstrated statistically significant decreases in median heart rate between post-physiotherapy time points, but not compared to pre-physiotherapy (Table 7.32).

Table 7.32 Wilcoxon signed-rank test with Bonferroni adjustment comparing median heart rate pre- and post-physiotherapy

Time point 1	Time point 2	Median of heart rate paired differences (IQR)	Wilcoxon signed rank test (p.adjust)
Pre-physiotherapy	5 minutes post	0 (-4-4)	p=1
Pre-physiotherapy	15 minutes post	0 (-4-4)	p=1
Pre-physiotherapy	30 minutes post	-1 (-5-4)	p=1
Pre-physiotherapy	60 minutes post	-1 (-6-5)	p=1
5 minutes post	15 minutes post	0 (-2-2)	p=0.947
5 minutes post	30 minutes post	-1 (-4.5-2)	p=0.011*
5 minutes post	60 minutes post	-1 (-6-3)	p=0.025*
15 minutes post	30 minutes post	-1 (-4-1)	p=0.001*
15 minutes post	60 minutes post	-1 (-5-3)	p=0.03*
30 minutes post	60 minutes post	0 (-3-3)	p=1

(\*p<0.05. p.adjust – adjusted p-value for multiple comparisons)

To account for confounders and patient level differences multi-level linear regression was performed. Median heart rate was the dependent variable, weight, admission type, unit and PELOD score were the fixed effect variables and unique patient identifier the random effect variable. Log transformations were included due to the skewed distribution of weight and PELOD score. See model below

$$lmer(\text{medianhr} \sim \text{time} + \log(\text{weight}) + \text{admission.type} + \text{Unit} + \log(\text{pelod\_score}) + (1|\text{project\_id}), \text{data}=\text{hr\_change10})$$

The regression coefficients and 95% confidence intervals are displayed in Table 7.33. The model demonstrated no significant differences in heart rate over the

post-physiotherapy period. Lower patient weight was associated with an increase in heart rate.

*Table 7.33 Coefficients for median heart rate from multi-level linear regression models with post-physiotherapy time points and baseline variables*

<b>Variable</b>	<b>Linear regression coefficient for heart rate</b>	<b>95% Confidence intervals for regression coefficient</b>
<b>5 minutes post-physiotherapy</b>	0.617	-0.318, 1.551
<b>15 minutes post-physiotherapy</b>	0.349	-0.587, 1.285
<b>30 minutes post-physiotherapy</b>	-0.518	-1.455, 0.419
<b>60 minutes post-physiotherapy</b>	-0.756	-1.701, 0.188
<b>(log)Weight</b>	-15.443	-19.317, -11.568
<b>Emergency admission</b>	1.742	-2.543, 6.027
<b>NICU</b>	2.186	-10.051, 14.423
<b>PICU</b>	1.586	-2.897, 6.070
<b>(log)PELOD score</b>	3.560	-3.936, 11.134

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for heart rate. 95% confidence intervals which do not cross 0 indicate statistical significance. PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric Intensive Care Unit, NICU – Neonatal Intensive Care Unit)

The incidence of heart rate adverse events post-physiotherapy was explored. The 5-minute period immediately pre-physiotherapy and the four epochs post-physiotherapy were used, as described previously in Figure 7.8. Change in heart rate was calculated and the proportion of patients with an adverse event (defined as a change >20%) determined for each post-physiotherapy time point. Given the potential for both increases and decreases in heart rate, further description was not possible. The results are displayed in Figure 7.30 and Table 7.34.

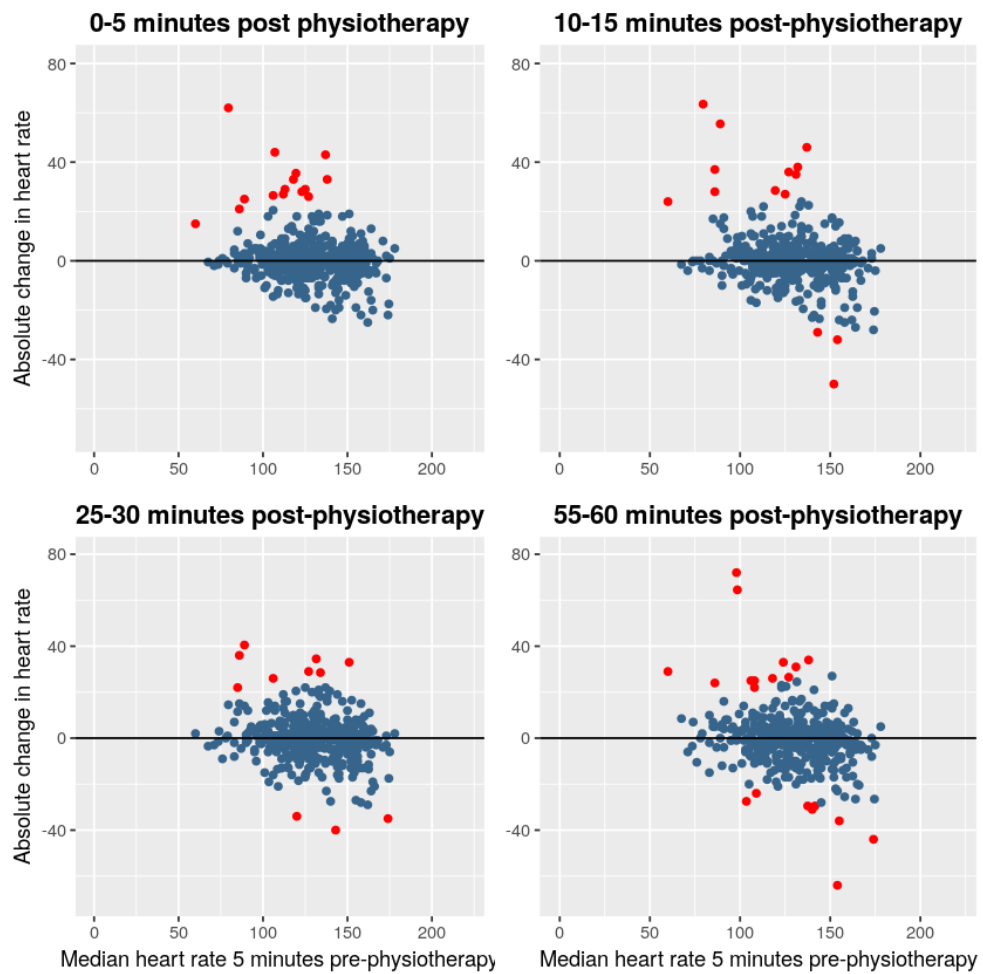


Figure 7.30 Changes in median heart rate plotted against pre-physiotherapy median heart rate. (Patients with an adverse event are highlighted in red. n=425)

Table 7.34 Proportions of heart rate adverse events at each time point post-physiotherapy

Post-physiotherapy time point	Adverse events, n (%)
5 minutes, (n=425)	15 (3.5)
15 minutes, (n=422)	14 (3.3)
30 minutes, (n=421)	11 (2.6)
60 minutes, (n=410)	20 (4.9)

(Number of patients at each time point in brackets)

The results demonstrated low rates of heart rate adverse events, with the lowest rate at 30 minutes post-physiotherapy. Immediately post physiotherapy adverse events only included increases in heart rate.

The final stage of heart rate analysis was to compare patients with and without an adverse event in the 60 minutes following physiotherapy. Forty individual patients accounted for the 60 adverse events displayed in Table 7.34. Baseline demographic comparisons are presented in Table 7.35. Median age was significantly lower in the group with no adverse events. Patients in the adverse event group were more likely to have a gestational age  $\leq$  36 weeks.

*Table 7.35 A comparison of baseline characteristics of patients with and without a heart rate adverse event*

Baseline characteristics	Adverse event group (n=40)	No adverse event group (n=385)	Mann Whitney/ Chi-squared/ Fishers
Sex, n (%)	Males 24 (60.0)	Males 227 (59.0)	p=1
Age in months, median (IQR)	7 (2-17)	3 (0-9)	p=0.005*
Weight (Kg), median (IQR)	5.7 (4.4-10.0)	5.0 (3.4-8.0)	p=0.07
Gestation at birth, weeks, n (%)			
≥ 37	17 (50.0)	257 (77.6)	p=0.0008*
30 to ≤ 36	15 (44.1)	54 (16.3)	
< 30	2 (5.9)	20 (6.0)	
	(n=34)	(n=331)	
Type of admission, n (%)			
Elective	14 (35.0)	148 (38.4)	p=0.798
Emergency	26 (65.0)	237 (61.6)	
PELOD score, median (IQR)	6 (5-7)	6 (6-8)	p=0.016
SARS-CoV-2, n (%)	2 (5.3) (n=38)	4 (1.0) (n=381)	P=0.1
Use of inhaled nitric oxide, n (%)	2 (5.0)	27 (7.0)	p=1
High frequency oscillatory ventilation, n (%)	1 (2.8) (n=36)	14 (4.0) (n=353)	p=1
Time of day, n (%)	Day 38 (95.0)	Day 370 (96.1)	p=0.668

(\*p<0.05. Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation and high frequency oscillatory ventilation, number of children is indicated. CICU – Cardiac intensive care unit, ICU – Intensive care unit, NICU – Neonatal intensive care unit, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care unit)

Fishers exact test demonstrated a statistically significant difference in admission diagnoses between the groups (Figure 7.31,  $p=0.003$ ). There was a higher proportion of patients with a respiratory diagnosis in the adverse event group (14/41, 34.1% vs 52/387, 13.4%). Over half of patients without an adverse event had a cardiovascular diagnosis (232/387, 59.9%).

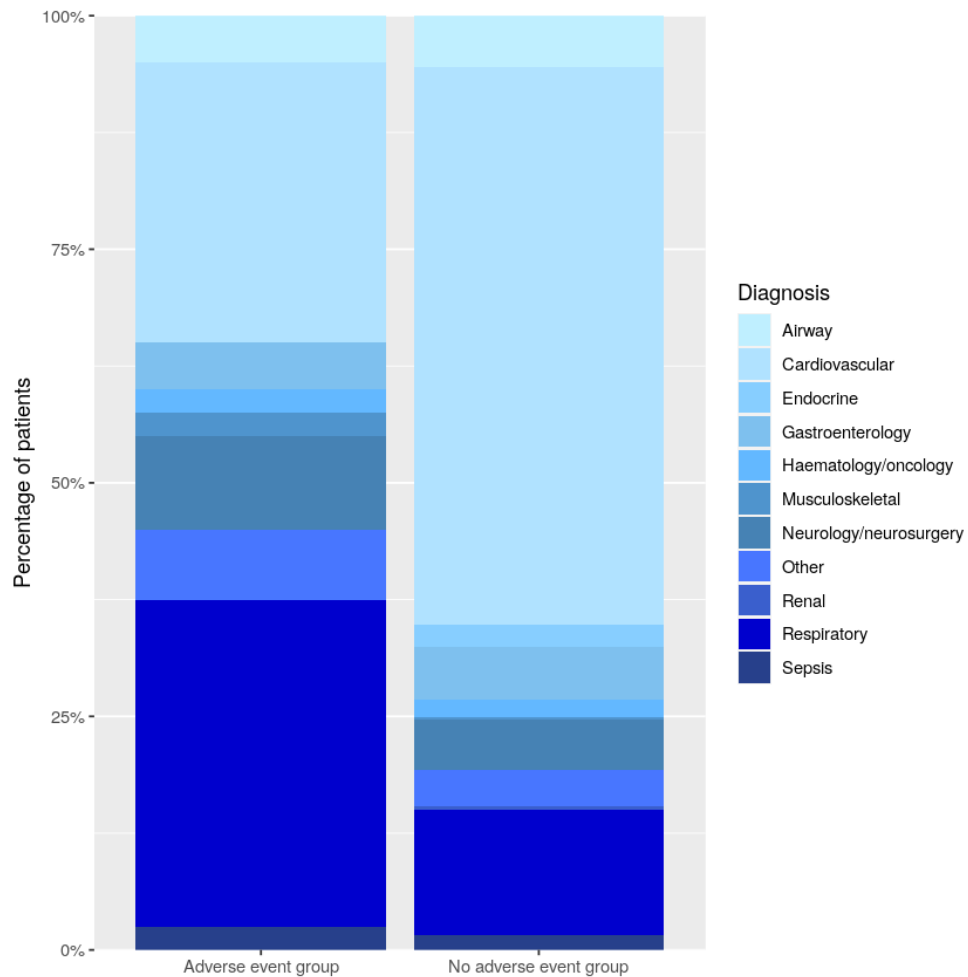


Figure 7.31 Comparison of patient diagnosis between the group with a heart rate adverse event and those without (Fishers exact,  $p=0.003$ )

Table 7.36 displays a comparison of the physiotherapy techniques used during treatment of patients who had a heart rate adverse event and those who did not. A combination of saline instillation and MHI with CWV was used most frequently with patients in both groups (41% and 60.6%). Fishers exact test indicated a statistically significant difference between the groups in terms of treatments used ( $p=0.002$ ). Due to the general nature of the test specific differences are not



provided. However, treatments which included CWV appeared to be used more frequently in patients without an adverse event.

*Table 7.36 Comparison of physiotherapy treatments used with patients with and without a heart rate adverse event*

Treatment	Adverse event group (n=39)	No adverse event group (n=383)
Saline, MHI with CWV, n (%)	16 (41.0)	232 (60.6)
MHI with CWV, n (%)	3 (7.7)	62 (16.2)
Saline and MHI, n (%)	8 (20.5)	45 (11.7)
MHI only, n (%)	4 (10.3)	11 (2.9)
Saline, MHI with CWV, and decompression, n (%)	4 (10.3)	11 (2.9)
Suction only, n (%)	0	9 (2.3)
Saline only, n (%)	2 (5.1)	7 (1.8)
MHI with CWV, and decompression, n (%)	1 (2.6)	3 (0.8)
CWV only, n (%)	0	1 (0.3)
Percussion only, n (%)	1 (2.6)	0
Saline, MHI and decompression, n (%)	0	1 (0.3)
Saline and percussion, n (%)	0	1 (0.3)

(Fishers exact, p=0.002, CWV – Chest wall vibrations, MHI – Manual hyperinflations)

### 7.3.5.2 Mean arterial blood pressure

The analysis of the first physiotherapy session was repeated for mean arterial blood pressure (MBP). Data were available for 340 patients. This is lower than heart rate data, as not all patients were subject to invasive blood pressure monitoring. The baseline characteristics of the group are displayed in Table 7.37, with the diagnosis data presented in Figure 7.32. As with all demographic analysis in this chapter a cardiovascular diagnosis was most common (242/340, 71.2%) followed by respiratory (29/340, 8.5%).

Table 7.37 Baseline characteristics of patients with mean blood pressure data

<b>Baseline characteristics (n=340)</b>	
<b>Sex, n (%)</b>	Males 206 (39.4)
	Females 134 (39.4)
<b>Age in months, median (IQR)</b>	3 (0-9.3)
<b>Weight (Kg), median (IQR)</b>	5.1 (3.5-8.0)
<b>Gestation at birth, weeks, n (%) (n=284)</b>	
≥ 37	218 (76.8)
30 to ≤ 36	53 (18.7)
< 30	13 (4.6)
<b>Unit, n (%)</b>	
CICU	264 (77.7)
PICU	71 (20.9)
NICU	5 (1.5)
<b>Type of admission, n (%)</b>	
Elective	166 (48.8)
Emergency	174 (51.2)
<b>PELOD score, median (IQR) (n=322)</b>	7 (6-8)
<b>SARS-CoV-2, n (%)</b>	4 (1.2)
<b>Length of ICU stay (days), median (IQR)</b>	6.9 (4.0-13.0)

(Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation and PELOD, number of children is indicated. CICU – Cardiac intensive care unit, ICU – Intensive care unit, NICU – Neonatal intensive care unit, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care unit)

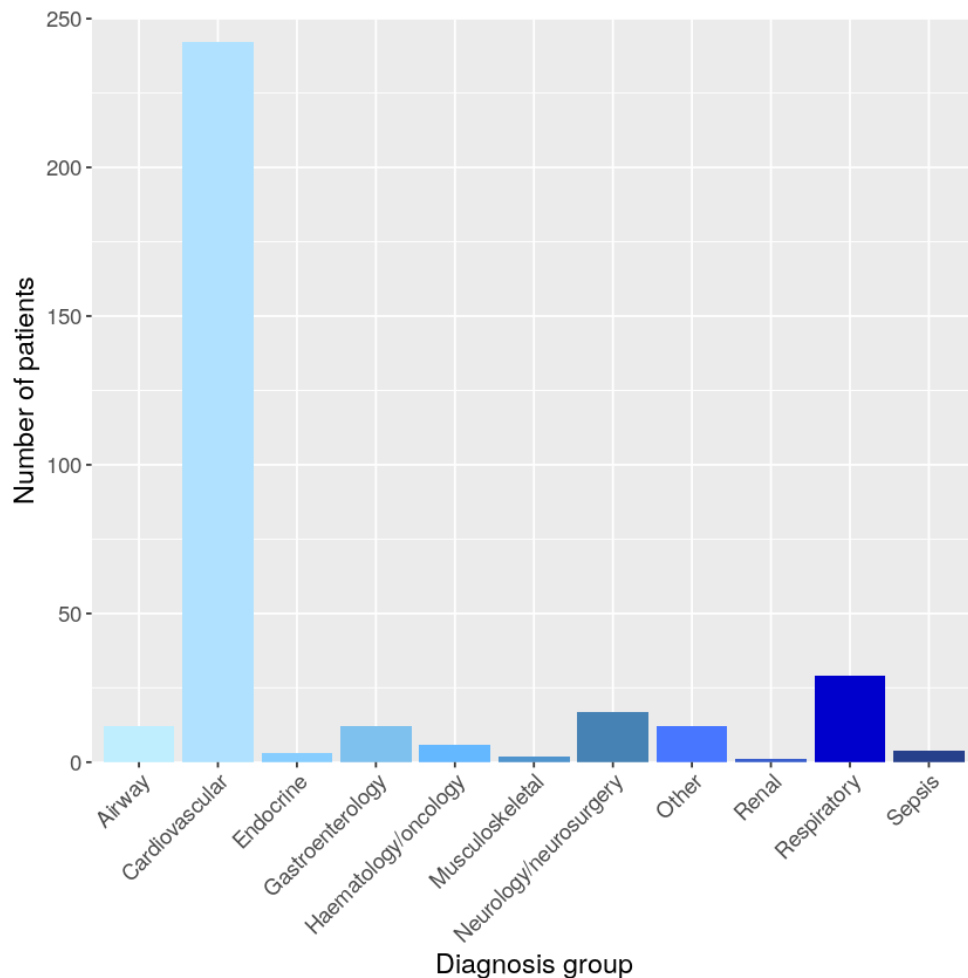
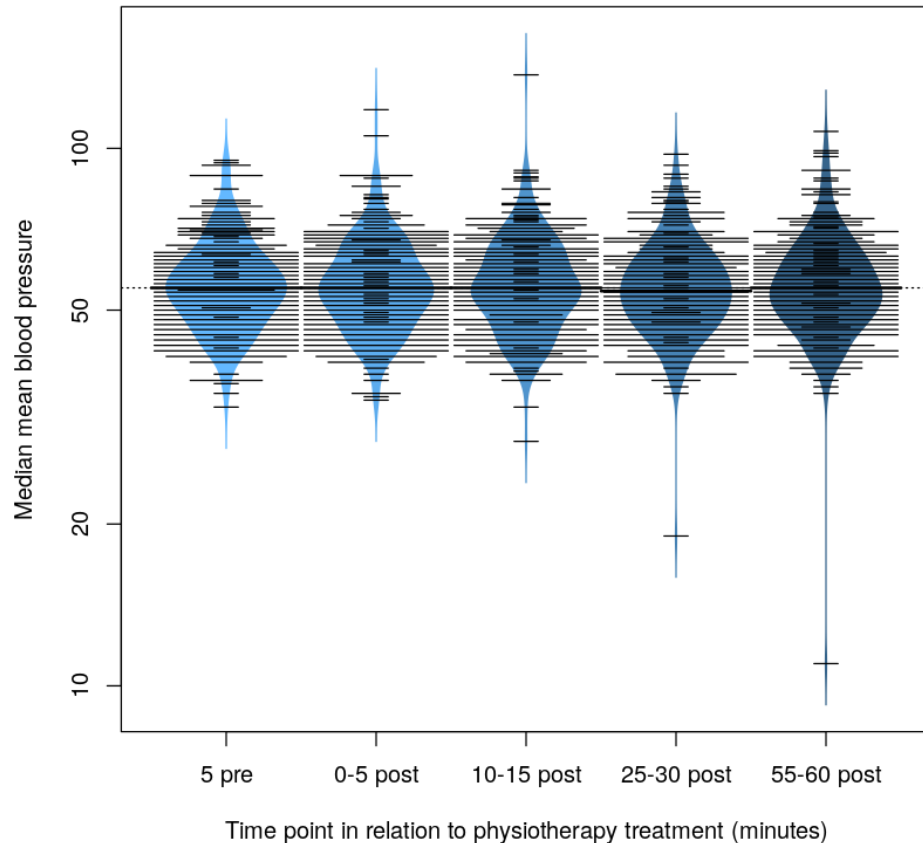


Figure 7.32 Breakdown of diagnoses for patients with mean blood pressure data

(n=340)

Physiologically implausible values (<0mmHg and >150mmHg) were removed (372/481 505, 0.08%). Following this, 481133 raw data values were available. Median pre-physiotherapy was 55mmHg (IQR 49-63, range 0 to 150), with post-physiotherapy median MBP also 55mmHg (IQR 49-62, range 0 to 150).

Median MBP was calculated for the 5-minute epochs pre- and post-physiotherapy for each patient (Appendix 40). Summary medians are displayed in Figure 7.33. The distributions differ slightly, however there are no clear trends in sample medians. This was confirmed by univariate analysis, using pairwise Wilcoxon signed-rank test with Bonferroni adjustment, which demonstrated no statistically significant differences (Appendix 41).



*Figure 7.33 Beanplots of the distribution of median mean blood pressure in relation to pre- and post-physiotherapy time points.*

(Time periods on the y axis refer to, 5 pre – pre-physiotherapy, 0-5 post – 5 minutes post-physiotherapy, 10-15 post – 15 minutes post-physiotherapy, 55-60 post – 60 minutes post-physiotherapy. The black dotted line shows the median value of the data set, with the thick line for each beanplot representing the median value for the time point. The short horizontal lines within each beanplot represent individual data points. n=340)

Mean blood pressure was further explored using multi-level linear regression, as described previously in Section 7.3.5.1, with median MBP as the dependent variable. Table 7.38 displays the regression coefficients and 95% confidence intervals. There was no significant association between MBP and the post-physiotherapy time points. Higher weight was significantly associated with increased mean blood pressure. This was an expected relationship as increased weight likely indicates an older patient, which accounts for normal physiological increases in blood pressure with age. Being on PICU was also associated with increased MBP, potentially linked to the older population on PICU compared to CICU and NICU. An increase in PELOD score was associated with lower mean

blood pressure. This was anticipated given blood pressure indices are included within PELOD, lower MBP equates to higher scoring within PELOD.

*Table 7.38 Coefficients for median mean blood pressure from multi-level linear regression models with post-physiotherapy time points and baseline variables*

	<b>Linear regression coefficient for MBP</b>	<b>95% Confidence intervals for regression coefficient</b>
<b>5 minutes post-physiotherapy</b>	0.051	-0.880, 0.982
<b>15 minutes post-physiotherapy</b>	0.112	-0.821, 1.045
<b>30 minutes post-physiotherapy</b>	-0.691	-1.625, 0.243
<b>60 minutes post-physiotherapy</b>	-0.337	-1.274, 0.600
<b>(log)Weight</b>	9.242	7.405, 11.078
<b>Emergency admission</b>	0.151	-1.843, 2.145
<b>NICU</b>	1.124	-6.061, 8.310
<b>PICU</b>	2.431	0.058, 4.803
<b>(log)PELOD score</b>	-3.871	-7.424, -0.318

(The multi-level linear regression coefficients, with 95% confidence intervals, are shown for mean blood pressure. 95% confidence intervals which do not cross 0 indicate statistical significance. PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric Intensive Care Unit, NICU – Neonatal Intensive Care Unit)

In line with the previous analysis in this chapter, change in median MBP was calculated between the 5-minute period immediately pre-physiotherapy and the four epochs post-physiotherapy. The proportion of patients with an adverse event (defined as a change >20%) was determined for each post-physiotherapy time point. The results are displayed in Figure 7.34 and Table 7.39. The MBP adverse event rate was lowest immediately post-physiotherapy (37/340, 10.9%). Variability in MBP was evident, with both increases and decreases in MBP over the 60 minutes. Slightly more adverse events were increases in MBP 114/194 (58.8%), compared to 80/194 (41.2%) decreases.

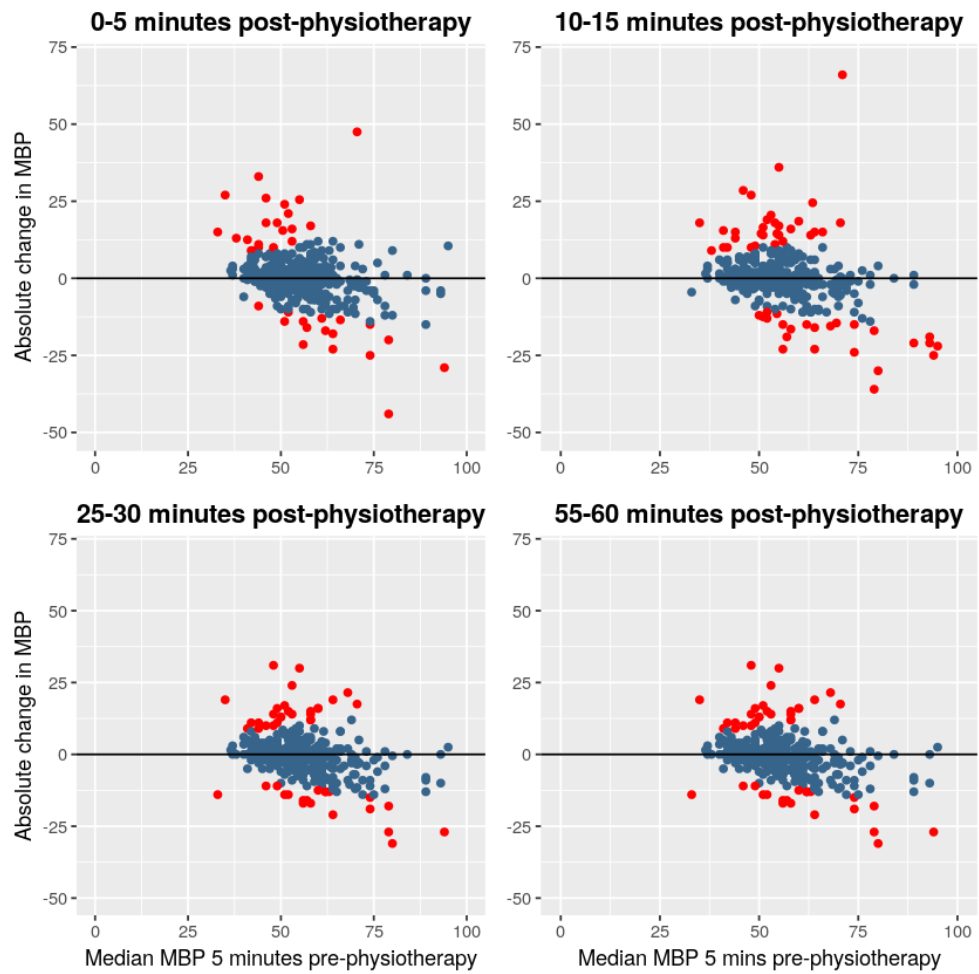


Figure 7.34 Changes in median mean blood pressure plotted against pre-physiotherapy median.

(Patients with an adverse event are highlighted in red. n=340)

Table 7.39 Proportions of mean blood pressure adverse events at each time point post-physiotherapy

Post-physiotherapy time point	Adverse events, n (%)
5 minutes, (n=340)	37 (10.9)
15 minutes, (n=337)	55 (16.3)
30 minutes, (n=336)	47 (14.0)
60 minutes, (n=333)	55 (16.5)

(Number of patients at each time point in brackets)

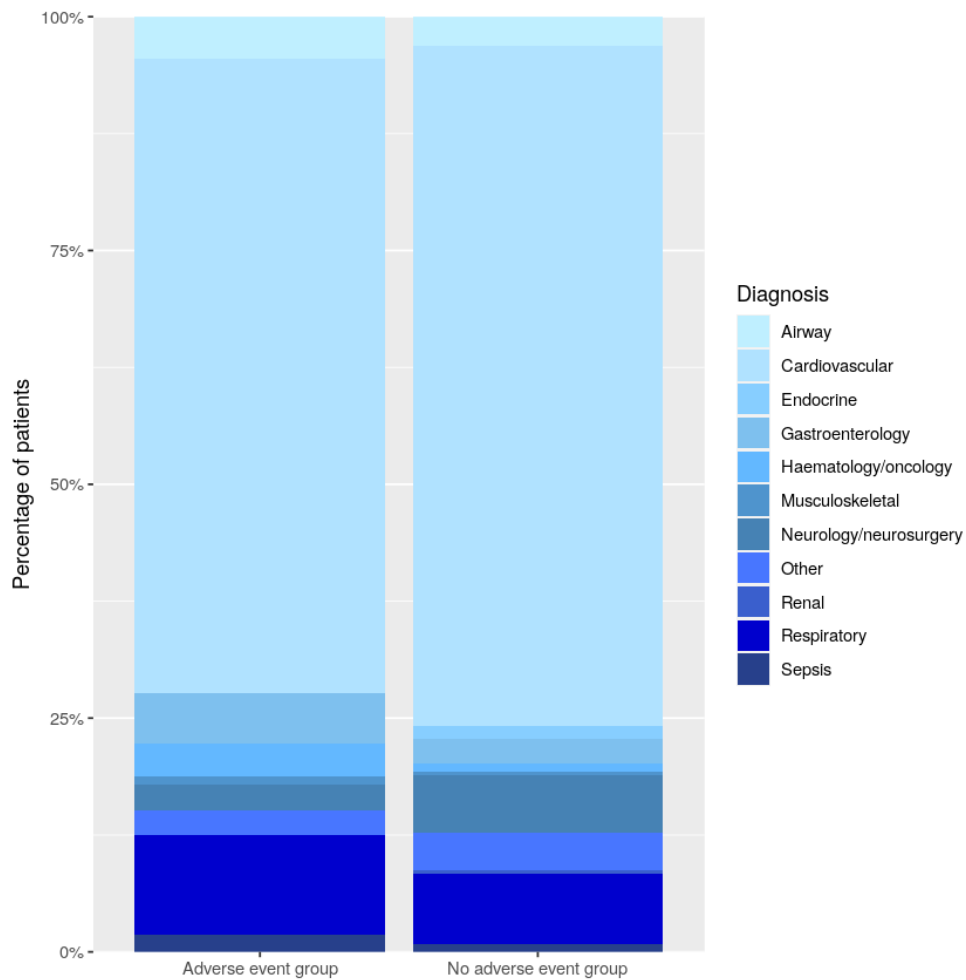
In total the 194 MBP adverse events identified in Table 7.39 related to 112 patients. Table 7.40 shows the comparison of baseline characteristics of the patients with adverse events and those without. The patients who were classified as having an adverse event were statistically significantly older than those without, however the difference was 1.5 months which has minimal clinical significance.

*Table 7.40 Comparison of baseline characteristics of patients with and without a mean blood pressure adverse event*

Baseline characteristics	Adverse event group (n=112)	No adverse event group (n=228)	Mann Whitney/ Chi-squared/ Fishers
Sex, n (%)	Males 67 (59.8)	Males 139 (61.0)	p=0.93
Age in months, median (IQR)	4.5 (1-14)	3 (0-7)	p=0.01*
Weight (Kg), median (IQR)	5.5 (3.6-9.0)	5.0 (3.4-7.5)	p=0.14
Gestation at birth, weeks, n (%)			
≥ 37	63 (67.7)	155 (79.1)	p=0.1
30 to ≤ 36	24 (25.8)	34 (17.3)	
< 30	6 (6.5)	7 (3.6)	
	(n=93)	(n=196)	
Type of admission, n (%)			p=0.18
Elective	61 (54.5)	105 (46.0)	
Emergency	51 (45.5)	123 (54.0)	
PELOD score, median (IQR)	7 (6-8)	6 (6-8)	p=0.18
SARS-CoV-2, n (%)	0	4 (1.8)	P=0.31
Use of inhaled nitric oxide, n (%)	7 (6.3)	25 (11.0)	p=0.23
High frequency oscillatory ventilation, n (%)	3 (3.0) (n=101)	11 (5.3) (n=207)	p=0.56
Time of day, n (%)	Day 111 (99.1)	Day 221 (96.9)	p=0.28

(\*p<0.05. Age calculated on admission. Unit and PELOD based on day of first physiotherapy session. Missing data for gestation and high frequency oscillatory ventilation, number of children is indicated. CICU – Cardiac intensive care unit, ICU – Intensive care unit, NICU – Neonatal intensive care unit, PELOD - Pediatric logistic organ dysfunction, PICU – Paediatric intensive care unit)

The diagnosis and physiotherapy treatment received were also compared between the groups, displayed in Figure 7.35 and Table 7.41 respectively. There were no statistically significant differences in diagnosis ( $p=0.31$ ) or treatment ( $p=0.08$ ) between groups.



*Figure 7.35 Comparison of patient diagnoses between patients with and without a mean blood pressure adverse event (Fishers exact,  $p=0.31$ )*



Table 7.41 Comparison of physiotherapy treatments used with patients with and without a mean blood pressure adverse event

	Adverse event group (n=111)	No adverse event group (n=227)
Saline, MHI with CWV, n (%)	63 (56.8)	150 (66.1)
MHI with CWV, n (%)	18 (16.2)	38 (16.7)
Saline and MHI, n (%)	20 (18.0)	20 (8.8)
MHI only, n (%)	3 (2.7)	6 (2.6)
Saline, MHI with CWV, and decompression, n (%)	3 (2.7)	4 (1.8)
Suction only, n (%)	0	6 (2.6)
Saline only, n (%)	3 (2.7)	2 (0.9)
MHI with CWV, and decompression, n (%)	1 (0.9)	1 (0.4)

(Fishers exact, p=0.08, CWV – Chest wall vibrations, MHI – Manual hyperinflations)

#### 7.3.5.3 Combination of adverse events

The final analysis investigated the proportion of patients who were identified with both OSI and cardiovascular adverse events in the 60 minutes following the first physiotherapy session. On pooling of the data 181 patients had data available for OSI, heart rate and MBP. Two patients (1.1%) demonstrated an adverse event in each variable. When the cardiovascular data were combined, 303 patients had data available for heart rate and MBP. Ten patients (3.3%) were identified as having both heart rate and MBP adverse events.

#### 7.3.6 Summary of results

The main findings of this chapter are summarised below.

##### *Primary outcome*

- OSI adverse event rates varied between 7.4% and 9.3%. The highest rate was in the 5-minute period immediately after physiotherapy, which then

decreased over 30 minutes, before increasing at the 60-minute epoch. A similar pattern of OSI adverse events was seen in physiotherapy treatments on days 2 to 4.

- When the components of OSI were analysed individually, very low rates of SpO<sub>2</sub> adverse events were observed (0-1.2%). The changes observed in OSI appeared to be related to FiO<sub>2</sub> and MAP.
- There was a trend of improved OSI over the 60 minutes post-physiotherapy.
- OSI adverse events occurred in patients with a lower pre-physiotherapy median OSI.
- A statistically significant higher proportion of patients with an adverse event were emergency admissions compared to those without.
- There was no association between occurrence of an OSI adverse event post-physiotherapy and length of ventilation or mortality.

#### *Secondary outcomes*

- Rates of heart rate adverse events were low (2.6-4.9%) but increased at 60 minutes post-physiotherapy.
- Patients identified as having a heart rate adverse event were older. They were more likely to have a respiratory diagnosis, have been born prematurely and treated less frequently with CWV.
- Higher rates of MBP adverse events were observed (10.9-16.5%), with the lowest rate immediately post-physiotherapy.
- Patients who were identified as having a MBP adverse event were statistically significantly older than those without, although not clinically significant.
- Very few patients were identified as having both OSI and cardiovascular adverse events.

## **7.4 Discussion**

The key findings highlighted above will be discussed in the context of the research questions and relevant literature.

#### **7.4.1 Research question 4: What is the incidence of physiological instability and adverse events associated with chest physiotherapy in ventilated children?**

This is the first study to primarily investigate adverse events following chest physiotherapy in ventilated children. The adverse event rates varied according to physiological outcome. Lower rates were observed with OSI (7.4-9.3%) and heart rate (3.5-4.9%), whilst mean blood pressure adverse event rate was higher (10.9-16.5%). To enable access to high-resolution monitor data, mean arterial blood pressure, measured invasively via an arterial line, was used in this study. This may have introduced selection bias as a decision to place an arterial line had been made in these children, possibly indicating haemodynamic instability. This may account for the higher rates of adverse events seen with this variable. However, the PELOD scores of this sample were comparable to the other samples used in this study.

Several studies investigating the effectiveness of chest physiotherapy in ventilated children have discussed the incidence of adverse events. The majority provide a generic statement of no adverse events (Almeida et al., 2005, Deakins and Chatburn, 2002, Gregson et al., 2007, Luadsri et al., 2022). Composite rates of adverse events during and after physiotherapy were reported by Main et al. (2004) and Shannon et al. (2015a). Adverse event rates between 4.8% and 12.7% were reported, with most events described as transient changes in SpO<sub>2</sub> or haemodynamics. Whilst these are similar rates to those seen in this study, direct comparison should be avoided given the differences in definitions used and age groups studied. A strength of the current study is the reporting of adverse event rates in the real-world setting. The inclusion criteria were wide, including all severities of illness, awake patients, patients conventionally ventilated and those on high frequency oscillatory ventilation (secondary outcomes only). The participants studied by Main et al. (2004) and Shannon et al. (2015a) were all conventionally ventilated and either deeply sedated or pharmacologically paralysed. It is possible these participants represented a subgroup with reduced variability in physiological response. Furthermore, the detrimental effects of high levels and/or prolonged use of sedatives are now well documented (Anand et al., 2010, Tobias, 2000). Within PICU liberation bundles are encouraged, hence these

patients may not reflect those receiving chest physiotherapy in current practice. In contrast to published data from PICU a very low rate of adverse events (0.2%, 27/12281) associated with chest physiotherapy and rehabilitation has been described in adult intensive care (Zeppos et al., 2007). Direct comparisons should be avoided given the anatomical and physiological differences between children and adults. Children may be more vulnerable to acute deteriorations or instability. Additionally, a limitation to the Zeppos et al. (2007) study was the self-reported data collection.

ETT suction was a component of all physiotherapy treatments included in this study. Several studies have exclusively investigated the safety of ETT suction in ventilated children. Schults et al. (2020) reported a 22% (211/955) rate of adverse events with ETT suctioning of ventilated children. This study used a composite definition of adverse events, of which de-saturation accounted for 85% (180/211). Similar findings have been reported by Owen et al. (2016), where 30% (586/1986) of ETT suction events in ventilated children were associated with an adverse event. De-saturation was reported as the most common type of adverse event. These studies used lower thresholds (decrease in SpO<sub>2</sub> < 5% and <10%) to define an adverse event which may account for the higher rates observed compared to the current study.

Oxygen saturation index was a novel outcome measure in this study. Historically SpO<sub>2</sub> has been a popular outcome within physiotherapy and PICU research. The secondary analysis involving the components of OSI in this study demonstrated a low rate of SpO<sub>2</sub> adverse events (0-1.2%) and minimal change over the 60 minutes post-physiotherapy. Changes seen in OSI appeared to be influenced more by FiO<sub>2</sub> and mean airway pressure. These findings suggest OSI may have value as an outcome measure in the wider clinical setting. With increasing access to electronic patient records, OSI could be calculated automatically at the bedside, as is currently the case with oxygenation index and P/F ratio.

The use of OSI has predominantly been described within the context of respiratory failure, defining paediatric acute respiratory distress syndrome (ARDS), and mortality risk (Khemani et al., 2015, Rawat et al., 2015, Thomas et al., 2010b). Thomas et al. (2010b) determined an OSI of 6.5 to be equivalent to acute lung

injury criteria and an OSI of 7.8 to ARDS criteria. However, what constitutes an important clinical change in OSI has not been explored within the literature. An OSI adverse event threshold of an increase  $\geq 0.3$  was used in this study. Although calculated logically from recently published individual component definitions, it was a relatively arbitrary and very sensitive value. Therefore, the results of this study and clinical relevance need to be interpreted with caution. If OSI is to be used in future studies further evaluation of change in a clinical context is required. However, advantages of OSI compared to other metrics, such as P/F ratio or oxygenation index, are that it can be continuously and non-invasively measured. Additionally, from a research perspective, the use of OSI avoids selection bias regarding the decision to obtain an arterial blood gas or place an arterial catheter (Khemani et al., 2015).

Whilst this study focussed on adverse events associated with chest physiotherapy, it is important to acknowledge the improvement observed in OSI over the 60-minute post-physiotherapy period. Causality cannot be inferred due to the observational nature of the study and potential confounders. However, the results offer insights into the potential benefits of chest physiotherapy in this population. Improvements in oxygenation ( $SpO_2$  and  $PaO_2$ ) following chest physiotherapy have been reported previously (Almeida et al., 2005, Bernard-Narbonne et al., 2003, Soundararajan and Thankappan, 2015). Theoretically the removal of secretions and recruitment of atelectatic areas achieved with chest physiotherapy, optimises oxygenation through improved regional/global ventilation and compliance, and improved ventilation/perfusion mismatch (Pathmanathan et al., 2015, Pryor and Prasad, 2008). Given the variable rate of adverse events in the current study, it is important to further explore the benefits of this frequently provided intervention.

In this study very few patients experienced both OSI and cardiovascular adverse events (1.1%). A similar pattern of an isolated event, involving one system, has been described in previous chest physiotherapy studies involving mechanically ventilated children (Main et al., 2004, Shannon et al., 2015a). These findings are likely indicative of the swift and effective management of instability on PICU, where rescue interventions are employed to prevent multi-system deterioration.

#### **7.4.2 Research question 5: What are the risk factors/characteristics of children who display instability and/or adverse events associated with chest physiotherapy?**

In this study emergency admissions accounted for a higher percentage of patients who experienced one or more OSI adverse events following physiotherapy compared to those without. The assumption that emergency admissions are more critically ill, and hence more vulnerable to instability, could provide an explanation. However, this was not reflected in the comparison of group PELOD scores, where there were no significant differences. No other significant differences were observed between the patients with an OSI adverse event and those without. These findings are in line with the results of Main et al. (2004) and Schults et al. (2020), where there were no differences in physiotherapy or ETT suction related adverse events with age, diagnosis or PIM3 score. As highlighted previously in this chapter OSI data were only available for patients on CICU, an important factor which needs considering when interpreting the above results. Diagnoses and most aspects of patient care will have been similar, resulting in a relatively comparable case mix. Further research is required with patients across all paediatric critical care units at GOSH and multi-site, to enable differences in populations to be more accurately investigated.

The results demonstrated that the majority of OSI adverse events occurred in patients with lower pre-physiotherapy OSI, possibly reflecting deterioration in less critically ill children. The ceiling of support available may have influenced this, as patients with higher pre-physiotherapy OSI were already receiving maximal therapy. However, given the composite nature of OSI, fluctuations in SpO<sub>2</sub> would have been possible. A similar phenomenon has been described in the treatment of sepsis on PICU, where interventions were found to be more harmful in lower risk populations or less severely ill subjects (Eichacker et al., 2002, Peters, 2021). From a clinical physiotherapy perspective, it is also worth considering how the approach to treatment may have influenced the results. There are several strategies employed by physiotherapists when treating patients perceived to be high risk or more critically ill e.g., pre-oxygenation, sedation bolus, recruitment manoeuvre (Duff et al., 2007, Gosselink et al., 2008, Morrow and Argent, 2008). These strategies may have been used more frequently in patients with higher pre-

physiotherapy OSI compared to those with lower OSI. The findings highlight that physiotherapists need to be aware of potential for adverse events in all patients and balance the risks and benefits.

Patients who were identified as having a heart rate or mean blood pressure adverse event were older than those without, with the differences being clinically significant in the heart rate analysis. This is contradictory to literature exploring critical incidents generally on PICU, where younger, smaller children were at higher risk of adverse events (Niesse et al., 2011). These unexpected findings may be due to collinearity of variables and the differences in diagnosis between the groups. There was a higher proportion of patients with a respiratory diagnosis in the heart rate adverse event group. This group also had a lower percentage of patients with a cardiovascular diagnosis. Children with congenital cardiac defects are predominantly a younger population and a broader age range would be found in patients with respiratory diagnosis. Owen et al. (2016) reported that underlying respiratory disease was present more often in patients with ETT suctioning episodes with an adverse event (42% vs 33%,  $p < 0.001$ ). However the majority of adverse events reported by Owen et al. (2016) were drops in SpO<sub>2</sub>. The differences in groups observed in the current study may also be attributed to the stricter haemodynamic management received by cardiovascular patients compared to respiratory patients.

In this study a higher percentage of patients in the heart rate adverse event group were ex-premature (born < 37 weeks). This characteristic has not been explored in physiotherapy literature. However, the vulnerability of ex-premature infants is well documented, they suffer greater co-morbidities and higher levels of re-hospitalisation (Frawley, 2017, Glass et al., 2015). Although not the focus in this study, premature infants are at risk of several suction and handling related complications, including bradycardia and tachycardia (Cone et al., 2013). Autonomic control of cardiac and other involuntary tissues is not fully developed until 37–38 weeks gestation. As a result, instability in heart rate, particularly bradycardia is common in premature infants. They are also more vulnerable to vaso-vagal responses resulting in bradycardia, due to activation of afferent receptors in the lower airway and increased parasympathetic activity (Segar et al.,

1993). Stimuli can include components of physiotherapy such as ETT saline instillation and suction. Cardiovascular instability may also be linked to pain and stress responses, with premature infants unable to buffer negative stimuli due to physiologic immaturity (Cone et al., 2013, Keels et al., 2016). Hence the findings related to ex-premature infants in this study are not unexpected.

The chest physiotherapy provided in this study differed significantly between patients identified with a heart rate adverse event and those without. Chest wall vibrations were used less frequently in patients who experienced an adverse event post-physiotherapy. Without knowing the individual decision making around the choice of technique it is difficult to unpick the clinical relevance of this finding. Individual components of physiotherapy have not been explored in this context previously. The use of ETT saline instillation has been reported as increasing the risk of adverse events with suction in ventilated children (Owen et al., 2016, Schults et al., 2020). This contrasts with the current study where saline use was similar between the groups.

#### **7.4.3 Research question 6: What is the long-term impact on the child of instability and adverse events associated with chest physiotherapy?**

The novel approach to this study, investigating multiple physiotherapy treatments, enabled the longer-term impact of OSI adverse events following physiotherapy to be explored. There was no association between the occurrence of an OSI adverse event and length of ventilation or mortality. There are no published data investigating long term outcomes related to chest physiotherapy in ventilated children with which these findings can be compared. In contrast to results from the current study, paediatric patients who experienced ETT suction related adverse events demonstrated a longer length of ventilation (mean days 14.7 vs 12.4,  $p < 0.001$ ) (Owen et al., 2016). This univariable analysis did not include adjustment for severity of illness or other potential confounding variables and therefore needs interpreting with caution.

Whilst the findings provide reassuring preliminary data regarding the risk of chest physiotherapy in this population, they must be interpreted in the context of the sensitive and limited definitions of adverse events used in this study. To gain more definitive data around longer-term impact of chest physiotherapy a wider scope of



adverse events needs to be investigated, including specific incidents such as accidental extubation and cardiorespiratory arrest.

## **7.5 Limitations**

Whilst this study is the first to combine high resolution monitor and ventilator data with electronic patient records, to provide a detailed exploration of adverse events associated with chest physiotherapy in ventilated children, there are several limitations and challenges which require explanation.

### **7.5.1 Retrospective data collection**

The main limitation with retrospective analysis is that it only detects association not causation. This needs to be considered when interpreting the results presented in this chapter. The analysis completed in this study provides description of the physiological adverse events that occurred in the 60 minutes post-physiotherapy. It cannot be concluded that they were a direct result of physiotherapy. Data were not available regarding other ICU interventions which took place within the 60-minute period. Although a limitation, this approach provides a pragmatic view in the context of usual care and has generated novel data regarding presentation of ventilated children following physiotherapy.

### **7.5.2 Availability of data**

The advantage of using high resolution data in this study was the number of data-points available for analyses, with repeated measures in the same individual. Whilst this study included the largest sample used in chest physiotherapy research in ventilated children, the availability of data was a limitation. The high-resolution ventilator data, collected from T<sup>3</sup> eitiometry, had not been accessed previously. Large amounts of data were missing within the study period, which reduced the sample size for the analysis of the primary outcome OSI. Additionally, ventilator data were only available for patients on CICU, reducing the representation of the study and its generalisability to the overall paediatric critical care population. Due to the retrospective nature of data collection and restricted time frame for the PhD project it was not possible to use an alternative data set. Hence it was necessary to complete the analysis on the CICU subgroup. An investigation into the inconsistencies of available data between paediatric critical care units determined

issues with ventilator connections at the bedside. Now recognised, this can hopefully be addressed to ensure the success of future studies.

The use of electronic patient records provided improved opportunity for standardised documentation and greater accessibility to retrospective data. Despite this, data processing was time consuming and challenging. A complex data processing pipeline was required including identifying the correct variables, collating, aligning time stamps, and converting into a compatible format. The learning and development from this study should enable more efficient processing of similar variables in future studies.

### **7.5.3 Analysis time frames**

A further limitation of using EPRs in this study was the inability to determine the length of physiotherapy or treatment start time. The only time stamp available was the end of physiotherapy. An estimated 30-minute window was allocated for treatment, to allow pre- and post-physiotherapy periods to be calculated. This was a pragmatic decision based on the results of a local audit (Appendix 25). The fact that several studies investigating chest physiotherapy on PICU have also reported average treatment length <30 minutes is reassuring (Main et al., 2004, Shannon et al., 2015b, Torreiro Diéguez et al., 2022). Despite this, there is a risk that for some patients treatment was longer than the allocated 30 minutes and data included within the pre-physiotherapy period were during treatment. This may reduce the accuracy of the results.

This study included analysis of the 60-minute period after physiotherapy. It would have been advantageous to also analyse the incidence of adverse events during physiotherapy. As discussed above, individual treatment length was unknown and therefore analysis during physiotherapy was not possible. Although physiological state post-physiotherapy is likely to reflect conditions during treatment, it is an area requiring further investigation. A function within electronic patient records to record treatment start and end would be required, or a different methodological approach considered.

#### **7.5.4 Use of oxygen saturation index**

A limitation of using OSI in this study was the automatic exclusion of patients receiving high frequency oscillatory ventilation. T<sup>3</sup> eitiometry system connectors are not compatible with the Sensormedics ventilator, therefore data were not available. Although these patients were included in the analysis of secondary outcomes, heart rate and MBP, they continue to be an under-represented group within physiotherapy research. Future studies including these patients are required.

Given the novel use of OSI in this study there were no adverse event thresholds or important clinical change metrics described within the literature. To ensure an *a priori* definition was used, the OSI adverse event threshold used was calculated from the best available adverse event definitions of its individual components. This threshold (change  $\geq 0.3$ ) did not undergo any sensitivity testing. The individual analysis of SpO<sub>2</sub> and FiO<sub>2</sub> demonstrated much lower adverse event rates than the OSI rates. It needs to be acknowledged that the OSI threshold used may have had much higher sensitivity. What constitutes an appropriate and clinically relevant threshold requires further investigation. Whilst this limits the clinical relevance of the findings, this study has provided novel data, experience accessing and calculating OSI using high resolution data, and contributed to the debate around potential outcome measures for physiotherapy research.

#### **7.5.5 Impact of COVID19**

The data collection for this study took place during the COVID19 pandemic. SARS-CoV-2 positive patients did not directly influence the sample (n=6). However, the data were not collected during a typical year, with the paediatric critical care caseload at GOSH impacted. During multiple national lockdowns and an NHS incident Level 4, elective surgeries were cancelled and GOSH received patients from other London sites. National lockdowns, home-schooling and less socialisation resulted in a reduced number of respiratory infections (e.g., RSV bronchiolitis). GOSH admission data from 2018 (pre-pandemic) and 2020 (during the pandemic) are displayed in Table 7.42. They demonstrate the slightly reduced number of admissions, reduction in planned surgical activity and differences in diagnoses (PICANet, 2022).

Table 7.42 Admission data for the intensive care units at GOSH in 2018 and 2020

	2018	2020
<b>Total number of admissions, n</b>	1849	1725
<b>Number of patients requiring invasive ventilation, n (%)</b>	1492 (80.7)	1321 (76.6)
<b>Planned surgical admissions, n (%)</b>	799 (43.2)	651 (37.7)
<b>Diagnosis, n (%)</b>		
Respiratory	405 (21.9)	322 (18.7)
Cardiovascular	740 (40.0)	644 (37.3)
Neurology	186 (10.1)	147 (8.5)
Gastroenterology	123 (6.7)	199 (11.5)
Infection	36 (1.9)	41 (2.4)
Musculoskeletal	65 (3.5)	41 (2.4)
Oncology	58 (3.1)	76 (4.4)
Endocrine/metabolic	43 (2.3)	88 (5.1)
Other	192 (10.4)	167 (9.7)

### 7.5.6 Single centre

This study investigated practice at a single centre. Physiotherapy practice together with more general ICU management will be specific to GOSH. The variability in physiotherapy practice in the UK has been demonstrated in Section 3.3.4. This limits the generalisability of the results to other national and international centres. However, it has provided novel data to inform hypothesis generation for future multi-site studies, whilst also allowing development of methodological expertise.

### 7.6 Conclusion

This chapter has presented work package 2 which provided novel data regarding the occurrence of adverse events in the 60 minutes post-physiotherapy, potential risk factors and the impact on long-term outcomes. Adverse event rates post-physiotherapy varied depending on the physiological outcome. Ex-prematurity, emergency admissions and a respiratory diagnosis were identified as potential risk factors for adverse events. There was no association between occurrence of an OSI adverse event post-physiotherapy and length of ventilation or mortality.

## **8. Data synthesis**

As previously discussed in Section 2.2.4.3, data integration is an essential component of mixed methods research (Plano Clark, 2019, Rauscher and Greenfield, 2009). Integration through a 'building' approach has already been described in both work package 1 and 2. In the explanatory sequential design of work package 1, the questionnaire findings informed the development of the interview and focus group topic guides and prompted the document analysis study. In the overall convergent mixed methods design the perceived risk factors highlighted by physiotherapists in work package 1 were included within work package 2 data collection and analysis.

Detailed results and discussion for each study component have been included in the individual chapters. This chapter will integrate and merge the relevant findings from work packages 1 and 2. Results will be compared for similarities and differences and presented as narrative and through visual methods.

### **8.1 Work package 1 synthesis**

The individual studies included in work package 1 have been presented independently. This section will present the synthesis and triangulation of the results from phase 1 (questionnaire) and phase 2 (interviews, focus groups and document analysis) in relation to the research questions.

#### **8.1.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

Across the questionnaire, interview, and focus group components of work package 1 two key areas related to practice were discussed: the personnel involved in delivery of chest physiotherapy and treatment techniques used.

Variation in the personnel involved in chest physiotherapy was apparent. Two preferences for delivery of treatment were described in both the questionnaire and interviews. Physiotherapists treated independently or with another person. In contrast, all physiotherapists in the focus group study preferred to treat with another person. However, it is important to consider the limited geographical

representation of the focus groups and risk of bias towards certain institutions. The results of the document analysis also indicated variation in the number of individuals involved in delivering chest physiotherapy, specifically the guidance for the use of MHI.

The rationale provided by physiotherapists for treatment preferences was consistent between the interviews and focus groups. Physiotherapists who treated alone perceived it to be more effective, particularly related to the timing of treatment components. Involvement of a second person was described as improving stability and efficiency, whilst ensuring safety. There was considerable debate across work package 1 regarding the profession of the second person, with opinion split between treating with a nurse or another physiotherapist. Overall nurses were involved more frequently. The focus group study allowed the exact role of the second person to be explored, again the results demonstrated variation.

There was consensus between the questionnaire, interviews, and focus group results regarding the most frequently used combination of chest physiotherapy techniques; positioning, ETT saline instillation, MHI and CWV. However, focus group data highlighted subtle differences in the use of these treatments. This included not routinely using saline and frequency and choice of manual techniques, together with who performs the individual treatment components. Variation in the popularity of other treatments, including decompression, MI:E and percussion, was highlighted in the results of the questionnaire. These techniques were not discussed in phase 2, preventing further exploration.

#### **8.1.2 Research question 2: How do physiotherapists make decisions regarding delivery of chest physiotherapy in UK paediatric intensive care units, and what other factors influence this decision making?**

Clinical decision making was explored in all components of phase 1 and phase 2. The findings from phase 1 were related to specific elements of decision making, including frequency of treatment and patients who do not receive physiotherapy. The interviews and focus groups allowed an in-depth exploration of decision making. Interview data related to factors influencing decision making, whereas focus group data were more practical in nature and predominantly related to the processes involved.

There were several overlapping themes between the components of work package 1. The patient focussed nature of clinical decision making was described in the questionnaire, interviews, and focus groups. Comprehensive patient assessment was important to generate a detailed understanding of the patient and their problems. This allowed specific indications for physiotherapy to be determined. The influence of the physiotherapists' knowledge, skills, and experience were discussed in detail in the interviews and focus groups. Decision making was thought to evolve with experience, increased expertise, and confidence. Shared decision making with physiotherapy colleagues and other members of the MDT was described within the questionnaire and interviews. The involvement of family/carers was an important component also discussed in the interviews. These collaborations facilitated and supported decision making, but also provided challenges to the process. The key findings from the questionnaire, interviews and focus groups have been merged and summarised in Figure 8.1.

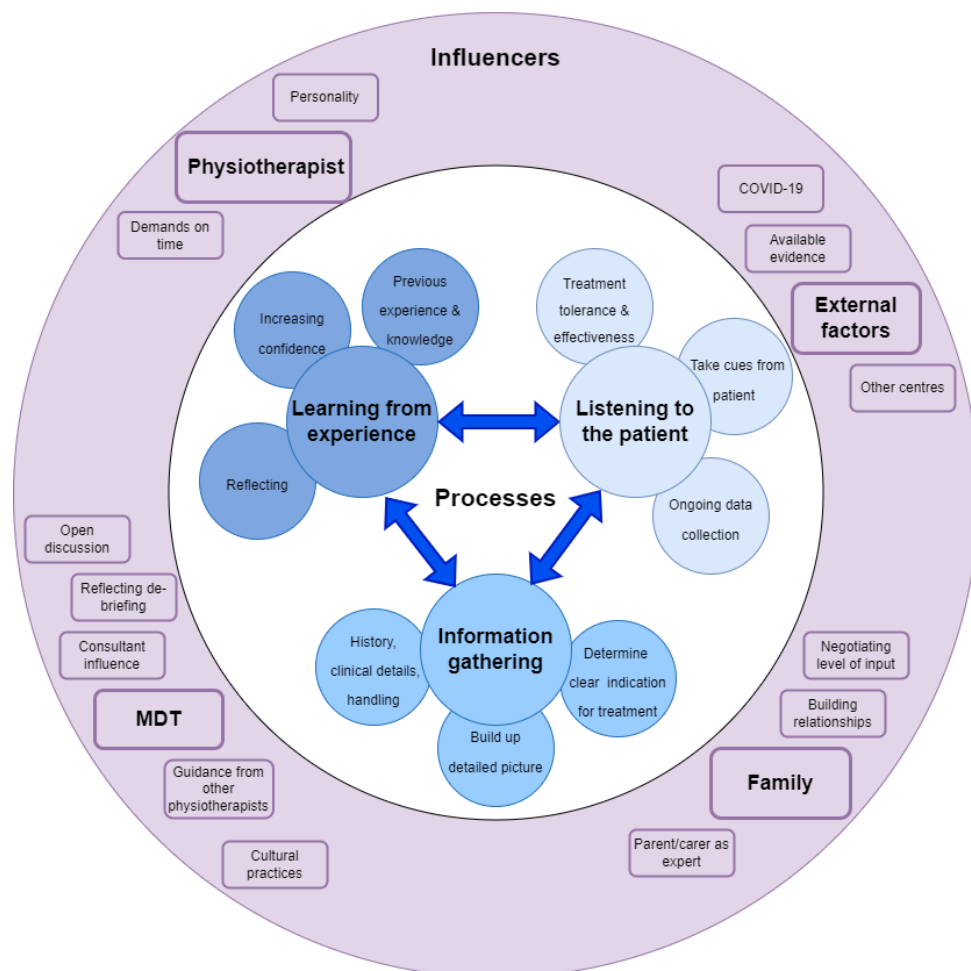


Figure 8.1 Summary of Physiotherapists' clinical decision making - processes and influencing factors

This conceptual model depicts physiotherapists' decision making on PICU as complex, iterative and collaborative, with experience and expertise important factors. It includes multiple, interacting components, and numerous challenges to effective decision making. The inner circle of the model focuses on the individual patient and physiotherapist involved in the process. The surrounding influencers incorporate other key stakeholders, together with external, wider factors. Higgs et al. (2019) also highlight the layered nature of factors influencing decision making in healthcare, describing local and global levels. An interprofessional shared decision making model developed by Légaré et al. (2011) comprises three levels, similar to those reported in the current study. The individual patient (micro) level, the meso level which acknowledges the influence of the professional team, and the macro level, the influence of system level factors.

Specific unit protocols or guidelines were highlighted in both the questionnaire and interviews as influencing practice and decision making. The inclusion of document analysis in phase 2 allowed these findings to be explored. Numerous clinical guidelines and standard operating procedures related to chest physiotherapy were available. The majority were related to specific treatments and were procedural documents, providing step by step instructions to standardise practice. The analysis indicated limited use to support decisions around choice of treatment and real-time bedside support. This contrasts with how they are perceived by some physiotherapists.

Similar findings of high levels of perceived autonomy were reported by physiotherapists in the questionnaire and interviews. In both data sets experience appeared to be associated with greater autonomy. The more detailed interview findings provided contextual details related to PICU hierarchy and discussed barriers and facilitators. Building a reputation, understanding of the physiotherapy role, rotational posts and developing MDT relationships were important considerations.



### **8.1.3 Research question 3: What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?**

Comprehensive data related to perceived risk factors for instability/adverse events were generated from the interviews, including types of patients, clinical presentation and support required. The focus group results were predominantly related to types of patients and included those highlighted in the interviews. Physiotherapists in the focus groups also mentioned additional patient types and those with a ceiling of care, where there was no room to escalate treatment. Figure 8.2 below illustrates the merged findings of the interviews and focus groups. It was discussed in both studies that complex patients who present with a combination of these characteristics, rather than just one in isolation, would be deemed higher risk.

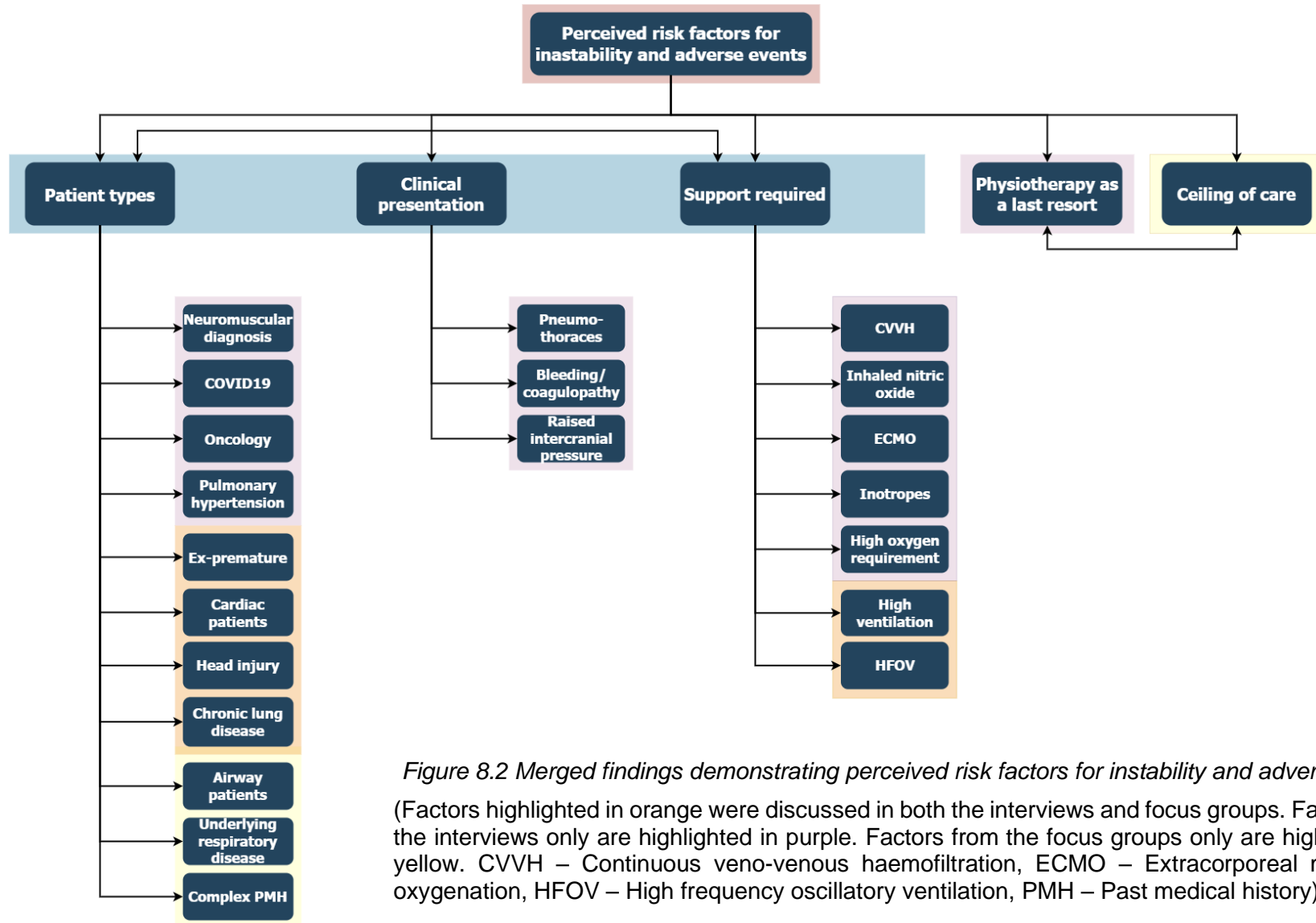


Figure 8.2 Merged findings demonstrating perceived risk factors for instability and adverse events (Factors highlighted in orange were discussed in both the interviews and focus groups. Factors from the interviews only are highlighted in purple. Factors from the focus groups only are highlighted in yellow. CVVH – Continuous veno-venous haemofiltration, ECMO – Extracorporeal membrane oxygenation, HFOV – High frequency oscillatory ventilation, PMH – Past medical history)

The physiological variables and strategies used to monitor patient stability during chest physiotherapy were highlighted in the questionnaire and focus groups. A range of variables were discussed and findings were similar. A direct comparison is displayed in Table 8.1. Five core measurements were described in both the questionnaire and focus group results.

*Table 8.1 A comparison of the approaches used by physiotherapists to monitor patient stability during treatment*

<b>Variables and strategies used to monitor stability</b>	
<b>Phase 1 - Questionnaire</b>	<b>Phase 2 – Focus groups</b>
Peripheral oxygen saturations Heart rate Blood pressure End tidal carbon dioxide Auscultation	Peripheral oxygen saturations Heart rate Blood pressure End tidal carbon dioxide Auscultation
Intercranial pressure Central venous pressure Blood gasses Sedation scores	Chest movement/expansion Lung compliance Observation of patient

Complementary data regarding the management strategies for instability and adverse events were collected in phase 1 and the phase 2 interviews and focus groups. Data synthesis resulted in five main themes linked to how physiotherapists manage instability and adverse events:

- Preparation and planning
- Involving the MDT
- Family inclusion
- Reacting and adapting
- Accepting instability

The importance of preparation and planning for an intervention was raised in the questionnaire results and discussed in both the interviews and focus groups.

Rationale provided was to ensure efficiency and safety. Physiotherapists aimed to minimise disruption to the patient, reducing opportunity for instability. The physiotherapists described wanting to understand the full picture of the patient, considering in detail what all potential consequences of treatment could be and how they would manage these. Practical approaches were used to minimise instability, including preparation of equipment, using pre-oxygenation, and sedation boluses.

Most physiotherapists reported that they shared the decision making for complex/unstable patients with other physiotherapists, the multidisciplinary team and the family/carers. This approach prevented any detrimental consequences of treatment lying solely with the physiotherapist. A popular opinion was the need to involve a second person with treatment. This linked to making the treatment as efficient and safe as possible. Physiotherapists of all levels of experience said they would consider having a consultant present in the bedspace or assisting with treatment in the case of instability.

There was consensus within the results around the importance of recognising instability during treatment and being able to react and adapt the treatment accordingly. Linked to acknowledging instability, having to sometimes accept shorter term unwanted effects for a better outcome in the longer term, was discussed. This was raised predominantly by the more experienced physiotherapists in the interviews and in focus group 1. It involved balancing the risks and benefits of treatment.

An interesting point raised during the managing instability and adverse events discussion was that of blame. This was only highlighted in focus group 2, by band 5/6 physiotherapists. Theoretically junior therapists may be more vulnerable to professional hierarchies. The interview findings support this. Less experienced physiotherapists reported fewer opportunities to develop rapport and gain respect within the MDT. Confidence levels may also play a part in the perception of being blamed for instability or adverse events. The lower confidence described by less experienced physiotherapists in the interviews may align with greater insecurity and a tendency to interpret comments from the wider team more personally.

## **8.2 Work package 1 and work package 2 synthesis**

Within the overall convergent mixed methods study there were two main areas for data synthesis between work packages 1 and 2. These related to chest physiotherapy treatments used and risk factors for instability and adverse events. Each will be linked to the research question and discussed in turn with data compared.

### **8.2.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

The merged findings of work package 1 determined position changes, ETT saline instillation, MHI and CWV to be the most frequently used chest physiotherapy treatments within UK PICUs. The results of work package 2 support these findings. Within the one-year study period, across the intensive care units at GOSH, the combination of ETT saline instillation and MHI with CWV was the most frequently used treatment (861/1361, 63.3%). When the treatment components were investigated individually a similar pattern emerged. MHI was used in 1312 (96.4%) treatments, CWV in 1103 (81%) treatments and ETT saline instillation in a total of 1072 (78.8%) treatments. It was not possible to determine the frequency of position changes within work package 2 as this variable was not captured consistently within the electronic patient records.

The phase 1 questionnaire demonstrated variation in frequency of use of other physiotherapy treatments, including percussion, MI:E, chest wall decompression and directed saline lavage. Use of these treatments ranged between 'often' and 'never'. Although difficult to compare accurately, due to the subjective nature of the Likert scale responses, these treatments were also used rarely within the study period at GOSH. Chest wall decompression was used in 78/1361 (5.7%) treatments, directed saline lavage in 24/1361 (1.8%), percussion in 8/1361 (0.6%) and MI:E was not used.

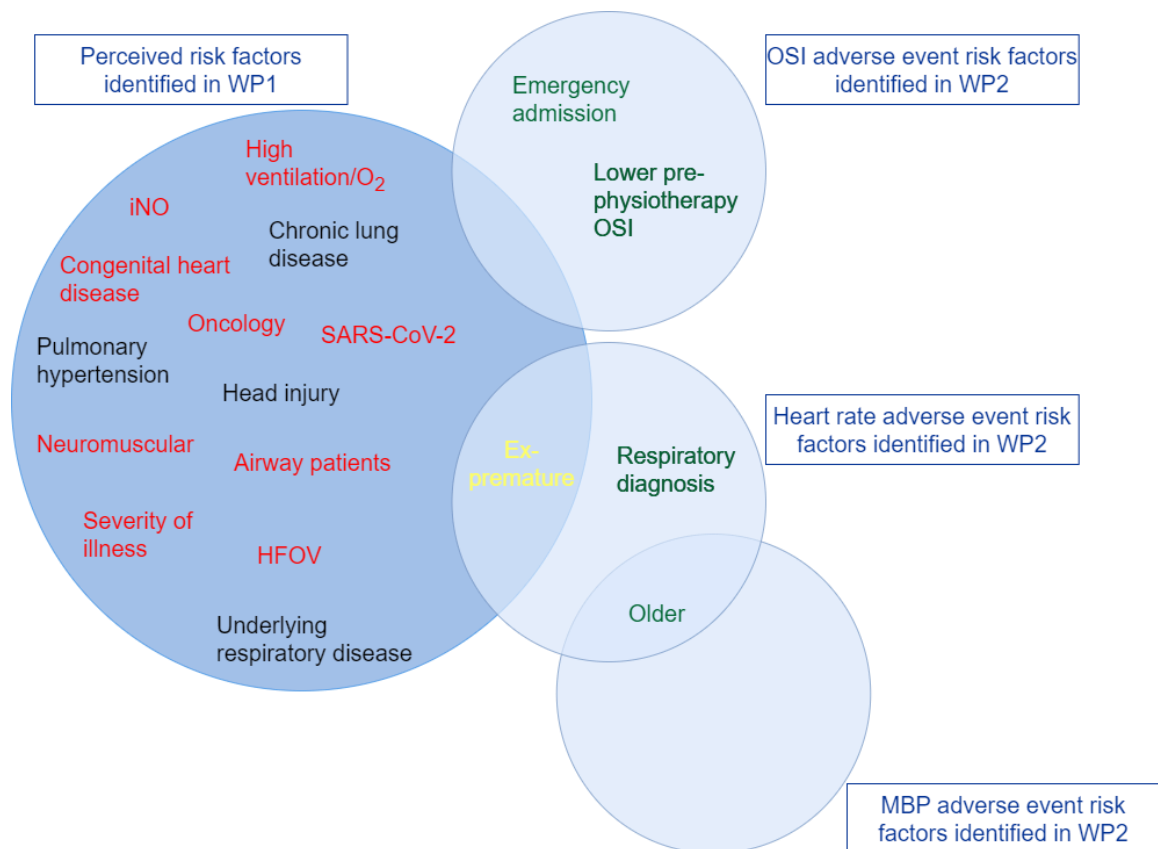
The questionnaire results indicated open ETT suction was more frequently used than closed suction in UK PICUs. This is in line with the practice described in work package 2. Open suction was used in 1260/1361 (92.6%) of physiotherapy treatments. In work package 2 closed suction was used infrequently by

physiotherapists at GOSH (67/1361, 5%). However, National practice appeared to be more variable, with reported frequency ranging between 'always' and 'never'. When comparing the findings of work packages 1 and 2, differences in the populations need to be considered. Data collected in work package 1 related to mechanically ventilated children of all ages (0-18 years), whereas specific inclusion criteria, children aged 0-4 years, were used in work package 2. This may account for some of the discrepancies related to physiotherapy practice.

### **8.2.2 Research question 5: What are the risk factors/characteristics of children who display instability and/or adverse events associated with chest physiotherapy?**

A key component of this study was to identify risk factors for instability and adverse events associated with chest physiotherapy. Within work package 1 physiotherapists discussed numerous risk factors and characteristics which they perceived to be associated with instability. These included specific patient types, clinical presentation and support required. Work package 2 provided a description of patients with and without adverse events. Univariable analysis was completed to determine any significant differences between groups, enabling potential risk factors/characteristics to be identified. However, it is important to reinforce the observational nature of this study and that causality cannot be inferred.

The perceived risk factors identified in work package 1 and those identified in work package 2 are compared in Figure 8.3.



*Figure 8.3 Comparison of perceived risk factors from work package 1 and risk factors identified in work package 2 analysis*

(Ex-premature highlighted in yellow was identified as a potential risk factor for adverse events in both work packages 1 and 2. Risk factors highlighted in red were also included in work package 2 analysis, but results were not statistically significant. Risk factors in black were discussed in work package 1 but not investigated in work package 2. Potential risk factors for adverse events identified in work package 2 are in green. HFOV – High frequency oscillatory ventilation, iNO – Inhaled nitric oxide, O<sub>2</sub> – Oxygen, OSI – Oxygen saturation index, WP1 – Work package 1, WP2 – Work package 2.)

Of the perceived risk factors discussed by the physiotherapists in work package 1 only ex-prematurity was also identified in the work package 2 analysis. This potential risk factor only related to heart rate adverse events. Several of the characteristics highlighted in work package 1 were included in the work package 2 analysis (those highlighted in red in Figure 8.3) however there were no statistically significant differences related to these. The limitations discussed previously (Section 7.5) related to availability of OSI data and the single centre study may account for the lack of variation between groups.

Within work package 1 patients requiring high levels of oxygen and/or ventilation were frequently discussed as being high risk for instability and adverse events.

Conflicting findings were presented in work package 2, with the majority of adverse events occurring in patients with lower pre-physiotherapy OSI. The discrepancy in these findings may be due to a more relaxed approach adopted by physiotherapists with these 'lower risk' patients. Alternatively, as previously discussed in Section 7.4.2, the intervention may be more harmful in those patients who are less critically ill.

### **8.3 Conclusion**

This chapter has presented the final stages of data integration. Data from work package 1 has been merged and appropriate findings triangulated, to allow overall results to be presented. Data exhibiting divergence has also been highlighted. Work packages 1 and 2 data have been synthesised to give wider context to the single-centre results.



## **9. Conclusions and future directions**

This chapter summarises the work completed as part of this doctoral thesis. It provides a summary of the main findings and an overview of the strengths and limitations. Recommendations for clinical practice and future research directions will be discussed. The chapter concludes with a personal reflection.

### **9.1 Summary of findings**

This was a mixed methods study to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children. To fully explore and achieve this aim six research questions were answered. Summaries of the main findings related to each question are discussed individually below.

#### **9.1.1 Research question 1: What is current chest physiotherapy practice within UK paediatric intensive care units?**

Chest physiotherapy was a popular treatment option for mechanically ventilated children on PICU. All responding physiotherapists reported providing treatment to this population. Treatments were provided based on individual patient need and clinical indications, rather than in a routine manner. A variety of chest physiotherapy techniques were used. The most frequently used techniques included positioning, ETT saline instillation, MHI and CWV. Mucoactive agents, as adjuncts to chest physiotherapy, were also frequently used, with nebulised 3% and 7% hypertonic saline the most common.

Variation in practice was apparent. This related to the personnel involved in treatment, with physiotherapists' preferences varying between treating alone, with another physiotherapist, or a nurse. There was further discordance in the role the nurse adopted, with some individuals describing a 'double' treatment (the nurse completing MHI and physiotherapist CWV). There was variation in the popularity of some physiotherapy techniques, including percussion, MI:E, chest wall decompression and directed saline lavage. Inconsistencies were also demonstrated in the frequency of use and delivery method of N-acetylcysteine.

Variation was attributed to individual and organisational factors. The lack of robust evidence supporting chest physiotherapy was frequently discussed and thought to reinforce reliance on individual experience and historical practice. Linked to this, difficulties affecting change within both physiotherapy and the wider MDT were reported. Resource availability, including physiotherapy staffing and nursing workload, also influenced treatment approaches.

### **9.1.2 Research question 2: How do physiotherapists make decisions regarding delivery of chest physiotherapy in UK paediatric intensive care units, and what other factors influence their decision making?**

Physiotherapists described decision making as complex, iterative and collaborative, with experience and expertise being important factors. A combination of elements from both analytical and intuitive clinical decision making models were described. The influencing factors can be considered at three levels, the individual, the team, and wider, external influences.

The individual patient was central to decision making. Active information gathering and a comprehensive patient assessment were described. This ensured a detailed understanding of the patient, individual problems to be identified and the risk and benefits of treatment balanced. This was an iterative process, continuing at the bedside. Individual physiotherapist experience was described as a key component. Less experienced physiotherapists in this study reported lower confidence and levels of autonomy, and communication challenges. Approach to decision making evolved with experience, facilitated by opportunities for reflection and learning, plus the development of gut instinct.

Collaboration was integral to physiotherapists' decision making. This included physiotherapy colleagues, the MDT and, importantly, patients' family/carers. Whilst this shared decision making was acknowledged as essential and advantageous it posed additional challenges. Several physiotherapists described a culture of professional hierarchy in which their opinions were disregarded. The involvement of family/carers in decision making was highlighted as creating additional pressure to provide treatment and the need for negotiation. Wider or external influences on decision making included national projects and initiatives, support from other centres, and the COVID19 pandemic. Physiotherapists

perceived institutional documents, such as guidelines and SOPs, to influence practice and decision making, however the document analysis findings contradict this. The analysis indicated limited support for decisions around choice of treatment or real-time bedside support.

### **9.1.3 Research question 3: What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?**

The physiotherapists provided a comprehensive list of perceived risk factors for instability and adverse events. This included specific patient types (e.g., congenital heart disease, ex-premature, chronic lung disease), clinical presentations (e.g., pneumothorax, coagulopathy) and support required (e.g., high ventilation, renal replacement therapy). A common opinion was that complex patients who presented with a combination of these characteristics would be deemed higher risk. Several physiotherapists discussed the high-risk nature of providing physiotherapy as a last resort or where a ceiling of care was in place. These patients were critically ill and often did not tolerate treatment well.

Five main themes were derived from the results related to how physiotherapists approach the management of these 'high-risk' patients: preparation and planning, involving the MDT, family inclusion, reacting and adapting, and accepting instability. Preparation and planning were key strategies to maximise efficiency and ensure safety. This approach included consideration of all possible consequences of treatment and the use of practical actions (e.g., pre-oxygenation). Decision making for complex/unstable patients was shared with other physiotherapists, the multidisciplinary team and the family/carers. Additionally, all physiotherapists described having more senior support available at the bedside in these circumstances. The importance of recognising instability during treatment and being able to modify treatment accordingly was highlighted. Physiotherapists also acknowledged that in some situations they would accept short-term unwanted effects for an improved outcome in the long-term.

#### **9.1.4 Research question 4: What is the incidence of physiological instability and adverse events associated with chest physiotherapy in ventilated children?**

The adverse event rates within the 60-minute post-physiotherapy period differed between OSI, heart rate and mean arterial blood pressure. For the first physiotherapy treatment OSI adverse event rates were between 7.4% and 9.3%. The highest rate was in the 5-minute period immediately after physiotherapy, which decreased over 30 minutes before increasing at the 60-minute epoch. A similar pattern of OSI adverse events was seen in subsequent physiotherapy treatments, days 2 to 4.

When the components of OSI were analysed individually for the first treatment, low rates of SpO<sub>2</sub> (0-1.2%) and FiO<sub>2</sub> (2.1-3.6%) adverse events were observed. This may indicate that the threshold used for OSI adverse events was more sensitive.

Rates of heart rate adverse events were lower than those reported for OSI (2.6-4.9%). Mean arterial blood pressure demonstrated the highest rate of adverse events in the 60 minutes post-physiotherapy (10.9-16.5%). However, this needs to be interpreted with caution as there is a risk of selection bias towards patients with an arterial line.

Very few patients were identified as having both OSI and cardiovascular adverse events (1.1%). These findings likely reflect the swift and effective management of instability on PICU, preventing multi-system deterioration.

#### **9.1.5 Research question 5: What are the risk factors/characteristics of children who display instability and/or adverse events associated with chest physiotherapy?**

An emergency admission to CICU was identified as a potential risk factor for an OSI adverse event following physiotherapy. In this study a statistically significant higher proportion of patients with an adverse event were emergency admissions compared to those without ( $\geq 2$  adverse events (n=18), elective admission n=1 (5.6%), emergency admission n=17 (94.4%),  $p < 0.001$ ). No other significant differences were observed between the patients with an OSI adverse event and

those without. A further observation was that the majority of OSI adverse events occurred in patients with a lower pre-physiotherapy median OSI. This may reflect deterioration in less critically ill children, highlighting the potential for adverse events in all patients, regardless of severity of illness.

Potential risk factors identified for heart rate adverse events were age-group, respiratory diagnosis, and ex-prematurity. There were statistically significant differences in these characteristics between patients with and without an adverse event. Patients identified as having a heart adverse event were also treated less frequently with CWV, however the clinical relevance of this finding is unknown. Patients with a mean blood pressure adverse event were statistically significantly older than those without, however this was not deemed clinically important.

#### **9.1.6 Research question 6: What is the long-term impact on the child of instability and adverse events associated with chest physiotherapy?**

The study demonstrated no association between the occurrence of an OSI adverse event in the 60 minutes post-physiotherapy and length of ventilation or mortality. These findings relate only to a subgroup of invasively ventilated children, aged 0-4 years, cared for on a cardiac intensive care unit. However, the results provide reassuring preliminary data regarding the risk of chest physiotherapy in this population.

## **9.2 Strengths**

This is the first study to primarily investigate the safety of chest physiotherapy in mechanically ventilated children and explore the wider contextual factors. It has provided novel data regarding a popular treatment used in a vulnerable patient group, with all study components capturing data not previously available.

The study involved several novel elements. Physiotherapists from UK PICUs were actively involved in work package 1. They were given opportunity to provide their perspective and have their 'voices heard'. This enabled comprehensive understanding of chest physiotherapy practice, delivery and clinical decision making, in a previously unstudied clinical setting. Additionally, it cultivated engagement, generated interest in the project and reinvigorated the professional

network. This will be essential for the dissemination of findings and any future multi-site projects. Work package 2 was designed specifically to address limitations identified in previous studies. The pragmatic design enabled patients to be studied in a real-life context. The effects of multiple physiotherapy treatments and impact on long-term outcomes were incorporated. This approach was possible due to the novel use of high-resolution monitor and ventilator data in combination with electronic patient records. Access to these capabilities improved data accuracy and standardised the data collection process. It also provided the largest sample of patients used in research involving chest physiotherapy ventilated children.

The use of mixed methods has provided a comprehensive and deeper contextual understanding of the research problem. By adopting a problem driven methodological approach, a range of different tools were used to gather complementary data. In work package 1 the synthesis and integration of questionnaire, interview, focus group and document analysis data minimised research bias and enhanced the validity of the findings. Although work package 2 was a single centre study the overall convergent design ensured the analysis was informed by national practice and enabled the results to be positioned in a wider context. Given the dual researcher/clinician role of the primary researcher (ES) a reflexive approach was adopted throughout. This enabled ES to provide clinical context and relevance, whilst being aware of her own biases. The use of an external moderator in the focus groups further enhanced the rigor and transparency of this study phase.

### **9.3 Limitations**

Detailed discussion of the limitations relevant to each study component has been included within the individual chapters.

A significant challenge during the project was the COVID19 pandemic, this had implications across work package 1 and 2. Data collection was delayed and extended over a longer period. The phase 1 response rate was lower than anticipated (61%), partially attributed to the re-purposing of PICUs and re-deployment of physiotherapy staff. Virtual interview and focus group methods had

to be adopted, altering the type of interactions experienced and potentially the level of data collected. The paediatric critical care caseload at GOSH was impacted, hence work package 2 data were not representative of a typical year.

A summary of key, non-COVID19 related limitations is displayed in Table 9.1.

*Table 9.1 Summary of key study limitations presented by work package*

Work package 1	Work package 2
<p><b>Geographical representation</b></p> <ul style="list-style-type: none"> <li>• Certain institutions over represented</li> </ul> <p><b>Practice and behaviour self-reported</b></p> <ul style="list-style-type: none"> <li>• Results may not reflect actual practice</li> </ul>	<p><b>Retrospective design</b></p> <ul style="list-style-type: none"> <li>• Causality cannot be inferred</li> </ul> <p><b>Only post-physiotherapy period analysed</b></p> <ul style="list-style-type: none"> <li>• Occurrence of instability/adverse events during physiotherapy unknown</li> </ul> <p><b>Missing data</b></p> <ul style="list-style-type: none"> <li>• OSI data only available for a sub-group of CICU patients</li> </ul>

(CICU – Cardiac intensive care unit, OSI – Oxygen saturation index)

#### **9.4 Implications and recommendations for clinical practice**

The results of this project and the discussion generated have highlighted a number of implications and recommendations for clinical practice. These relate to individual physiotherapist practice, educational needs, psychological support, and the wider system. These will be explored individually.

##### *The individual physiotherapist*

This study highlighted emergency admission to CICU and a respiratory diagnosis as potential risk factors for an OSI or heart rate adverse event respectively. These characteristics were not amongst the numerous risk factors discussed by

physiotherapists in work package 1. Hence it is important to share these findings with clinicians. These risk factors need to be presented in the context of new or additional characteristics physiotherapists may want to consider during decision making and in post-treatment management. Given the numerous limitations related to work package 2 it should be emphasised that recommendations do not include to disregard those established perceived risk factors discussed in work package 1. Instead, the results of this study aim to enhance and support physiotherapists current knowledge base and approach to treatment.

In this study the majority of OSI adverse events were identified in patients with lower pre-physiotherapy OSI, which conflicts with physiotherapists' perceptions that more critically ill, complex patients, i.e., those with higher OSI, are at greater risk of instability and adverse events. These findings highlight the importance of clinicians anticipating instability and adverse events in all patients, irrespective of severity of illness.

Understanding which children may benefit most from physiotherapy and in which situations it poses a significant risk, is a complex process. The preliminary long-term data presented in this study demonstrated no association between occurrence of OSI adverse event following physiotherapy and length of ventilation or mortality. These findings offer support for the approach described by physiotherapists to accept some degree of instability in the short-term for improvements in the long-term, indicating circumstances in which the benefits of chest physiotherapy outweigh the risks. Although caution is required when interpreting these results due to the retrospective design and subgroup under investigation, they provide novel insight for PICU physiotherapists regarding the risk versus benefit conundrum.

#### *Educational needs*

The results of this project have highlighted several areas that require consideration from an education perspective. The impact of experience was a common theme in this study. Less experienced physiotherapists reported lower confidence and described decision making as more challenging. The increased support and supervision required by junior physiotherapists working on PICU was clearly



highlighted. This has several implications for individuals working on PICU and physiotherapy teams. Joint treatment sessions and opportunity for reflection should be part of day-to-day practice, to provide junior therapists with adequate support. However, this has an additional impact on workforce planning. The increased demands on senior/static physiotherapists needs to be accommodated. Physiotherapists described learning through exposure. In response to this the role of simulation-based learning should be considered. Simulation education is commonplace within PICU and is becoming more popular within physiotherapy. It provides hands-on learning in an immersive environment, which is safe and supportive (Harwayne-Gidansky et al., 2020). Currently simulation education specifically for PICU physiotherapists is only available in a limited number of UK centres, further development to improve access would be beneficial.

The challenges of communicating and negotiating with families was also raised by the less experienced physiotherapists in this study. Shared decision making and family centred care are considered the gold standard within PICU (Davidson et al., 2017, Sánchez-Rubio et al., 2021). Therefore, effective communication with parents/carers is essential. However, the interaction between therapist and parent/carer is unique and complex. Formal training and opportunities to practice and develop these skills are limited. The results of this study suggest greater emphasis should be placed in this area both at an undergraduate level, where paediatrics is not yet a compulsory module, as well as within the workplace.

The educational needs of the wider MDT were also raised in this study. In situations where colleagues had a good understanding of the role of physiotherapy, including indications and contra-indications, relationships were more positive and respectful, and levels of perceived autonomy higher. This was also thought to facilitate shared decision making. It is therefore recommended that education related to the role of the physiotherapist is incorporated as an element of routine training for new starters of any profession on PICU.

### *Psychological support*

Paediatric intensive care is a complex, stressful and unpredictable environment. The psychological burden of working in this challenging field, including end of life

care, moral distress, and burnout, is widely acknowledged within medical and nursing professions (Jones et al., 2020, Mu et al., 2019). This subject is relatively overlooked within the field of physiotherapy. This study highlighted a cohort of PICU physiotherapists who found themselves present and feeling responsible for a patient's death. How these circumstances are managed, and physiotherapists' distress and experiences processed, are important considerations. Mechanisms should be in place to support PICU physiotherapists. All members of the PICU team should have routine access to wellbeing initiatives and training related to stress management, avoiding burning out and end of life care. Close working relationships with palliative and symptom care teams are important. These specialists can support decision making and provide advice on appropriate communication strategies. PICU physiotherapists should have access to psychological support, including 1-to-1 sessions with a psychologist. Following the death of a patient it is essential physiotherapists are involved in team de-briefs and have opportunities to attend clinical review or morbidity and mortality meetings.

### *The wider system*

Reliance on historical practice within both physiotherapy and the wider MDT was a common theme in this study. To reduce variability, facilitate evidence-based practice and initiate progress within the profession, PICU physiotherapists could take greater responsibility for implementing change. PICU physiotherapists are ideally placed to champion new ideas, provide multi-professional education to gain buy in and engagement, and communicate success, all of which are key components to implementing change (Hopkins et al., 2015, Kotter, 1995, Steffen et al., 2021). There are several examples of successful change implementation in PICU involving the multidisciplinary team (Patel et al., 2021, Simone et al., 2017). Physiotherapists involved in this study demonstrated willingness and enthusiasm to collaborate and network with peers from other centres, which will help maximise physiotherapy impact.

This study has outlined how variability in service provision, related to physiotherapy staffing levels on PICU, influences variability in practice. Central guidance on physiotherapy workforce levels is necessary, to ensure all critically ill patients receive similar levels of physiotherapy input. To initiate this, national

collaboration and involvement of key stakeholders are required. Standardisation would also provide greater opportunities to conduct robust, multi-site studies investigating the effects of chest physiotherapy.

## **9.5 Future research directions**

Specific suggestions for further exploration and investigation have been highlighted within the relevant discussions and limitations of the individual chapters. However, there are four key areas for future research that have emerged through this project.

1. An ongoing challenge identified by this study is the lack of consensus regarding adverse event definitions for ventilated children. In the studies discussed, change in physiological variables, used as adverse event definitions, ranged between 5-20% (e.g., SpO<sub>2</sub>, heart rate). Development of a set of standardised instability and adverse events definitions is required. This could be achieved through consensus methodology, such as a Delphi study. This approach has been used previously to successfully determine core-outcome sets (Blackwood et al., 2019). A standardised description would improve the relevance and generalisability of future research.
2. Whilst this study has provided novel data regarding potential risk factors for instability and adverse events, this is only preliminary and in a limited patient cohort. Further research to formally identify risk factors for instability and adverse events associated with physiotherapy would be useful. Ideally this would enable the development of a risk stratification tool or predictive model to support decision making. Suggestions include a multi-site study, involving a larger heterogeneous sample and incorporating during- and post-physiotherapy time periods.
3. The effectiveness and safety of single and double treatment approaches for MHI with CWV requires further investigation. This was a key area demonstrating variation in practice. A pragmatic approach could be used in the form of a prospective, observational study involving sites which employ the different treatment approaches. It would involve single physiotherapy

treatments and outcome measures including force and respiratory profiles e.g., expiratory flow bias and peak inspiratory pressure, together with clinical variables. Alternatively, a crossover methodology may be suitable, in which participants act as their own controls. This design has previously been used in physiotherapy research on PICU (Main et al., 2004, Shannon et al., 2015a).

4. Mucoactive agents are a popular treatment used in children who are mechanically ventilated. All physiotherapists in this study reported using mucoactives as an adjunct to chest physiotherapy. Only provisional data were gathered in this study. There is mixed evidence to support their effectiveness in this population, and minimal literature to guide choice of agent and delivery method. This is an area requiring further research.

### **9.5.1 Priorities**

A range of potential areas for further investigation have been discussed throughout the thesis and within this chapter. However, in completing this thesis and to build on the programme of study there are two priority areas for future work.

One priority is to complete the secondary analysis of the data collected in work package 2. This component of the study generated a novel data set, and it is important to fully explore this. Specific areas for further analysis include: the investigation of different OSI adverse event thresholds, more detailed exploration of adverse events from an individual participant perspective, and analysis of heart rate and mean blood pressure adverse events days 2-4.

Investigating the use of mucoactive agents within UK PICUs is a priority area. This subject is relevant to a variety of clinicians on PICU, including medics, nursing staff and pharmacists. Additionally, research in this area has the potential to impact care for a wide range of patient populations on PICU. A starting point, to provide an accurate understanding of current practice and data to inform an interventional trial, would be a point prevalence study involving PICUs within the UK.

## 9.6 Personal reflection

Work within this thesis has been completed over 42 months and has provided numerous opportunities to gain knowledge and skills, and for collaboration and networking. There have also been challenges, predominantly related to COVID19, the implications of which have been discussed throughout. I will conclude this thesis by discussing three key areas of personal development.

### *Navigating research processes*

Completing a research study is fraught with complex processes and red tape. As a novice researcher it can be challenging to navigate these pathways effectively and efficiently. Early in the study I faced numerous delays starting data collection. There was initial confusion around the study approvals required, which resulted in an incorrect IRAS submission. The process had to be re-started, which resulted in a significant delay. A further delay occurred due to work package 1 being considered multi-site and the additional site-specific approvals this required. I found this process extremely frustrating. On reflection my naivety and feelings of 'imposter syndrome' led me to blindly follow incorrect advice. As my PhD journey continued I gained knowledge and confidence. Subsequently I have developed experience in completing HRA amendments, participant recruitment, consent and budget management. In leading this multi-site study I have developed research management skills which will be transferable to future projects.

### *Use of high-resolution data*

As part of this project I used routinely collected high-resolution monitor and ventilator data from T<sup>3</sup> eitiometry in combination with electronic patient records from EPIC. From a practical skills perspective this required me to understand data programming language and learn to code in R project. Experience working with high-resolution data and possessing analysis skills will prove to be valuable tools for further research. It provides scope over and above traditional methods, including multivariable analysis and augmented decision making. I was the first person to use both monitor and ventilator data with electronic patient records. This required a close working relationship with the GOSH DRIVE data science team. Identifying and extracting the relevant variables from electronic patient records

was a steep learning curve for all involved but has provided methodological experience for other projects within GOSH. Related to the physiotherapy variables, I have created a data processing pipeline which can be used to streamline future data collection. Work package 2 has strengthened my enthusiasm for quantitative methodology and I believe the skills developed over the course of the study will enable my involvement in wider critical care trials.

### *Qualitative methodology*

Prior to completing this study I had minimal experience in qualitative methodology. I have now had exposure to a range of qualitative data collection methods, having developed expertise in interviewing, focus groups and document analysis. By consistently using Framework analysis I have gained an in-depth understanding of this analysis technique. The qualitative process I found most challenging was the introspection and personal reflection required to establish my own influences and biases. Whilst this pushed me outside my comfort zone, it has resulted in improved self-awareness and reflexivity. Completing this mixed methods study has allowed me to appreciate the value of qualitative methods and their relevance in clinical practice, where context and perspective are vital.

## **9.7 Overall conclusion**

This thesis has presented the first study to exclusively investigate the safety of chest physiotherapy in mechanically ventilated children. A convergent mixed methods approach was used to provide a comprehensive exploration of the risk factors for instability and adverse events associated with chest physiotherapy and allow the wider contextual factors to be examined. Novel data have been generated, related to current UK practice, the complex decision making processes on PICUs, the incidence of adverse events following physiotherapy and potential risk factors. Several recommendations for future research have been included to ensure the risks and benefits of chest physiotherapy in this vulnerable population are more extensively understood.

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## 12. Appendices

Appendix 1 – Chest physiotherapy for mechanically ventilated children: a systematic review.

Available at <https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0041-1732448>

## Appendix 2 – Qualitative training programme

<b>Training</b>	
<i>UCL</i>	Statistics for Researchers: Observational Studies
	CASC Introduction to R course
	CASC Introduction to regression analysis
	CASC Further Topics in R
	Mixed method approach in social sciences
<i>External</i>	Introduction to Qualitative Research: Thematic Analysis
	Digital Qualitative Interviews, Social Research Association
	Reporting qualitative data, Social Research Association
	SPCR Mixed Methods, NIHR School for Primary Care Research
	Conducting online focus groups, Social Research Association





## Appendix 4 – Ethical approvals



Miss Emma Shkurka  
Physiotherapist/PhD student  
Great Ormond Street Hospital for Children NHS  
Foundation Trust  
Great Ormond Street  
London  
WC1N 3JH

06 February 2020

Dear Miss Shkurka,

**HRA and Health and Care  
Research Wales (HCRW)  
Approval Letter**

**Study title:** Identifying and understanding risk factors for instability and adverse events associated with chest physiotherapy in ventilated children  
**IRAS project ID:** 278215  
**Sponsor:** UCL GOS Institute of Child Health

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.



Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)  
[HCRW.approvals@wales.nhs.uk](mailto:HCRW.approvals@wales.nhs.uk)

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

**What are my notification responsibilities during the study?**

The "[After HRA Approval – guidance for sponsors and investigators](#)" document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

**Who should I contact for further information?**

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 278215. Please quote this on all correspondence.

Yours sincerely,  
Laura Greenfield

Approvals Specialist

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)



---

06 February 2020

Professor Mark Peters  
Institute of Child Health  
UCL

Dear Prof. Peters

**Notification of Ethics Approval**

**Project ID/Title: 16837/001: Identifying and understanding risk factors for instability and adverse events associated with chest physiotherapy in ventilated children.**

I am pleased to confirm in my capacity as Chair of the UCL Research Ethics Committee (REC) that I have ethically approved your study until 30 April 2022.

Ethical approval is granted subject to the following conditions:

**Notification of Amendments to the Research**

You must seek Chair's approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing an 'Amendment Approval Request Form'  
<http://ethics.grad.ucl.ac.uk/responsibilities.php>

**Adverse Event Reporting – Serious and Non-Serious**

It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator ([ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Joint Chairs will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Joint Chairs of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Joint Chairs will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

**Final Report**

At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research

Office of the Vice Provost Research, 2 Taviton Street  
University College London  
Tel: +44 (0)20 7679 8717  
Email: [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)  
<http://ethics.grad.ucl.ac.uk/>

i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.

In addition, please:

- ensure that you follow all relevant guidance as laid out in UCL's Code of Conduct for Research: <https://www.ucl.ac.uk/srs/file/579>
- note that you are required to adhere to all research data/records management and storage procedures agreed as part of your application. This will be expected even after completion of the study.

With best wishes for the research.

Yours sincerely



Professor Lynn Ang  
Joint Chair, UCL Research Ethics Committee

## Appendix 5 – All UK NHS Paediatric intensive care units

### **UK NHS Paediatric Intensive Care Units (PICANET, 2021)**

Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust  
Alder Hey Children's NHS Foundation Trust  
Birmingham Children's Hospital, Birmingham Women's and Children's NHS Foundation Trust  
Bristol Royal Hospital for children, University Hospitals Bristol NHS Foundation Trust  
Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust  
Freeman Hospital, The Newcastle Upon Tyne Hospitals NHS Foundation Trust  
Glenfield Hospital, University Hospitals of Leicester NHS Trust  
Great North Children's Hospital – The Newcastle Upon Tyne Hospitals NHS Foundation Trust  
Cardiac Intensive Care, Great Ormond Street Hospital for Children NHS trust  
Paediatric Intensive Care, Great Ormond Street Hospital for Children NHS trust  
John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust  
Kings College Hospital NHS Foundation Trust  
Leeds Children's Hospital, The Leeds Teaching Hospitals NHS Trust  
Leicester Royal Infirmary, University Hospitals of Leicester NHS Trust  
Noah's Ark Children's Hospital for Wales, Cardiff and Vale University Health Board  
Royal Belfast Hospital for Sick Children  
Royal Brompton & Harefield NHS Foundation Trust  
Royal Hospital for Children – NHS Greater Glasgow and Clyde  
Royal Hospital for Sick Children Edinburgh, NHS Lothian  
Royal Manchester Children's Hospital, Manchester University NHS Foundation Trust  
Royal Stoke University Hospital, University Hospitals of North Midlands NHS Trust  
Sheffield Children's NHS Foundation Trust  
St Georges University Hospitals NHS Foundation Trust  
St Mary's Hospital, Imperial College Healthcare NHS Trust  
The Queen's Medical Centre, Nottingham University Hospitals NHS Trust  
The Royal London Hospital, Bart's Health NHS Trust  
University Hospital Southampton NHS Foundation Trust



Participant Information Sheet for Physiotherapist Questionnaire



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with CHest physiotherapy in ventilated children**

UCL Research Ethics Committee Approval ID Number: 16837/001  
IRAS Project ID: 278215  
Researcher:  
Emma Shkurka, Physiotherapist and PhD student, Great Ormond Street Institute of Child Health, UCL  
Supervisors:  
Professor Mark Peters  
Dr Harriet Shannon  
Dr Jo Wray

Thank you for showing an interest in completing a questionnaire for this project. Before deciding whether to complete the questionnaire, please read all the information below to make sure that you understand what is involved. I am carrying out this study as part of an educational project, specifically a PhD which I am completing at University College London. A link to complete the questionnaire is at the bottom of this document.

**What is the project's purpose?**

Paediatric intensive care units (PICU) support the complex medical needs of children with life threatening conditions. There are 20000 admissions annually within the United Kingdom. Chest physiotherapy is considered an integral part of care for these patients and national standards report that PICUs require 24 hour access to physiotherapy. Despite the role of chest physiotherapy being widely acknowledged the overall clinical impact is unknown. Chest physiotherapy has been associated with instability and adverse events. Significant fluctuations in stability can contribute to organ failure or lung damage, with the potential to lead to a prolonged PICU admission or even death. At present the risks and benefits of chest physiotherapy in ventilated children are unknown. Additionally how PICU physiotherapists make decisions regarding delivery of chest physiotherapy and manage risks of instability and adverse events has not been studied. It is important to identify which patients are likely to benefit most and in which situations chest physiotherapy may present a significant risk.

The overall study aim is to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children. This specific phase of the study will use an anonymous questionnaire to describe current chest physiotherapy practice in the UK.

In this questionnaire we would like to find out;

- What chest physiotherapy techniques are used
- What the referral processes are for chest physiotherapy on paediatric critical care units
- How physiotherapists make decisions about treatments
- How chest physiotherapy treatments are monitored

**Why have I been chosen?**

You have been asked to take part as you are a physiotherapist on a paediatric intensive care unit within the UK. All physiotherapists who work in the UK in paediatric intensive care units have been asked to take part.

**Do I have to take part?**

No, you do not have to take part. If you do decide to take part submission of a completed survey will imply consent. Because the survey is completed anonymously, once you have submitted your answers you will not be able to withdraw from the study.

**What will happen to me if I take part?**

You will receive a link to an electronic questionnaire. You can complete the questionnaire at any time convenient to you, it will take up to 15 minutes and it will be submitted anonymously.

**What are the possible risks and benefits of taking part?**

We do not anticipate any risks with taking part. It is expected that this project will create a new network of specialist PICU physiotherapists, increasing collaboration, sharing of practice and joint research. As a participant you will be invited to join this group. It is hoped that this project will provide some guidance for chest physiotherapy on PICU and help shape future research.

**What if something goes wrong?**

If you have a concern about any aspect of this study, you should first ask to speak to Emma Shkurka (tel: 020 7405 9200). If your issue has not been handled satisfactorily you can contact the Chair of the UCL Research Ethics Committee – [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)

**Will my taking part in this project be kept confidential?**

Yes, completed questionnaires will be submitted anonymously. All information collected about you during this study will be confidential, and will be handled, stored and destroyed in accordance with The General Data Protection Regulation. Data will be stored securely with Smart-Survey while the questionnaire is ongoing, and will be stored securely on a GOSH computer once data collection is complete. Your anonymous answers will be kept for 15 years after the end of the study.



#### Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: For participants in health and care research studies, click [here](#)

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

This project has been approved by the Health Research Authority. The project is sponsored by UCL ICH.

#### What will happen to the results of the research project?

Once the study is completed the results will be disseminated through journal articles and conference proceedings, a summary will be included on the hospitals research website. The results will also be presented within a PhD thesis. You will not be identified in any report or publication.

#### Who is funding the research?

This study is funded by Health Education England and the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship.

Thank you for reading this information sheet and for considering to take part in this research study.

You can access the survey by clicking here. <https://www.smartsurvey.co.uk/s/Chest-Physiotherapy-in-ventilated-children/>

If you require any further information you can contact me, the researcher, Emma Shkurka at UCL Great Ormond Street Institute of Child Health, Guilford Street, London, WC1N 1EH, on email [emma.shkurka.18@ucl.ac.uk](mailto:emma.shkurka.18@ucl.ac.uk) or via telephone on [REDACTED]



## Appendix 7 – Pre-pilot text version of questionnaire

LOGO

### **Identifying and understanding Risk factors for instability and adverse Events Associated with Chest physiotherapy in ventilated children**

Thank you for your interest in completing a questionnaire as part of this study.

#### **PHASE 1 AIM**

To describe current chest physiotherapy practice in UK paediatric intensive care units

#### **Why have I been chosen?**

You have been asked to take part as you are a physiotherapist on a paediatric critical care unit within the UK. All physiotherapists who work in the UK in paediatric critical care units have been asked to take part.

#### **Study Overview**

Paediatric intensive care units (PICU) support the complex medical needs of children with life threatening conditions. There are 20000 admissions annually within the United Kingdom. Chest physiotherapy is considered an integral part of care for these patients and national standards report that PICUs require 24 hour access to physiotherapy. Despite the role of chest physiotherapy being widely acknowledged the overall clinical impact is unknown. Chest physiotherapy has been associated with instability and adverse events. Significant fluctuations in stability can contribute to organ failure or lung damage, with the potential to lead to a prolonged PICU admission or even death. At present the risks and benefits of chest physiotherapy in ventilated children are unknown. Additionally how physiotherapists make decisions and manage the risks of instability and adverse events has not been studied. It is therefore important to identify which patients are likely to benefit most and in which situations chest physiotherapy may present a significant risk. This study aims to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children.

In this questionnaire we would like to find out;

- What chest physiotherapy techniques are used
- What the referral processes are for chest physiotherapy on paediatric critical care units
- How physiotherapists make decisions about treatments
- How chest physiotherapy treatments are monitored

Thank you for your time (which should be no more than 15 minutes) in completing this questionnaire.

Emma Shkurka

Draft 17.6.2019

1. What type of unit do you work on? (tick all that apply)

PICU  
NICU  
CICU  
Other

2. Do you assess/treat intubated and ventilated patients on your unit?

Yes  
No

3. What is the physiotherapy referral process for patients on your unit?  
(comment box)

4. How often do you use the following treatment techniques with intubated and ventilated children?

Always, very often, sometimes, rarely, never

Manual hyperinflation  
Ventilator hyperinflation  
Expiratory Vibrations  
Percussion  
Open Suction  
Closed suction  
Modified postural drainage  
Position change  
ETT saline instillation  
Mobility (eg: sitting on edge of bed/in chair)  
Cough assist  
Intrapulmonary percussive ventilation  
Vest (HFCWO)  
Nebulised Mucolytics  
Instilled mucolytics  
Directed (mini) saline lavage  
Chest wall decompression  
Other

5. Which mucolytics do you use? (Please tick all that apply)

	Nebulised	Instilled
DNase		
Acetylcysteine (NAC)		
Hypertonic Saline		
3%		
5%		
6%		
7%		
Other		
Do not use mucolytics		

Draft 17.6.2019

6. In general who is involved in delivering the chest physiotherapy treatments?
- I treat on my own
  - I treat with another physiotherapist
  - I treat with the bedside nurse
  - I treat with a member of the medical team
  - Other
7. (if 'treat on own' to 6a) In what situation/circumstance would you consider treating with an additional person?
8. How do you decide how many times to assess/treat an intubated and ventilated patient in a day? (comment box)
9. How do you monitor the patient's stability and tolerance of your chest physiotherapy intervention?  
(comment box)
10. What outcomes do you use to measure the success/effectiveness of your physiotherapy treatment? (please tick all that apply)
- Oxygen saturations
  - End Tidal CO2
  - Ventilator parameters (TV/PIP)
  - Auscultation
  - Chest Expansion
  - CXR
  - Lung Ultrasound
  - Secretion yield
  - Blood Gases
  - Other
11. How frequently do you encounter the following associated with your chest physiotherapy intervention?  
Always, very often, sometimes, rarely, never
- Changes in heart rate
  - Cardiac arrhythmia
  - Changes in blood pressure
  - Desaturation
  - Increased EtCO2
  - Accidental extubation
  - Loss of a line/central access
  - Cardiorespiratory arrest

12. How do you manage/deal with instability or an adverse event?

13. How confident do you feel dealing with instability/adverse events associated with chest physiotherapy?

(Completely confident, fairly confidence, somewhat confident, slightly confident, not confident at all)

14. Please outline any specific patient groups that you do not assess/treat whilst they are intubated and ventilated?  
(comment box)

15. In what circumstances would you not assess/treat an intubated and ventilated patient?  
(comment box)

16. How frequently do you feel that you are able to work as an autonomous practitioner on your unit?  
Always, very often, sometimes, rarely, never  
(comment box)

17. Does your paediatric critical care unit have chest physiotherapy cover on weekends? Yes/no

18. Does your paediatric critical care unit have access to an out of hours/emergency oncall physiotherapist? Yes/no

19. Number of years experience working in a paediatric critical care unit?

- < 1 year
- 1 to <5 years
- 5 to <10 years
- 10 to <15 years
- 15 to <20 years
- More than 20 years

20. In which region is your paediatric critical care unit?

- Scotland & North East
- North west & Yorkshire and the Humber
- Midlands
- Wales & South West
- East Anglia, South East & Greater London



## Identifying and understanding Risk factors for instability and adverse Events Associated with Chest physiotherapy in ventilated children

Chest physiotherapy in ventilated children

**1. Do you provide chest physiotherapy assessment/treatment to intubated and ventilated patients on your paediatric intensive care unit? \***

Yes

No

**2. How are intubated and ventilated patients on your PICU referred for physiotherapy? Please detail all possible processes/pathways. \***

**3. How frequently do you use the following treatment techniques with intubated and ventilated children? (Please list any additional treatment techniques you use in the comments box) \***

	Always	Often	Sometimes	Rarely	Never
Manual hyperinflation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ventilator hyperinflation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Expiratory chest wall vibrations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Percussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chest wall decompression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Open endotracheal tube suction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Closed endotracheal tube suction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Modified postural drainage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Position changes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mobility (e.g. sitting on edge of bed/in chair)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Always	Often	Sometimes	Rarely	Never
Endotracheal tube saline instillation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nebulised mucolytics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Instilled mucolytics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Directed (mini) saline lavage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-bronchoscopic bronchoalveolar lavage (therapeutic)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physiotherapy assisted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
bronchoscopy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cough assist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intrapulmonary percussive ventilation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High frequency chest wall oscillation (vest)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Metaneb	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

**4. How frequently do you use the following mucolytics with intubated and ventilated patients? \***

	Always	Often	Sometimes	Rarely	Never
Dornase alpha (DNase)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acetylcysteine (NAC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3% Hypertonic saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6% Hypertonic saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7% Hypertonic saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

**5. Which methods do you use to deliver the following mucolytics? (please tick all that apply) \***

	Nebulised	Instilled	Do not use
Dornase alpha (DNase)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acetylcysteine (NAC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3% Hypertonic saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Nebulised	Instilled	Do not use
6% Hypertonic saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7% Hypertonic saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**6. Which additional skills do you use with intubated and ventilated patients on PICU?**

- Physiotherapy led ventilator weaning
- Physiotherapy led extubation
- Independent prescribing
- Lung ultrasound
- Other (please specify):

**7. When delivering chest physiotherapy treatments do you most commonly \***

- Treat on your own
- Treat with another physiotherapist
- Treat with the bedside nurse
- Treat with a member of the medical team
- Other (please specify):

**8. In what situations/circumstances would you consider treating with an additional person?**

**9. How do you decide how many times to assess/treat an intubated and ventilated patient in a day? \***

**10. Which variables do you use to monitor the stability of your patient during chest physiotherapy treatment? (please tick all that apply) \***

- Heart rate



- Blood pressure
- Central venous pressure
- Intracranial pressure
- Oxygen saturations
- End tidal carbon dioxide
- Blood gas
- Sedation score
- Auscultation
- Other (please specify):

Comments:

**11. Which variables do you use to measure the effectiveness of your chest physiotherapy treatment? (please tick all that apply) \***

- Oxygen saturations
- End tidal carbon dioxide
- Ventilator parameters
- Auscultation
- Palpation
- Chest x-ray
- Lung ultrasound
- Secretion yield
- Blood gas
- Other (please specify):

Comments:

**12. How frequently do you encounter the following during your chest physiotherapy treatment? \***

	Always	Often	Sometimes	Rarely	Never
Changes in heart rate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Always	Often	Sometimes	Rarely	Never
Changes in blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Desaturation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased end tidal carbon dioxide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accidental extubation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Loss of a line/central access	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiorespiratory arrest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory arrest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

**13. What management strategies do you use to minimise/prevent instability or adverse events associated with chest physiotherapy? \***

**14. How confident would you feel managing the following situations? \***

	Completely confident	Mostly confident	Somewhat confident	Slightly confident	Not at all confident
An intubated and ventilated 5 month old baby with bronchiolitis who becomes bradycardic to 75 during chest physiotherapy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An intubated and ventilated 1 year old girl with SMA 1 who de-saturates to the	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Completely confident	Mostly confident	Somewhat confident	Slightly confident	Not at all confident
70% during chest physiotherapy. A 14 year old boy, who has had a posterior spinal fusion, self-extubates after your physiotherapy treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An intubated and ventilated 3 year old boy goes into cardiac arrest whilst you are completing your respiratory assessment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

**15. Please outline any specific patient groups on PICU that you do not complete chest physiotherapy assessment/treatment with whilst they are intubated and ventilated. \***

**16. How frequently do you feel that you are able to work as an autonomous practitioner on your unit? \***

- Always
- Often
- Sometimes
- Rarely
- Never

Comments:

**17. Does your paediatric intensive care unit have access to an emergency on-call physiotherapist overnight? \***

Yes

No

Comments:

**18. Does your paediatric intensive care unit have chest physiotherapy cover on weekends? \***

Yes

No

Comments:

**19. What types of patients do you have on your paediatric intensive care unit? (please tick all that apply) \***

Respiratory

Neonatal

Trauma

Cardiac

Extracorporeal life support (ECMO/VAD)

General surgery

Orthopaedic surgery

Neurology/Neuro surgery

Thoracic surgery

Other (please specify):

**20. How many years experience do you have working in a paediatric intensive care unit? \***

< 1 year

1 to < 5 years

5 to < 10 years

10 to < 15 years

15 to < 20 years

More than 20 years

**21. In which region is your paediatric intensive care unit? \***

- Scotland, Northern Ireland and North East
- North West & Yorkshire and The Humber
- Midlands
- Wales & South West
- East Anglia, South East & Greater London

Appendix 9 – Comparison of years of PICU experience and approach to delivery of chest physiotherapy

Years of PICU experience	Delivery of chest physiotherapy n (%)		
	Treat on own	Treat with bedside nurse	Treat with another physiotherapist
< 1 year	0	3 (75)	1 (25)
1 to < 5 years	9 (39)	13 (57)	1 (4)
5 to < 10 years	5 (26)	13 (68)	1 (5)
10 to < 15 years	2 (25)	6 (75)	0
15 to < 20 years	1 (9)	9 (81)	1 (9)
> 20 years	2 (29)	4 (57)	1 (14)

(Fishers exact test p=0.574)

Appendix 10 – Comparison of geographical region and the frequency of use of physiotherapy treatments

Table 1: Treatments demonstrating statistically significant but not clinically significant differences

<b>Geographical region n (%)</b>	<b>East Anglia, South East and Greater London</b>	<b>Midlands</b>	<b>Scotland, Northern Ireland, and North East</b>	<b>North West, Yorkshire and The Humber</b>	<b>Wales and South West</b>	<b>Fishers exact test</b>
<b>Physiotherapy treatment</b>						
<b>Manual hyperinflations</b>						
Always	5 (16)	0	1 (9)	3 (33)	4 (57)	p=0.13
Often	26 (84)	14 (100)	10 (91)	6 (67)	3 (43)	
Sometimes	0	0	0	0	0	
Rarely	0	0	0	0	0	
Never	0	0	0	0	0	
<b>IPV</b>						
Always	0	0	0	0	0	p=0.005
Often	0	0	0	0	0	
Sometimes	0	0	4 (36)	0	1 (14)	
Rarely	4 (13)	0	2 (18)	1 (11)	1 (14)	
Never	27 (87)	14 (100)	5 (45)	8 (89)	5 (71)	

Table 2: Treatments demonstrating no statistically significant differences

<b>Geographical region % (n)</b>	<b>East Anglia, South East and Greater London</b>	<b>Midlands</b>	<b>Scotland, Northern Ireland, and North East</b>	<b>North West, Yorkshire and The Humber</b>	<b>Wales and South West</b>	<b>Fishers exact test</b>
<b>Physiotherapy treatment</b>						
<b>Position changes</b>						
Always	13 (42)	4 (29)	7 (64)	4 (44)	3 (43)	p=0.553
Often	18 (58)	10 (71)	4 (36)	5 (56)	4 (57)	
Sometimes	0	0	0	0	0	
Rarely	0	0	0	0	0	
Never	0	0	0	0	0	
<b>Mobility</b>						
Always	1 (3)	0	2 (18)	0	0	p=0.366
Often	21 (68)	7 (50)	8 (73)	5 (56)	4 (57)	
Sometimes	8 (26)	7 (50)	1 (9)	4 (44)	3 (43)	
Rarely	1 (3)	0	0	0	0	
Never	0	0	0	0	0	
<b>Open ETT suction</b>						
Always	7 (23)	5 (36)	4 (36)	3 (33)	4 (57)	p=0.589
Often	13 (42)	6 (43)	7 (64)	4 (44)	2 (29)	
Sometimes	2 (6)	0	0	0	1 (14)	
Rarely	8 (26)	2 (14)	0	1 (11)	0	
Never	1 (3)	1 (7)	0	1 (11)	0	
<b>Modified postural drainage</b>						
Always	4 (13)	0	0	1 (11)	1 (14)	p=0.268
Often	22 (71)	10 (71)	5 (45)	6 (67)	4 (57)	
Sometimes	3 (10)	2 (14)	2 (18)	1 (11)	1 (14)	
Rarely	2 (6)	2 (14)	1 (9)	0	1 (14)	
Never	0	0	3 (27)	1 (11)	0	
<b>Chest wall decompression</b>						
Always	0	0	0	0	0	p=0.954
Often	7 (23)	3 (21)	3 (27)	2 (22)	2 (29)	
Sometimes	17 (55)	6 (43)	4 (36)	4 (44)	3 (43)	
Rarely	4 (13)	4 (29)	2 (18)	3 (33)	1 (14)	
Never	3 (10)	1 (7)	2 (18)	0	1 (14)	
<b>MI:E</b>						
Always	0	0	0	0	0	p=0.66
Often	13 (42)	3 (21)	2 (18)	2 (22)	2 (29)	
Sometimes	7 (23)	5 (36)	5 (45)	4 (44)	3 (43)	
Rarely	6 (19)	6 (43)	3 (27)	2 (22)	1 (14)	
Never	5 (16)	0	1 (9)	1 (11)	1 (14)	
<b>NBBAL</b>						
Always	0	0	0	0	0	p=0.069
Often	3 (10)	2 (14)	3 (27)	2 (22)	2 (29)	
Sometimes	16 (52)	10 (71)	1 (9)	3 (33)	2 (29)	
Rarely	9 (29)	2 (14)	3 (27)	3 (33)	3 (43)	
Never	3 (10)	0	4 (36)	1 (11)	0	
<b>VHI</b>						
Always	0	0	0	0	0	p=0.369
Often	1 (3)	0	0	1 (11)	0	
Sometimes	8 (26)	5 (36)	2 (18)	2 (22)	1 (14)	
Rarely	17 (55)	3 (21)	6 (55)	2 (22)	3 (43)	
Never	5 (16)	6 (43)	3 (27)	4 (44)	3 (43)	



<b>Directed saline lavage</b>						
Always	0	0	0	0	0	p=0.09
Often	11 (35)	2 (14)	2 (18)	5 (56)	3 (43)	
Sometimes	13 (42)	5 (36)	3 (27)	1 (11)	4 (57)	
Rarely	3 (10)	6 (43)	3 (27)	3 (33)	0	
Never	4 (13)	1 (7)	3 (27)	0	0	
<b>Physiotherapy assisted bronchoscopy</b>						
Always	0	0	0	0	0	p=0.477
Often	2 (6)	0	0	1 (11)	0	
Sometimes	5 (16)	1 (7)	4 (36)	2 (22)	0	
Rarely	10 (32)	4 (29)	4 (36)	1 (11)	4 (57)	
Never	14 (45)	9 (64)	3 (27)	5 (56)	3 (43)	

Appendix 11 – Comparison of years of PICU experience and the frequency of use of physiotherapy treatments.

Years of experience n (%)	< 1 year (n=4)	1 to < 5 years (n=23)	5 to < 10 years (n=19)	10 to < 15 years (n=8)	15 to < 20 years (n=11)	> 20 years (n=7)	Fishers exact test
<b>Physiotherapy treatment</b>							
<b>Manual hyperinflations</b>							p=0.882
Always	0	5 (22)	5 (26)	1 (13)	1 (9)	1 (14)	
Often	4 (100)	18 (78)	14 (74)	7 (88)	10 (91)	6 (86)	
Sometimes	0	0	0	0	0	0	
Rarely	0	0	0	0	0	0	
Never	0	0	0	0	0	0	
<b>Position changes</b>							p=0.730
Always	1 (25)	9 (39)	8 (42)	5 (63)	6 (55)	2 (29)	
Often	3 (75)	14 (61)	11 (58)	3 (38)	5 (45)	5 (71)	
Sometimes	0	0	0	0	0	0	
Rarely	0	0	0	0	0	0	
Never	0	0	0	0	0	0	
<b>ETT saline instillation</b>							p=0.364
Always	0	3 (13)	1 (5)	1 (13)	0	0	
Often	3 (75)	19 (83)	16 (84)	7 (88)	9 (82)	6 (86)	
Sometimes	1 (25)	0	0	0	2 (18)	0	
Rarely	0	1 (4)	2 (11)	0	0	1 (14)	
Never	0	0	0	0	0	0	
<b>Chest wall vibrations</b>							p=0.781
Always	0	4 (17)	3 (16)	1 (13)	0	0	
Often	3 (75)	17 (74)	13 (68)	7 (88)	9 (82)	6 (86)	
Sometimes	0	1 (4)	2 (11)	0	1 (9)	1 (14)	
Rarely	0	1 (4)	0	0	0	0	
Never	1 (25)	0	1 (5)	0	0	0	
<b>Mobility</b>							p=0.682
Always	0	1 (4)	1 (5)	1 (13)	0	0	
Often	2 (50)	13 (57)	11 (58)	6 (75)	8 (73)	5 (71)	
Sometimes	1 (25)	9 (39)	7 (37)	1 (13)	3 (27)	2 (29)	

Rarely	1 (25)	0	0	0	0	0	
Never	0	0	0	0	0	0	
<b>Open ETT suction</b>							
Always	0	8 (35)	6 (32)	4 (50)	4 (36)	1 (14)	p=0.772
Often	2 (50)	11 (48)	9 (47)	2 (25)	5 (45)	3 (43)	
Sometimes	0	0	1 (5)	1 (13)	0	1 (14)	
Rarely	1 (25)	3 (13)	2 (11)	1 (13)	2 (18)	2 (29)	
Never	1 (25)	1 (4)	1 (5)	0	0	0	
<b>Modified postural drainage</b>							
Always	0	1 (4)	2 (11)	2 (25)	1 (9)	0	p=0.168
Often	2 (50)	19 (83)	8 (42)	5 (63)	8 (73)	5 (71)	
Sometimes	1 (25)	2 (9)	2 (11)	0	2 (18)	2 (29)	
Rarely	0	1 (4)	4 (21)	1 (13)	0	0	
Never	1 (25)	0	3 (16)	0	0	0	
<b>Closed ETT Suction</b>							
Always	1 (25)	3 (13)	5 (26)	1 (13)	1 (9)	2 (29)	p=0.913
Often	1 (25)	8 (35)	3 (16)	2 (25)	2 (18)	1 (14)	
Sometimes	2 (50)	7 (30)	4 (21)	3 (38)	3 (27)	2 (29)	
Rarely	0	5 (22)	7 (37)	2 (25)	5 (45)	2 (29)	
Never	0	0	0	0	0	0	
<b>Chest wall decompression</b>							
Always	0	0	0	0	0	0	p=0.530
Often	1 (25)	8 (35)	4 (21)	2 (25)	1 (9)	1 (14)	
Sometimes	1 (25)	11 (48)	8 (42)	4 (50)	6 (55)	4 (57)	
Rarely	0	2 (9)	5 (26)	1 (13)	4 (36)	2 (29)	
Never	2 (50)	2 (9)	2 (11)	1 (13)	0	0	
<b>Percussion</b>							
Always	0	0	1 (5)	0	0	0	p=0.354
Often	2 (50)	10 (43)	8 (42)	1 (13)	4 (36)	3 (43)	
Sometimes	0	9 (39)	4 (21)	3 (38)	2 (18)	4 (57)	
Rarely	1 (25)	3 (13)	3 (16)	4 (50)	3 (27)	0	
Never	1 (25)	1 (4)	3 (16)	0	3 (18)	0	
<b>MI:E</b>							
Always	0	0	0	0	0	0	p=0.400
Often	1 (25)	8 (35)	6 (32)	3 (38)	3 (27)	1 (14)	
Sometimes	0	6 (26)	5 (26)	2 (25)	7 (64)	4 (57)	

Rarely	2 (50)	5 (22)	6 (32)	3 (38)	0	2 (29)	
Never	1 (25)	4 (17)	2 (11)	0	1 (9)	0	
<b>NBBAL</b>							
Always	0	0	0	0	0	0	p=0.087
Often	0	1 (4)	2 (11)	4 (50)	3 (27)	2 (29)	
Sometimes	1 (25)	12 (52)	8 (42)	3 (38)	4 (36)	4 (57)	
Rarely	0	8 (35)	7 (37)	1 (13)	3 (27)	1 (14)	
Never	3 (75)	3 (13)	2 (9)	0	1 (9)	0	
<b>Ventilator hyperinflations</b>							
Always	0	0	0	0	0	0	p=0.278
Often	0	0	1 (5)	0	1 (9)	0	
Sometimes	0	5 (22)	3 (16)	4 (50)	3 (27)	3 (43)	
Rarely	0	12 (52)	9 (47)	3 (38)	5 (45)	2 (29)	
Never	4 (100)	6 (32)	6 (32)	1 (13)	2 (18)	2 (29)	
<b>HFCWO</b>							
Always	0	0	0	0	0	0	p=0.441
Often	1 (25)	1 (4)	0	0	0	1 (14)	
Sometimes	0	3 (13)	2 (11)	2 (25)	1 (9)	1 (14)	
Rarely	1 (25)	5 (22)	5 (26)	1 (13)	4 (36)	4 (57)	
Never	2 (50)	14 (61)	12 (63)	5 (63)	6 (55)	1 (14)	
<b>Metaneb®</b>							
Always	0	0	0	0	0	0	p=0.160
Often	0	1 (4)	0	0	1 (9)	0	
Sometimes	0	0	4 (21)	2 (25)	1 (9)	0	
Rarely	2 (50)	4 (17)	11 (2)	0	0	1 (14)	
Never	2 (50)	18 (78)	68 (13)	6 (75)	9 (82)	6 (86)	
<b>IPV</b>							
Always	0	0	0	0	0	0	p=0.658
Often	0	0	0	0	0	0	
Sometimes	0	2 (9)	2 (11)	1 (13)	0	0	
Rarely	1 (25)	1 (4)	4 (21)	0	1 (9)	1 (14)	
Never	3 (75)	20 (87)	13 (68)	7 (88)	10 (91)	6 (86)	

(ETT – Endotracheal tube, HFCWO – High frequency chest wall oscillation, IPV – Intrapulmonary percussive ventilation, MI:E – Manual insufflation/exsufflation, NBBAL – Non-bronchoscopic alveolar lavage)

Appendix 12 – Subgroup analysis of frequency of use of mucoactive agents

Table 1: Frequency of use of 6% hypertonic saline by geographical region

Region	Frequency of use of 6% hypertonic saline, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	18 (58)	7 (23)	4 (13)	2 (7)	0
Midlands	8 (57)	4 (29)	1 (7)	1 (7)	0
Scotland, Northern Ireland, and North East	4 (36)	4 (36)	2 (18)	1 (9)	0
North West, Yorkshire and The Humber	6 (67)	0	1 (11)	2 (22)	0
Wales and South West	4 (57)	0	1 (14)	2 (29)	0

(Fishers exact, p=0.499)

Table 2: Frequency of use of 7% hypertonic saline by geographical region

Region	Frequency of use of 7% hypertonic saline, n (%)				
	Never	Rarely	Sometimes	Often	Always
East Anglia, South East and Greater London	5 (16)	5 (16)	7 (23)	14 (45)	0
Midlands	0	1 (7)	5 (36)	8 (57)	0
Scotland, Northern Ireland, and North East	0	4 (36)	2 (18)	5 (46)	0
North West, Yorkshire and The Humber	1 (11)	4 (44)	3 (33)	1 (11)	0
Wales and South West	0	0	3 (43)	4 (57)	0

(Fishers exact, p=0.175)

Table 3: Frequency of use of 3% Hypertonic saline by years of experience

Years of PICU experience	Frequency of use of 3% Hypertonic saline n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year (n=4)	0	0	1 (25)	3 (75)	0
1 to < 5 years (n=23)	1 (4)	1 (4)	3 (13)	17 (74)	1 (4)
5 to < 10 years (n=19)	2 (11)	3 (16)	2 (11)	11 (58)	1 (5)
10 to < 15 years (n=8)	0	2 (25)	3 (38)	3 (38)	0
15 to < 20 years (n=11)	2 (18)	3 (17)	4 (36)	2 (18)	0
> 20 years (n=7)	0	1 (14)	3 (43)	3 (43)	0
<b>Total</b>	n=5	n=10	n=16	n=39	n=2

(Fishers exact, p=0.224)

Table 4: Frequency of use of 6% Hypertonic saline by years of experience

Years of PICU experience	Frequency of use of 6% Hypertonic saline n (%)				
	Never	Rarely	Sometimes	Often	Always
< 1 year (n=4)	0	1 (25)	1 (25)	2 (50)	0
1 to < 5 years (n=23)	10 (43)	8 (35)	2 (9)	3 (13)	0
5 to < 10 years (n=19)	15 (79)	2 (11)	1 (5)	1 (5)	0
10 to < 15 years (n=8)	5 (63)	0	3 (38)	0	0
15 to < 20 years (n=11)	7 (64)	2 (18)	1 (9)	1 (9)	0
> 20 years (n=7)	3 (43)	2 (29)	1 (14)	1 (14)	0
<b>Total</b>	n=40	n=15	n=9	n=8	n=0

(Fishers exact, p=0.059)

Table 5: Frequency of use of DNase by years of experience

Years of PICU experience	Frequency of use of DNase n (%)				
	Never	Rarely	Sometimes	Often	Always
<b>&lt; 1 year (n=4)</b>	1 (25)	2 (50)	1 (25)	0	0
<b>1 to &lt; 5 years (n=23)</b>	0	4 (17)	15 (65)	4 (17)	0
<b>5 to &lt; 10 years (n=19)</b>	0	4 (21)	12 (63)	3 (16)	0
<b>10 to &lt; 15 years (n=8)</b>	0	1 (13)	3 (38)	4 (50)	0
<b>15 to &lt; 20 years (n=11)</b>	0	2 (18)	5 (45)	4 (36)	0
<b>&gt; 20 years (n=7)</b>	0	0	4 (57)	3 (43)	0
<b>Total</b>	n=1	n=13	n=40	n=18	n=0

(Fishers exact, p=0.203)

Appendix 13 – Subgroup analysis of delivery of mucoactive agents

Table 1: Comparison of geographical region and delivery methods of mucoactive agents

<b>Geographical region n (%)</b>	<b>East Anglia, South East and Greater London</b>	<b>Midlands</b>	<b>Scotland, Northern Ireland, and North East</b>	<b>North West, Yorkshire and The Humber</b>	<b>Wales and South West</b>	<b>Fishers exact test</b>
<b>Mucoactive</b>						
<b>DNase (n=71)</b>						
Nebulised only	4 (13)	3 (21)	5 (45)	2 (22)	0	p=0.1
Instilled only	6 (20)	0	0	2 (22)	0	
Both	20 (67)	11 (79)	6 (55)	5 (56)	7 (100)	
<b>3% Hypertonic saline (n=65)</b>						
Nebulised only	25 (83)	14 (100)	10 (100)	7 (88)	3 (100)	p=0.357
Instilled only	0	0	0	0	0	
Both	5 (17)	0	0	1 (13)	0	
<b>6% Hypertonic saline (n=27)</b>						
Nebulised only	11 (100)	4 (100)	6 (100)	3 (100)	2 (67)	p=0.222
Instilled only	0	0	0	0	0	
Both	0	0	0	0	1 (33)	
<b>7% Hypertonic saline (n=65)</b>						
Nebulised only	23 (88)	13 (100)	10 (91)	8 (100)	6 (86)	p=0.367
Instilled only	0	0	1 (9)	0	0	
Both	3 (13)	0	0	0	1 (14)	



Table 2: Comparison of years of experience and delivery of mucoactive agents

<b>Years of experience n (%)</b>	<b>&lt; 1 year</b>	<b>1 to &lt; 5 years</b>	<b>5 to &lt; 10 years</b>	<b>10 to &lt; 15 years</b>	<b>15 to &lt; 20 years</b>	<b>&gt; 20 years</b>	<b>Fishers exact test</b>
<b>Mucoactive</b>							
<b>DNase (n=71)</b>							
Nebulised only	2 (67)	4 (17)	6 (32)	0	1 (9)	1 (14)	p=0.271
Instilled only	0	2 (9)	2 (11)	0	3 (27)	1 (14)	
Both	1 (33)	17 (74)	11 (58)	8 (100)	7 (64)	5 (71)	
<b>3% Hypertonic saline (n=65)</b>							
Nebulised only	4 (100)	17 (81)	16 (94)	8 (100)	8 (89)	6 (100)	p=0.717
Instilled only	0	0	0	0	0	0	
Both	0	4 (19)	1 (6)	0	1 (11)	0	
<b>6% Hypertonic saline (n=27)</b>							
Nebulised only	3 (100)	8 (89)	4 (100)	3 (100)	4 (100)	4 (100)	p=1.0
Instilled only	0	0	0	0	0	0	
Both	0	1 (11)	0	0	0	0	
<b>7% Hypertonic saline (n=65)</b>							
Nebulised only	3 (100)	20 (87)	17 (89)	7 (100)	7 (100)	6 (100)	p=0.91
Instilled only	0	0	1 (5)	0	0	0	
Both	0	3 (13)	1 (5)	0	0	0	
<b>N-Acetylcysteine (n=47)</b>							
Nebulised only	2 (67)	11 (50)	7 (70)	2 (50)	3 (75)	2 (50)	p=0.811
Instilled only	0	4 (18)	0	0	1 (25)	1 (25)	
Both	1 (33)	7 (32)	3 (30)	2 (50)	0	1 (25)	

Appendix 14 – Extended scope skills subgroup analysis

Table 1: Comparison of geographical region and number of extended scope skills

Geographical region	Number of extended scope skills n (%)			
	0	1	2	3
<b>East Anglia, South East and Greater London (n=31)</b>	15 (48)	7 (23)	8 (26)	1 (3)
<b>Midlands (n=14)</b>	6 (43)	6 (43)	2 (14)	0
<b>Scotland, Northern Ireland, and North East (n=11)</b>	6 (55)	2 (18)	2 (18)	1 (9)
<b>North West, Yorkshire and The Humber (n=9)</b>	4 (44)	2 (22)	3 (33)	0
<b>Wales and South West (n=7)</b>	3 (43)	1 (14)	3 (43)	0

(Fishers exact p=0.893)

Table 2: Comparison of years of PICU experience and number of extended scope skills

Years of PICU experience	Number of extended scope skills n (%)			
	0	1	2	3
<b>&lt; 1 year (n=4)</b>	4 (100)	0	0	0
<b>1 to &lt; 5 years (n=23)</b>	9 (39)	7 (30)	6 (26)	1 (4)
<b>5 to &lt; 10 years (n=19)</b>	11 (58)	5 (26)	3 (16)	0
<b>10 to &lt; 15 years (n=8)</b>	3 (38)	1 (13)	3 (38)	1 (13)
<b>15 to &lt; 20 years (n=11)</b>	3 (27)	4 (36)	4 (36)	0
<b>&gt; 20 years (n=7)</b>	4 (57)	1 (14)	2 (29)	0

(Fishers exact p=0.602)

Appendix 15 – Comparison of geographical region and frequency of self-reported autonomy

	Frequency of self-reported autonomy, n (%)				
	Never	Rarely	Sometimes	Often	Always
<b>East Anglia, South East and Greater London (n=31)</b>	0	1 (3)	3 (10)	9 (29)	18 (58)
<b>Midlands (n=14)</b>	0	0	1 (7)	5 (38)	8 (57)
<b>Scotland, Northern Ireland, and North East (n=11)</b>	0	0	0	3 (27)	8 (73)
<b>North West, Yorkshire and The Humber (n=9)</b>	0	0	0	3 (33)	6 (67)
<b>Wales and South West (n=7)</b>	0	0	0	5 (71)	2 (29)

(Fishers exact, p=0.792)

Appendix 16 – Comparison of years of PICU experience and self-reported frequency of instability and adverse events during physiotherapy

480

Years of experience n (%)	< 1 year (n=4)	1 to < 5 years (n=23)	5 to < 10 years (n=19)	10 to < 15 years (n=8)	15 to < 20 years (n=11)	> 20 years (n=7)	Fishers exact test
<b>Changes in heart rate</b>							
Always	0	1 (4)	1 (5)	2 (25)	0	0	p=0.208
Often	1 (25)	17 (74)	14 (74)	6 (75)	8 (73)	6 (86)	
Sometimes	3 (75)	5 (22)	4 (21)	0	3 (27)	1 (14)	
Rarely	0	0	0	0	0	0	
Never	0	0	0	0	0	0	
<b>Desaturation</b>							
Always	0	0	0	0	0	0	p=0.254
Often	1 (25)	9 (39)	6 (32)	3 (38)	1 (9)	2 (29)	
Sometimes	3 (75)	14 (61)	12 (63)	5 (63)	10 (91)	3 (43)	
Rarely	0	0	1 (5)	0	0	2 (29)	
Never	0	0	0	0	0	0	
<b>Increased end-tidal carbon dioxide</b>							
Always	0	0	0	0	0	0	p=0.275
Often	0	5 (22)	5 (26)	1 (13)	0	1 (14)	
Sometimes	3 (75)	16 (70)	8 (42)	6 (75)	9 (82)	3 (43)	
Rarely	1 (25)	2 (7)	6 (32)	1 (13)	2 (18)	3 (43)	
Never	0	0	0	0	0	0	
<b>Cardiac arrhythmia</b>							
Always	0	0	0	0	0	0	p=0.329
Often	0	0	0	0	0	0	
Sometimes	0	5 (22)	5 (26)	0	3 (27)	3 (43)	
Rarely	4 (100)	17 (74)	14 (74)	8 (100)	8 (73)	3 (43)	
Never	0	1 (4)	0	0	0	1 (14)	

<b>Respiratory arrest</b>							
Always	0	0	0	0	0	0	p=0.364
Often	0	0	0	0	0	0	
Sometimes	0	0	0	0	0	0	
Rarely	1 (25)	13 (57)	11 (58)	7 (88)	8 (73)	5 (71)	
Never	3 (75)	10 (43)	8 (42)	1 (13)	3 (27)	2 (29)	
<b>Cardiorespiratory arrest</b>							
Always	0	0	0	0	0	0	p=0.647
Often	0	0	0	0	0	0	
Sometimes	0	0	0	0	0	0	
Rarely	1 (25)	7 (30)	7 (37)	4 (50)	6 (55)	4 (57)	
Never	3 (75)	16 (70)	12 (63)	4 (50)	5 (45)	3 (43)	
<b>Accidental extubation</b>							
Always	0	0	0	0	0	0	p=0.385
Often	0	0	0	0	0	0	
Sometimes	0	0	0	0	0	0	
Rarely	0	6 (26)	7 (37)	4 (50)	3 (27)	4 (57)	
Never	4 (100)	17 (74)	12 (63)	4 (50)	8 (73)	3 (43)	



**Participant Information Sheet for Physiotherapist Interviews**



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with CHest physiotherapy in ventilated children.**

UCL Research Ethics Committee Approval ID Number: _____
IRAS Project ID: 278215
Researcher: Emma Shkurka, Physiotherapist and PhD student, Great Ormond Street Institute of Child Health, UCL
Supervisors: Professor Mark Peters Dr Harriet Shannon Dr Jo Wray

You are being invited to take part in a research project. Before you decided it is important for you to understand why the research us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. I am carrying out this study as part of an educational project, specifically a PhD which I am completing at University College London. Thank you for reading this.

**What is the project's purpose?**

Paediatric intensive care units (PICU) support the complex medical needs of children with life threatening conditions. There are 20000 admissions annually within the United Kingdom. Chest physiotherapy is considered an integral part of care for these patients and national standards report that PICUs require 24 hour access to physiotherapy. Despite the role of chest physiotherapy being widely acknowledged the overall clinical impact is unknown. Chest physiotherapy has been associated with instability and adverse events. Significant fluctuations in stability can contribute to organ failure or lung damage, with the potential to lead to a prolonged PICU admission or even death. At present the risks and benefits of chest physiotherapy in ventilated children are unknown. Additionally how PICU physiotherapists make decisions regarding delivery of chest physiotherapy and manage risks of instability and adverse events has not been studied. It is important to identify which patients are likely to benefit most and in which situations chest physiotherapy may present a significant risk.

The overall study aim is to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children.

This phase of the study will use interviews to explore and understand the decision making processes that guide delivery of chest physiotherapy on UK paediatric intensive care units. To answer the following questions;

1. How do physiotherapists make decisions regarding provision of chest physiotherapy in UK paediatric intensive care units and what other factor influence this decision making?
2. What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?

#### Why have I been chosen?

You have been asked to take part as you are a physiotherapist on a paediatric intensive care unit within the UK. Up to 24 other physiotherapists will be included in the study, from seven other centres across the UK. Eight centres have been selected to be representative of all national paediatric intensive care units in the UK.

#### Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw without giving a reason at any time before the interview takes place and withdraw your data from the study for up to 4 weeks following the interview.

#### What will happen to me if I take part?

If you decide to take part the researcher will arrange to visit you at a time and location that are convenient for you. The visit will begin by completing a written consent form with the researcher. The researcher will then carry out an interview, this will last between 30-60 minutes. Following the interview nothing further is required.

If the interview is unable to take place in person a Skype/telephone interview will be arranged. In this situation the written consent form can be signed and emailed back to the researcher prior to the interview.

#### Will I be recorded and how will the recorded media be used?

The interview will be audio recorded and the researcher will take some written notes. It is necessary to audio record the interview for analysis purposes. No personal details will be recorded or documented. The audio recordings made during your interview will be transcribed into a written format for analysis. This will be completed by a secure UK transcription company called TakeNote. Anonymous written quotes from the interviews may be used in the presentation of the data analysis. No one outside the project will be allowed access to the original recordings and no other use will be made of them without your written permission.

#### What are the possible disadvantages of taking part?

The researchers visit may take up to an hour, however interviews will be arranged to fit in with your schedule to minimise any inconvenience.

#### What are the possible benefits of taking part?

It is anticipated that this project will create a new network of specialist PICU physiotherapists, increasing collaboration, sharing of practice and joint research. As a participant you will be invited to join this group and attend a dissemination event. It is hoped that this project will provide some guidance for chest physiotherapy on PICU and help shape future research.

#### What if something goes wrong?

If you have a concern about any aspect of this study, you should first ask to speak to Emma Shkurka (tel: 020 7405 9200). If your issue has not been handled satisfactorily you can contact the Chair of the UCL Research Ethics Committee – [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)

#### Will my taking part in this project be kept confidential?

All the information that we collect about you during the study will be kept strictly confidential, and will be handled, stored and destroyed in accordance with The General Data Protection Regulation. The interview data will be de-identified. You will not be able to be identified in any ensuing reports or publications.

#### Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: For participants in health and care research studies, click [here](#)

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows: Name, Email address.

The lawful basis that would be used to process your personal data will be performance of a task in the public interest.

Your personal data (e.g. your name) will be kept for up to 12 months after the study ends. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible. The de-identified interview data will be kept for 15 years after the end of the study.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

#### What will happen to the results of the research project?

Once the study is completed the results will be disseminated through journal articles and conference proceedings, a summary will be included on the hospital's research website. The results will also be presented within a PhD thesis. You will not be identified in any report or publication. Participants will receive a written report of the study findings.



**Who is funding the research?**

This study is funded by Health Education England and the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship.

Thank you for reading this information sheet and for considering to take part in this research study.

If you require any further information you can contact me, the researcher, Emma Shkurka at UCL Great Ormond Street Institute of Child Health, Guilford Street, London, WC1N 1EH, on email [emma.shkurka.18@ucl.ac.uk](mailto:emma.shkurka.18@ucl.ac.uk) or via telephone on [REDACTED].



Appendix 18 – Interview consent form



Physiotherapist Interview Consent Form



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with Chest physiotherapy in ventilated children.**

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Participant Study Number: \_\_\_\_\_

Chief Investigator: Emma Shkurka [emma.shkurka.18@ucl.ac.uk](mailto:emma.shkurka.18@ucl.ac.uk)

UCL Data Protection Officer: Alexandra Potts [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

IRAS: 278215 UCL REC Reference:

Thank you for considering this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions, please ask the researcher before you decide whether to take part. You will be given a signed copy of this consent form to keep for your records and refer to at any time. The researcher will also have a signed copy of the consent form.

I confirm that I understand that by ticking/initialling each box below I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes means that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element that I may be deemed ineligible for the study.

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time prior to the interview without giving any reason, without my legal rights being affected.
3. I consent to participate in the study. I understand that my personal information (*Name*) will be used for the purposes explained to me. I understand that according to data protection legislation, 'public task' will be the lawful basis for processing.
4. I understand that I will be able to withdraw my data for up to 4 weeks after the interview.
5. I agree to being audio recorded and understand that the recordings will be stored anonymously, using password-protected software.
6. I understand that all personal information will remain confidential. I understand that the data gathered in this study will be stored securely. It will not be possible to identify me in any publications.
7. I agree to my interview being transcribed by a secure UK transcription service.
8. I agree to the anonymous results of the study being published in medical, academic and conference journals and websites.
9. I agree to anonymised quotes being used publications and understand that I will not be identifiable.

If you would like your contact details to be retained so that you can be contacted in the future by UCL researchers who would like to invite you to participate in follow up studies to this project, or in future studies of a similar nature, please tick the appropriate box below.

Yes, I would be happy to be contacted in this way	
No, I would not like to be contacted	

\_\_\_\_\_

Name of Participant

\_\_\_\_\_

Date

\_\_\_\_\_

Signature

\_\_\_\_\_

Name of Person  
taking consent

\_\_\_\_\_

Date

\_\_\_\_\_

Signature



## Appendix 19 – Interview topic guide



### Topic Guide for Physiotherapist Interviews



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with CHest physiotherapy in ventilated children.**

UCL Research Ethics Committee Approval ID Number: 16837/001  
IRAS Project ID: 278215  
Researcher:  
Emma Shkurka, Physiotherapist and PhD student, Great Ormond Street Institute of Child Health, UCL  
Supervisors:  
Professor Mark Peters  
Dr Harriet Shannon  
Dr Jo Wray

*[Interviewer notes: This document is a guide to the principle themes and questions to be covered. Questions may be modified/followed up on as appropriate or omitted if already discussed]*

**Introduction** *[Reassure and settle participant. Provide context to study and interview]*

- Introduce self
- Thank participant for taking part
- Provide details on plan for interview
  - List of topics to discuss
  - Participant able to ask questions at any stage during the interview
  - Field notes may be taken
  - Time frame of interview up to approx. 1 hour
- Provide overview of study and general aims of interviews; reiterate that there is no right or wrong answer

**Confidentiality and consent**

- State the confidential nature of the interview and plan for management of interview data
- Discuss escalation process related to disclosure of material of concern *[For example safety concerns, bullying]*

- Gain verbal consent for participation and recording of the interview *[Ensure participant happy to proceed]*

## Topics & Questions

### 1. Participant experience

Q. Could you start by telling me a bit about your career pathway into PICU?

Prompts – How did you get into PICU physiotherapy?/Did you always want to work on PICU?/How long have you worked on PICU?/Agenda for change banding?/ Size of PICU?

*[Ice breaker question. To help researcher understand experience of participant, current role, give context regarding their current working environment PICU]*

### 2. Variation in personnel involved in delivery of treatment

(Link – Now have understanding of you as an individual, helpful to understand wider physiotherapy team)

Q. I am interested to know about how the physiotherapy team works on your PICU – can you tell me a bit about that?

Prompts – Do you work as individuals or more jointly?/What about involvement of other healthcare professionals e.g. nursing staff/What might influence who is involved?

*[Unpick who is involved in physiotherapy delivery, what determines this]*

### 3. Treatment variation

(Link – Discussed who involved in treatments want to move on to think about treatments themselves)

Q. I am interested in understanding more about why there might be variation in treatment techniques used – what are your thoughts about this?

Prompts - What are your treatment preferences?/What influences treatment choice?/Why pick one technique over another?/Do protocols or guidelines have any impact at your centre?

*[Unpick variation in treatments, could provide with specific treatment examples]*

### 4. Concept of patients being ‘too unstable for treatment’ and ‘risk versus benefit’

(Link – Let’s move on to think about specific patient groups or types of patients)

Q. Are you able to tell me about a clinical situation with a patient where you found the decision making around physiotherapy treatment challenging?

Prompts - What helped you to make decisions?/How did you feel in this situation?/Who else might be involved in the decision making in this type of situation?

*[Aim to explore concept of 'being unstable' and risk management. Understand patients that wouldn't be treated. Internal and external factors that influence decision making]*

#### **5. Autonomous working**

(Link – Final area want to explore working relationships with other members of physiotherapy and MDT)

**Q. I am interested in understanding from your perspective the level of autonomy physiotherapists have on PICU and your thoughts about this?**

Prompts – How often have you experiences disagreements or conflict with MDT?/What factors may impact this?/ Are there any specific barriers or facilitators?

*[Understand participant's ability to work autonomously, why might be variation between physiotherapists]*

#### **End of interview**

- Invite participant to provide any further comments or ask questions
- Thank participant for time
- Ask participant if happy to be contacted about taking part in focus groups



**Participant Information Sheet for Physiotherapist Focus Groups**



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with Chest physiotherapy in ventilated children.**

UCL Research Ethics Committee Approval ID Number: 16837/001  
IRAS Project ID: 278215  
PI: Professor Mark Peters, Professor of Paediatric Intensive Care, Institute of Child Health, UCL, mark.peters@ucl.ac.uk  
Researcher: Emma Shkurka, Physiotherapist and PhD student, Great Ormond Street Institute of Child Health, UCL, emma.shkurka.18@ucl.ac.uk  
**Additional supervisors:**  
Dr Harriet Shannon  
Dr Jo Wray

You are being invited to take part in a research project. Before you decided it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. I am carrying out this study as part of an educational project, specifically a PhD which I am completing at University College London. Thank you for reading this.

**What is the project's purpose?**

Paediatric intensive care units (PICU) support the complex medical needs of children with life threatening conditions. There are 20000 admissions annually within the United Kingdom. Chest physiotherapy is considered an integral part of care for these patients and national standards report that PICUs require 24 hour access to physiotherapy. Despite the role of chest physiotherapy being widely acknowledged the overall clinical impact is unknown. Chest physiotherapy has been associated with instability and adverse events. Significant fluctuations in stability can contribute to organ failure or lung damage, with the potential to lead to a prolonged PICU admission or even death. At present the risks and benefits of chest physiotherapy in ventilated children are unknown. Additionally how PICU physiotherapists make decisions regarding delivery of chest physiotherapy and manage risks of instability and adverse events has not been studied. It is important to identify which



patients are likely to benefit most and in which situations chest physiotherapy may present a significant risk.

The overall study aim is to identify and understand the risk factors for physiological instability and adverse events associated with chest physiotherapy in ventilated children.

This phase of the study will use interviews to explore and understand the decision making processes that guide delivery of chest physiotherapy on UK paediatric intensive care units. To answer the following questions;

1. How do physiotherapists make decisions regarding provision of chest physiotherapy in UK paediatric intensive care units and what other factor influence this decision making?
2. What do physiotherapists perceive to be risk factors for physiological instability and adverse events and how do they manage these?

**Why have I been chosen?**

You have been asked to take part as you are a physiotherapist on a paediatric intensive care unit within the UK and you have already participated in an interview for this study. Up to eight other physiotherapists will be included in the study, from eight other centres across the UK. Nine centres have been selected to be representative of all national paediatric intensive care units in the UK.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw without giving a reason at any time before the focus group takes place.

**What will happen to me if I take part?**

If you decide to take part the researcher will arrange a telephone call at a time that is convenient for you. This short meeting will be used to complete a written consent form with the researcher, which will then be emailed to the researcher. You will then be invited to join a virtual focus group with three other physiotherapists who are of a similar Agenda for Change banding. The focus group will last up to 90 minutes. You will be asked to give verbal consent to take part before the start of the group. The focus group will involve reading a clinical case study and watching a brief video. You will be provided with some questions to discuss with the other physiotherapists, there will be a facilitator present to help this process. There will be an observing researcher who will not take part in the focus group.

**Will I be recorded and how will the recorded media be used?**

The interview will be audio recorded and the observing researcher will take some written notes. It is necessary to audio record the focus group for analysis purposes. No personal details will be recorded or documented. The audio recordings made during the focus group will be transcribed into a written format for analysis. This will be completed by a secure UK transcription company called TakeNote. Anonymous written quotes may be used in the presentation of the data analysis. No one outside the project will be allowed access to the original recordings and no other use will be made of them without your written permission.

What are the possible disadvantages or risks of taking part?

A breach of confidentiality is a recognised risk with focus groups. Prior to starting the focus group the confidential nature of the group will be discussed and a verbal agreement of confidentiality made between the physiotherapists. The focus group will take up to 90 minutes, but will be arranged to fit in with your schedule to minimise any inconvenience.

What are the possible benefits of taking part?

It is anticipated that this project will create a new network of specialist PICU physiotherapists, increasing collaboration, sharing of practice and joint research. As a participant you will be invited to join this group and attend a dissemination event. It is hoped that this project will provide some guidance for chest physiotherapy on PICU and help shape future research.

What if something goes wrong?

If you have a concern about any aspect of this study, you should first ask to speak to Mark Peters or Emma Shkurka (tel: [REDACTED]). If your issue has not been handled satisfactorily you can contact the Chair of the UCL Research Ethics Committee – [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)

Will my taking part in this project be kept confidential?

All the information that we collect about you during the study will be kept strictly confidential, and will be handled, stored and destroyed in accordance with The General Data Protection Regulation. The focus data will be de-identified. You will not be able to be identified in any ensuing reports or publications.

Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: For participants in health and care research studies, click [here](#)

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows: Name, Email address.

The lawful basis that would be used to process your personal data will be performance of a task in the public interest.

Your personal data (e.g. your name) will be kept for up to 12 months after the study ends. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible. The de-identified interview data will be kept for 15 years after the end of the study.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

**What will happen to the results of the research project?**

Once the study is completed the results will be disseminated through journal articles and conference proceedings, a summary will be included on the hospital's research website. The results will also be presented within a PhD thesis. You will not be identified in any report or publication. Participants will receive a written report of the study findings.

**Who is funding the research?**

This study is funded by Health Education England and the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship.

Thank you for reading this information sheet and for considering to take part in this research study.

If you require any further information you can contact me, the researcher, Emma Shkurka at UCL Great Ormond Street Institute of Child Health, Guilford Street, London, WC1N 1EH, on email [emma.shkurka.18@ucl.ac.uk](mailto:emma.shkurka.18@ucl.ac.uk) or via telephone on 02074950000.



## Appendix 21 – Focus group consent form



### Physiotherapist Focus Group Consent Form



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with CHest physiotherapy in ventilated children.**

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Participant Study Number: \_\_\_\_\_

PI: Professor Mark Peters [mark.peters@ucl.ac.uk](mailto:mark.peters@ucl.ac.uk)

Researcher: Emma Shkurka [emma.shkurka.18@ucl.ac.uk](mailto:emma.shkurka.18@ucl.ac.uk)

UCL Data Protection Officer: Alexandra Potts [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)

IRAS: 278215 UCL REC Reference: 16837/001

Thank you for considering this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions, please ask the researcher before you decide whether to take part. You will be given a signed copy of this consent form to keep for your records and refer to at any time. The researcher will also have a signed copy of the consent form.

I confirm that I understand that by ticking/initialling each box below I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes means that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element that I may be deemed ineligible for the study.

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time prior to the focus group without giving any reason, without my legal rights being affected.
3. I consent to participate in the study. I understand that my personal information (*Name*) will be used for the purposes explained to me. I understand that according to data protection legislation, 'public task' will be the lawful basis for processing.
4. I agree to being audio recorded and understand that the recordings will be stored anonymously, using password-protected software.
5. I understand that all personal information will remain confidential. I understand that the data gathered in this study will be stored securely. It will not be possible to identify me in any publications.
6. I agree to the focus group being transcribed by a secure UK transcription service.
7. I agree to the anonymous results of the study being published in medical, academic and conference journals and websites.
8. I agree to anonymised quotes being used publications and understand that I will not be identifiable.

If you would like your contact details to be retained so that you can be contacted in the future by UCL researchers who would like to invite you to participate in follow up studies to this project, or in future studies of a similar nature, please tick the appropriate box below.

Yes, I would be happy to be contacted in this way	
No, I would not like to be contacted	

\_\_\_\_\_

Name of Participant                      Date                      Signature

\_\_\_\_\_

Name of Person                      Date                      Signature  
taking consent





**Case-study**

6 month old, ex-prem (30/40) admitted yesterday with RSV bronchiolitis. Picked up as a new patient.

CXR – RUL consolidation, nil else of note.

I&V, sedated, no inotropes

CVS HR 140, BP 77/50

Vent PC & PS, PC 16, PS 14, PEEP 8, RR 28, FiO2 0.5



Topic Guide for Physiotherapist Focus Group



**Research Study: Identifying and understanding Risk factors for instability and adverse Events Associated with CHest physiotherapy in ventilated children.**

UCL Research Ethics Committee Approval ID Number: 16837/001

IRAS Project ID: 278215

Researcher:

Emma Shkurka, Physiotherapist and PhD student, Great Ormond Street Institute of Child Health, UCL

Supervisors:

Professor Mark Peters

Dr Harriet Shannon

Dr Jo Wray

*[Research notes: The focus groups will be facilitated by a physiotherapist with experience in group research methods. This document outlines the structure of the focus groups and is a guide to the general themes and questions to be discussed. The emphasis however will be on the discussion being led by the participants. It is anticipated that the group involving the more junior physiotherapists may require more facilitation. The researcher will be present in purely an observational role and will not participate in the discussion.]*

**Introduction** *[Reassure and settle participants. Provide context to study and focus group]*

- Facilitator to introduce self and observer (researcher)
- Thank participants for taking part
- Provide details on plan for the focus group
  - Time frame of interview up to approx. 60-90 minutes
  - Outline structure – 2 part case-study with SIM video discussion
- Provide brief overview of study
- Provide participants with rules of the focus group (including how to join conversation, guiding principles etc)
- Clarify the aims of the focus group are related to the processes of decision making and strategies. Reassure there are no correct/incorrect comments *[to create non-threatening/judgmental environment]*



## Confidentiality and consent

- State the confidential nature of the focus group and plan for management of data
- Gain verbal consent for participation and recording of the session [*Ensure participants are happy to proceed*]

## Topics & Discussion points

*[The aim of the focus groups is to understand how physiotherapists make decisions regarding provision of physiotherapy and what other factors influence this decision making, whilst also allowing further exploration of what physiotherapists perceive to be risk factors for physiological instability and adverse events and management strategies.]*

Physiotherapists will be asked to briefly introduce themselves and tell the group about their favourite food.

*[To allow introduction, lighten the mood, act as an ice breaker]*

### Part 1

Following the introductions the participants will be provided with a patient case-study including present condition, history of present condition, past medical history and subjective/objective clinical information. This will be provided in writing on the screen and also read aloud by the facilitator. The participants will then have 5 minutes to consider the information and write notes.

Discussion will then be facilitated. The following questions will be posed to the group by the facilitator.

- Is there any additional information physiotherapists would like to know about the patient?
- Are there any red flags in the history/assessment?
- What other characteristics/types of patients would you consider to be high risk for instability/AEs

*[In an attempt to simulate a real life clinical situation the group will not be provided with the case-study in advance. As much as possible discussion will be led by the participants.]*

### Part 2

The group will then watch the first part of the SIM video (to 03:14) which involves assessment and interaction with the bedside nurse. The group will be asked to make notes and there will be opportunity to watch the video several times or recap certain elements if required.

Discussion will then be facilitated. The following questions will be posed to the group by the facilitator.

- Would you have done anything different/asked anything else?

- What variables/measurements could be used to monitor the stability of the patient during physiotherapy?
- What could the treatment plan include?

### **Part 3**

The remainder of the SIM video will then be played demonstrating a treatment of the patient from the case-study. The group will be asked to make notes and there will be opportunity to watch the video a number of times or recap certain elements.

Discussion will then be facilitated. The following questions will be posed to the group by the facilitator.

- What are the group's first impressions of the scenario in the video?
- Does anyone have any personal experience of this situation? What did they do?
- Are there any specific comments about treatment/management of patient?
- Would they have done anything differently? (and why?)

*[Aiming to explore practical management strategies by reproducing a more 'real life' environment]*

### **End of focus group**

- Invite participants to provide any further comments or ask questions
- Thank participants for time

Appendix 24 – Chapter 6 Framework analysis

Framework I - Bronchiolitis

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Development</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D16</b>	Clinical guideline  Standard trust layout	Created 2020  (review 2023)	PICU consultant. Physiotherapist involved in development.	All staff on PICU	Not explicitly stated  Aimed at invasively and mechanically ventilated children only.	Introduction to and definition of disease  Non physiotherapy related content (nursing/infection control etc).  Specific guidance for physiotherapy input. Criteria and specific indications with suggested treatments. Some guidance for CDM.  General guideline covering all elements of treatment for these patents. Evidence based.

Framework II - Directed saline lavage

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Development</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D3</b>	Clinical guideline  Standard trust layout.	Updated 2019  (review in 2022)	Physiotherapists	Physiotherapists	Description of technique.  Children with endotracheal tube or tracheostomy.	Brief indications  List of CI and precautions  Step by step guide of procedure  Relatively brief document  Minimal support for CDM

Framework III - High frequency chest wall oscillation

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	Document type	Year created/updated	Development	Target audience	Purpose	Content
<b>D27</b>	Guidance document	Created 2012	Not comment on	Not covered	Not explicitly stated	<p>Device explanation, how it works.</p> <p>Indications for use. CI and precautions</p> <p>Overview of procedure</p> <p>Very brief document. No references. Appears more of an informal guide.</p>
<b>D4</b>	Clinical guideline  Standard trust layout	Updated 2018  (review 2021)	Physiotherapists	Physiotherapists (ward/PICU)	Not explicitly stated  All PICU patients	<p>Indications</p> <p>Safety considerations, CI, precautions, appropriate monitoring.</p> <p>Equipment and set up. Method for use, step by step, clear/labelled images.</p> <p>No rationale. 4 references; minimal support for clinical decision making.</p>

Framework IV – Manual assisted cough

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Development</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D23</b>	Local guideline/policy  Standard trust layout	Updated 2020  (review in 2024)	Physiotherapists	Physiotherapists completing paediatric on calls.	Safe and consistent practice of manual assisted cough.  All paediatric patients within hospital.	Goal of technique, indications for use and types of patients. Some support for clinical decision making, related to indications.  Background physiology to technique.  Safety aspects, contra-indications and precautions.  Practical explanation of technique.  Comprehensive. Evidence based and up to date.

Framework V - Manual techniques

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Development</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D14</b>	Procedural document  Standard trust layout	Created 2019  (review in 2022)	Physiotherapists	Physiotherapists	Guidelines for use of techniques. And to support training.  All paediatric patients within hospital.	Safety considerations, contra-indications, precautions and considerations. Potential adverse events.  Brief Indications for use for each manual technique.  Step by step procedure for each technique with rationale. Including links to other trust guidelines.  Some support for clinical decision making related to indications and adaptations.  References included but not evidence based.

Framework VI – Metaneb

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Development</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D7</b>	Standard operating procedure  Standard trust layout	Created 2019  (review 2021)	Physiotherapist	Paediatric physiotherapists	Improve confidence working with device.  All paediatric patients within hospital, specific instructions for those intubated and ventilated.	Brief paragraph on indications. Requires own clinical reasoning.  Contraindications, precautions and potential adverse events listed.  List of equipment Step by step guide to assembly, treatment and cleaning.  Minimal support for CDM. Indications included. But no management strategies for adverse events or problem solving guidance



Framework VII – Manual hyperinflations

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	<b>Document type</b>	<b>Year created/ updated</b>	<b>Development</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D11</b>	Guideline  Standard trust layout	Created 2020  (review 2023)	Physiotherapists	Paediatric physiotherapists - deemed competent in use of MHI	Not explicitly stated  Intubated and ventilated patients.	Physiology underpinning technique and evidence. Indications for use. Safety considerations, Precautions and CI.  Treatment procedure, including detailed rationale, with photographs of all equipment.  Some support for CDM, full assessment described, rationale during treatment.  Thorough document, referenced.

<b>D13</b>	Clinical guideline Standard trust layout	Created 2020 (review 2023)	Physiotherapists, reviewed by other members of MDT.	Physiotherapy staff	To provide standardised outline of technique to optimise safety.  Intubated paediatric patients.	Brief introduction to technique.  Indications, brief list. Safety considerations. Contra-indications and precautions. Possible adverse events of technique.  List and photos of equipment required, step by step guide to completing procedure, actions and rationale.  Support for CDM during treatment with rationale section. Adaptations, things to look for.
<b>D25</b>	Local clinical guideline Standard trust layout	Updated 2020 (review 2032)	Physiotherapists	Physiotherapists, nursing and medical staff.	Formalise a consistent and safe method of MHI for ACT. Evidence based and up to date.  Intubated and ventilated patients or those with a tracheostomy.	Indications for use with associated evidence.  Safety considerations. Contra-indications and precautions. Hazards and complications, including actions to manage these, guidance for decision making.  Equipment and settings. Step by step guide to procedure, with information to improve effectiveness and ensure safety.  Well referenced and evidence-based.

D6	Standard operating procedure  Standard trust layout	Updated 2020  (review 2022)	Physiotherapist	Physiotherapists	To provide guidance and ensure competence and effectiveness.  Intubated patients.	Equipment required.  Brief comment on precautions/CI, and side effects.  Step by step guide to procedure. No rationale, indications provided.  Describes throughout physiotherapists having to use own clinical reasoning.
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Framework VIII – Manual insufflation/exsufflation

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Developed by</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D2</b>	Clinical guideline  Standard trust layout	Updated 2021  (review 2024)	Physiotherapists	Physiotherapists. Other staff and carers.	To standardise practice, ensure safe and evidence-based use.  All paediatric patients within hospital.	Introduction to device and effects.  Indications for use  Safety considerations, CI, precautions. No adverse events/risks.  Clear explanation of device and procedure for use; including, set up, display, modes, cleaning. Images included.  Some guidance for CDM in considerations for use section.  Includes references but not integrated into document.

<b>D18</b>	Clinical guideline Standard trust layout	Updated 2019  (review 2022)	Physiotherapists	Children's physiotherapists  Medical staff on wards and senior nurses on PICU should be aware of doc.  Specific guidance to how each group should use.	Guidance for the use of the device as an adjunct to physiotherapy techniques.  All paediatric patients within hospital.	Brief introduction to device and how works.  Detailed indications for use, including types of patients.  Safety considerations, CI, precautions, AEs/risks.  Equipment and step by step instructions for use, including labelled images.  Section on monitoring and ending treatment. Some support for CDM.  Additional bedside documents/log of use.
<b>D8</b>	Standard operating procedure  Standard trust layout	Created 2013	Physiotherapist	Paediatric physiotherapists	Guidance for safe use of device.  All paediatric patients within hospital.	Indications for use. Contra-indications and precautions.  Step by step instructions for use. No details about settings/modes to use.  Brief document.  No support for decision making.

Framework IX - Non-bronchoscopic bronchoalveolar lavage

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Developed by</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D10</b>	Clinical guideline	Created 2017	Physiotherapists	Physiotherapists	Not explicitly outlined	<p>Indications</p> <p>Referral process for procedure</p> <p>Brief comment on safety, contra-indications and adverse events. Assumes certain level of knowledge</p> <p>Description of equipment with photo. Step by step guide.</p> <p>Minimal support for decision making</p>

D12	<p>Clinical guideline (draft version provided)</p> <p>Standard trust layout</p>	Created 2015	Physiotherapists	<p>Physiotherapists</p> <p>Other PICU staff (indications)</p>	<p>To provide standardised outline of technique, optimise safety. Support competency. to inform PICU staff of indications.</p> <p>Intubated paediatric patients.</p>	<p>Introduction to procedure. Indications</p> <p>Safety considerations, contra-indications, precautions, potential adverse events with detailed rationale. Infection control.</p> <p>Equipment needed and photo.</p> <p>Links to other relevant guidelines.</p> <p>Step by step procedure with rational and reasoning. Includes support for decision making</p>
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D17	Clinical guideline Standard trust layout	Updated 2019 (review 2022)	Physiotherapists	Physiotherapists Other PICU staff should be aware	To provide support for set up and completion of procedure.	<p>Background to procedure.</p> <p>Safety considerations, contraindications and precautions, potential complications.</p> <p>Organisational information and preparation of patient</p> <p>Equipment preparation with photos. Step by step guide to procedure.</p> <p>Evidence-based.</p> <p>Some CDM support with regards to indication and appropriateness of procedure, but not during.</p>
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D20	Clinical guideline Standard trust layout	Not stated	Physiotherapist	PICU physiotherapists and medical team	Not explicitly discussed. Intubated children.	Brief introduction. Indications. Cautions and potential complications Equipment with photos. Step by step procedure with rationale and actions to implement in reaction to patients response. Support for decision making in indications and appropriateness also during procedure. Evidenced based and referenced throughout
D21	Standard operating procedure	Created 2019 (review 2021)	Physiotherapist	Physiotherapist, medic, senior nurse	Not explicitly discussed	Rationale and indications. Safety considerations, contra-indications and potential complications. Equipment with photos. Step by step procedure with photos. Some decision making support for indications and preparation. Minimal for during procedure. Referenced throughout.

D24	Local guideline Standard trust layout	Updated 2021 (review 2023)	Physiotherapist and Intensivist.	All individuals trained in procedure. (physiotherapist, nurse, medic)	Best practice guidelines. Also to ensure in line with ongoing research study.	Introduction to procedure and indications  Safety considerations, complications, contra-indications and precautions  Equipment with photos. Step by step guide to procedure. Few comments around actions.  Summary table of evidence/benchmarking.  Support for CDM with regards to indications and preparation of patient but minimal for during procedure.
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<b>D5</b>	Guideline	Updated 2018 (review 2020)	Clinical lead PICU, lead nurse, PICU consultant.	Medical staff  All HCPs involved ?if relevant for physiotherapists.	To establish clear guidance on how to perform procedure.  Intubated patients.	Background to procedure and indications.  Potential complications, contraindications.  Equipment required with photos. Step by step guide to procedure with a few rationale points.  How to request, with photos.  Practical guide with minimal support for CDM.
<b>D28</b>	Guideline  Standard trust layout	Updated 2017 (review 2020)	Physiotherapists	Those trained to undertake procedure (physiotherapists, PICU advanced nurse practitioners, medics)	To establish consensus and evidence-based guidelines for safe and effective use.  Patients with an artificial airway.	Indications  Safety considerations, contra-indications, Potential risk/issues and how to manage these. Support for clinical decision making.  Pre-procedure observations with rationale.  Equipment with photos. Step by step procedure with photos. Including bedside check list.  Evidence-based throughout.

Framework X – Ventilator hyperinflations

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	<b>Document type</b>	<b>Year created/ updated</b>	<b>Developed by</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D15</b>	Clinical guideline  Standard trust layout	Created 2020  (review 2023)	Physiotherapists. Reviewed by lead consultant and matron.	Paediatric physiotherapists. Medical and nurses should be aware of document	Standardise and facilitate best practice, using evidence-based approach. Ensure safety and effectiveness.  Invasively and non-invasively ventilated children.	Introduction to technique, physiology, definitions.  Aim of technique, indications for use.  Safety considerations. Lists of contra-indications, precautions and adverse events.  Equipment required. Step by step method including calculations. Includes how to adapt/progress treatment. Guidance on what to monitor and document.  Support with decision making provided.  Referenced and evidence-based.

D22	<p>Standard operating procedure/guideline</p> <p>Standard trust layout</p>	<p>Created 2021</p> <p>(review 2023)</p>	Physiotherapist	Physiotherapists. Although circulated to wider PICU team.	<p>Guide practice in relation to evidence and standards available.</p> <p>Invasively ventilated children.</p>	<p>Introduction to technique, including description, physiology, evidence.</p> <p>Indications for use with associated evidence.</p> <p>Safety considerations, including contra-indications, precautions. Hazards and complications included with actions.</p> <p>Comment on importance of individual, comprehensive assessment.</p> <p>Equipment required, and step by step method, including rationale behind. Adds decision making support.</p>
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D26	Local clinical guideline  Standard trust layout	Created 2020  (review 2022)	Physiotherapist	Paediatric physiotherapists	Formalise a consistent and safe method. Evidence based and up to date.	Purpose and indications, including associated rationale.  Safety considerations, including contra-indications and precautions. Hazards/complications including actions to manage these.  Equipment needed. Step by step method, including adjustments to improve effectiveness. Guides decision making during treatment. Referenced throughout.
D29	Guideline	Created 2020  (review 2022)	Physiotherapists	Physiotherapists	Not explicitly mentioned.  Ventilated patients.	Brief intro on aims of treatment and indications for use.  Brief comment on risks. Does link to MHI guideline.  Step by step procedure including example calculations. Video link.  No real support for clinical reasoning. Comment including on evaluating

						<p>effectiveness and progressing treatment.</p> <p>Mainly related to COVID19, more of a technical guide.</p>
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Framework XI – Mucoactive agents

	<b>Document type</b>	<b>Year created/ updated</b>	<b>Developed by</b>	<b>Target audience</b>	<b>Purpose</b>	<b>Content</b>
<b>D1</b>	Clinical guideline  Standard trust layout	Updated 2020  (review 2023)	Physiotherapists and PICU consultant.	PICU doctor, advanced nurse practitioner and physiotherapist.	Guideline for use of DNase in critical mucus plugging.  Mechanically ventilated children.	Brief introduction to DNase  Indications. Contra-indications and precautions. Potential side effects.  Preparation of drug.  Summary of procedure, photos of positions, guidance of how to adapt treatment depending on how tolerating. Documentation requirements.  Some support for decision making related to indications, adaptations during treatment and monitoring requirements after.



<b>D9</b>	Guideline	Created 2020  (review 2022)	Physiotherapist, pharmacist and PICU consultant.	PICU doctor or physiotherapist	Guideline for DNase use.  Ventilated patients on PICU.	Indications.  Mechanism of action  Dosage information  Step by step procedure, photos of positioning. Brief guidance for adapting/managing response.  Safety considerations, contra-indications, adverse events, pharmacokinetics/interactions.  Referenced but not integrated into guideline.
<b>D19</b>	Guideline  Standard trust layout	Updated 2020  (review 2024)	Physiotherapist and pharmacist	Staff at trust	Guideline for use of 0.9% sodium chloride, 3 and 7% hypertonic saline, DNase.  All paediatric patients.	Brief description of action of each medication.  Indications for use.  Dosage and how delivered.  Detailed step by step guide and safety considerations for instilled DNase.  Minimal support for decision making, other than specific indications for DNase.

Appendix 25 – Local audit of length of physiotherapy treatment

<b>Gender</b>	<b>Age in months</b>	<b>Unit</b>	<b>Treatment length (minutes)</b>
Male	3	CICU	00:06:00
Female	11	CICU	00:04:00
Male	0.03	CICU	00:10:00
Male	12	CICU	00:05:00
Male	4	CICU	00:05:48
Male	17	CICU	00:04:00
Male	3	CICU	00:03:48
Male	0.5	PICU	00:10:05
Male	0.6	PICU	00:08:30
Male	6	CICU	00:04:21
Male	5	CICU	00:06:15
Male	0.7	PICU	00:20:00
Male	58	PICU	00:06:00
Female	2	PICU	00:08:00
Male	0.5	PICU	00:09:06
Female	0.3	CICU	00:12:00
Female	4	CICU	00:03:50
Female	8	PICU	00:12:00
Female	48	PICU	00:10:00
Female	3	PICU	00:20:00
Female	18	PICU	00:23:00
Female	0.5	CICU	00:07:00
Male	2	CICU	00:06:30
Male	0.2	NICU	00:17:45
Female	8	PICU	00:08:22

## Appendix 26 – Oxygen saturation index 30-minute summary R Script

```
#####  
##load in osi files  
#####  
  
##data set 1  
osi1 <- xap.read_table("first_osi1_23june")  
str(osi1)  
osi1a <- select(osi1, project_id, record_date_time_x, map, fio2, spo2, osi)  
unique(osi1a$project_id)  
str(osi1a)  
  
##data set 2  
osi2 <-xap.read_table("first_osi2_23june")  
str(osi2)  
osi2a <- select(osi2, project_id, record_date_time_x, map, fio2, spo2, osi)  
str(osi2a)  
unique(osi2a$project_id)  
  
##partial data set  
osi_p <- xap.read_table("first_partialosi_23june")  
str(osi_p)  
osi_p1 <- select(osi_p, project_id, record_date_time_x, map, fio2, spo2, osi)  
str(osi_p1)  
unique(osi_p1$project_id)  
  
### combine part 1 and part 2 and partial osi files  
  
#combine 1 & 2  
  
OSI_first <- rbind(osi1a, osi2a, osi_p1)  
str(OSI_first)  
unique(OSI_first$project_id)  
summary(OSI_first)  
  
#####  
###bring in times  
#####  
  
##load in physio times data and check 1  
physiotimes1_data <- xap.read_table("complete01_wp2_physio_times_check")  
str(physiotimes1_data)  
head(physiotimes1_data)  
unique(physiotimes1_data$project_id)  
  
##load in physio times data and check 2  
physiotimes2_data <- xap.read_table("complete02_wp2_physio_times_check")  
str(physiotimes2_data)  
head(physiotimes2_data)  
unique(physiotimes2_data$project_id)
```

```

##load in physio times data and check partial
physiotimes_partial <- xap.read_table("partial_wp2_physio_times_check")
str(physiotimes_partial)
head(physiotimes_partial)
unique(physiotimes_partial$project_id)

##join 1 and 2
physiotimes1 <- rbind(physiotimes1_data, physiotimes2_data)

###join partial
physiotimes <- rbind(physiotimes1, physiotimes_partial)
str(physiotimes)

##pick only first session
firstsession <- subset(physiotimes, day==1 & session==1)
str(firstsession)

####create times

#generate pre physio time - subtract 60 mins
firstsession1 <- firstsession %>%
  mutate(pre_datetime =(datetime - (minutes=3600)))

# generate start time for physio each patient - subtracting 60 minutes
firstsession1a <- firstsession1 %>%
  mutate(start_datetime =(datetime - (minutes=1800)))

# generate end times for 30 mins after physio each patient - adding 30 mins
firstsession1b <- firstsession1a %>%
  mutate(end_datetime =(datetime + (minutes=1800)))
str(firstsession1b)

firstsession1b <- select(firstsession1b, project_id, datetime, pre_datetime,
start_datetime, end_datetime)
str(firstsession1b)

#####
##join OSI to physiotimes
#####

osi_firstx <- inner_join(firstsession1b, OSI_first, by = 'project_id')
str(osi_firstx)
unique(osi_firstx$project_id)

#####
# Plot raw data on graph - calculate time difference from first recorded (baseline)
#####

osi_first_data <- osi_firstx %>%
  arrange(project_id, record_date_time_x) %>%

```

```

group_by(project_id) %>%
mutate(diff = record_date_time_x - pre_datetime,
      diff_secs = as.numeric(diff, units = 'secs')) %>%
  ungroup()

str(osi_first_data)

ggplot(osi_first_data, aes(x=diff_secs, y=osi, color = project_id)) +
  geom_point(aes(color = project_id), size = 1) +
  ggtitle("OSI pre and post physio") + # add a title
  xlab('Time') + ylab('OSI') + # add axis names
  xlim(0,5400) +
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
        legend.position="none") +
  geom_vline(xintercept = c(1800, 3600), color = "red")

#####
###create pre and post data set
#####

## pre physio
pre_osi_first <- osi_firstx %>% group_by(project_id) %>%
filter(record_date_time_x > pre_datetime & record_date_time_x <
start_datetime) %>% ungroup()
str(pre_osi_first)

## post physio
post_osi_first <- osi_firstx %>% group_by(project_id) %>%
filter(record_date_time_x > datetime & record_date_time_x < end_datetime)
%>% ungroup()
str(post_osi_first)

#####
###summary statistics of raw values by ID
#####

str(post_osi_first)
str(pre_osi_first)

pre_summary <- pre_osi_first %>%
group_by(project_id) %>%
summarise(Median=median(osi, na.rm = TRUE), Max=max(osi), Min=min(osi))
print(pre_summary)

post_summary <- post_osi_first %>%
group_by(project_id) %>%
summarise(Median=median(osi, na.rm = TRUE), Max=max(osi, na.rm = TRUE),
Min=min(osi, na.rm = TRUE))
print(post_summary)

```

```

str(pre_summary)
str(post_summary)

#rename median columns
pre_summary$premedian <- pre_summary$Median
post_summary$postmedian <- post_summary$Median

###join summaries by project id
summary_OSI_data <- full_join(pre_summary, post_summary, by="project_id")
str(summary_OSI_data)
unique(summary_OSI_data$project_id)

#####
##create difference variable
#####

summary_OSI_data$OSI_diff <- summary_OSI_data$postmedian -
summary_OSI_data$premedian
str(summary_OSI_data)
is.na(summary_OSI_data$OSI_diff)
tail(summary_OSI_data)

####remove NAs

summary_OSI_data1 <- na.omit(summary_OSI_data)
unique(summary_OSI_data1$project_id)
str(summary_OSI_data1)

#####
#### create new variable for above or below threshold
#####

summary_OSI_data1$OSI_threshold <- ifelse(summary_OSI_data1$OSI_diff >=
0.3, "yes", "no")
str(summary_OSI_data1)

t.OSI <- table(summary_OSI_data1$OSI_threshold)
addmargins(t.OSI)
round(prop.table(t.OSI)*100, 2) #to give percentage

####create new variable above, isq, below
str(summary_OSI_data1)

summary_OSI_data1$OSI_result <- ifelse(summary_OSI_data1$OSI_diff < 0,
'Improved',
      ifelse(summary_OSI_data1$OSI_diff == 0, 'ISQ',
            ifelse(summary_OSI_data1$OSI_diff > 0 &
summary_OSI_data1$OSI_diff < 0.3, 'Worse', 'AE')))
str(summary_OSI_data1)

```

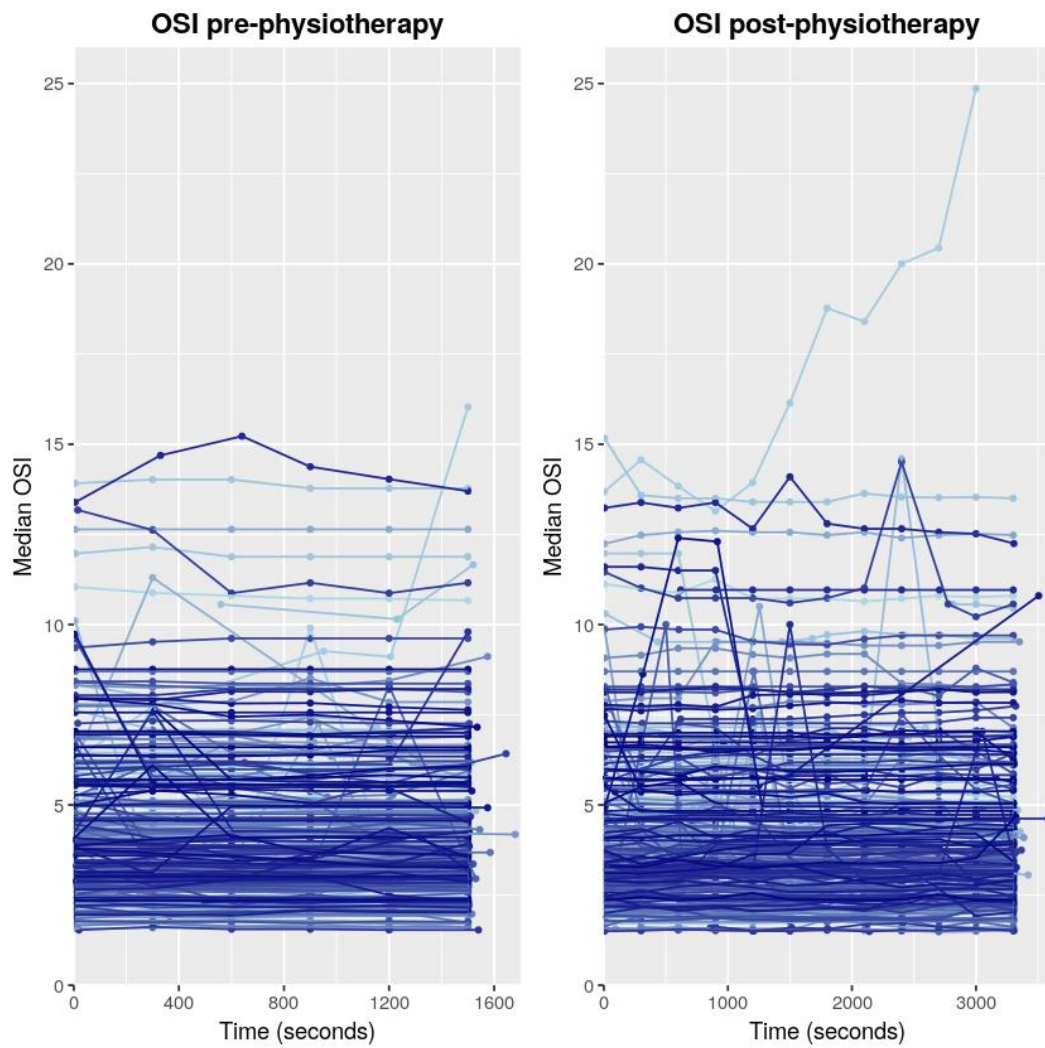
```

ggplot(summary_OSI_data1, aes(x = premedian, y=OSI_diff,
colour=OSI_threshold)) +
  geom_point(size=1.5) +
  xlab('Median oxygen saturation index pre-physiotherapy') + ylab('Change in
oxygen saturation index') + # add axis names
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none") +
  scale_color_manual(breaks = c("yes", "no"),
  values=c("red", "steelblue4")) +
  geom_hline(yintercept = 0.3, color = "red")+
  geom_hline(yintercept = 0, color = "black")

result1 <- table(summary_OSI_data1$OSI_result)
addmargins(result1)
round(prop.table(result1)*100, 2) #to give percentage

```

Appendix 27 – Five-minute summary OSI medians for individual patients pre- and post-physiotherapy



(n=247, OSI – oxygen saturation index)



## Appendix 28 – Oxygen saturation index first session R script

```
#####  
##load in osi files  
#####  
##data set 1  
osi1 <- xap.read_table("osi1_1_1")  
##data set 2  
osi2 <-xap.read_table("osi2_1_1")  
##partial data set  
osi_p <- xap.read_table("osipartial_1_1")  
#combine 1 & 2  
OSI_first1 <- rbind(osi1, osi2)  
OSI_first <-rbind(OSI_first1, osi_p)  
  
#####  
# Plot raw data - calculate time difference from first recorded (baseline)  
#####  
osi_first_data <- OSI_first %>%  
  arrange(project_id, record_date_time_x) %>%  
  group_by(project_id) %>%  
  mutate(diff = record_date_time_x - pre_datetime_x,  
         diff_secs = as.numeric(diff, units = 'secs')) %>%  
  ungroup()  
  
str(osi_first_data)  
fun_color_range <- colorRampPalette(c("lightblue", "navy"))  
my_colors <- fun_color_range(261)  
  
ggplot(osi_first_data, aes(x=diff_secs, y=osi)) +  
  geom_point(aes(color = project_id), size = 0.5) +  
  xlab('Time (seconds)') + ylab('Oxygen saturation index') + # add axis names  
  scale_y_continuous(expand = c(0, 0), limits = c(0, 55)) +  
  scale_x_continuous(expand = c(0, 0), limits = c(0,7500)) +  
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),  
        legend.position="none") +  
  scale_color_manual(values = my_colors) +  
  geom_vline(xintercept = c(1800, 3600), color = "red")  
  
#####  
###create pre and post data set  
#####  
  
## pre physio  
pre_osi_first <- OSI_first %>% group_by(project_id) %>%  
  filter(record_date_time_x > pre_datetime_x & record_date_time_x <  
  start_datetime_x) %>% ungroup()  
str(pre_osi_first)  
summary(pre_osi_first)  
  
## post physio
```

```

post_osi_first <- OSI_first %>% group_by(project_id) %>%
filter(record_date_time_x > datetime_x & record_date_time_x < end_datetime_x)
%>% ungroup()
str(post_osi_first)
summary(post_osi_first)

#####
# prepare data to calculate 5 min epochs
#####

###pre physio, prepare constant dates times
str(pre_osi_first)

pre_OSI_first2 <- pre_osi_first %>%
  arrange(project_id, record_date_time_x) %>%
  group_by(project_id) %>%
  mutate(diff = record_date_time_x - pre_datetime_x,
         diff_secs = as.numeric(diff, units = 'secs')) %>%
  ungroup()
str(pre_OSI_first2)

pre_OSI_first_test <- mutate(pre_OSI_first2, osi_time = as.POSIXct(diff_secs,
origin = "1970-01-01"))
str(pre_OSI_first_test)

####generate 5 min epochs and summaries
pre_OSI_first_5 <- pre_OSI_first_test %>% group_by(project_id,
by5=cut(osi_time, "5 min")) %>%
  summarise(median=median(osi), across())

str(pre_OSI_first_5)
head(pre_OSI_first_5)

##remove repeated rows 'by 5'
pre_OSI_first_5a <- pre_OSI_first_5 %>% group_by(project_id, by5) %>%
  filter(row_number()==1) %>%
  ungroup()

str(pre_OSI_first_5a)

###check how many values for each
table(pre_OSI_first_5a$project_id)

##post physio prepare new times
post_OSI_first2 <- post_osi_first %>%
  arrange(project_id, record_date_time_x) %>%
  group_by(project_id) %>%
  mutate(diff = record_date_time_x - datetime_x,
         diff_secs = as.numeric(diff, units = 'secs')) %>%

```

```

    ungroup()
    str(post_OSI_first2)

post_OSI_first_test <- mutate(post_OSI_first2, osi_time = as.POSIXct(diff_secs,
origin = "1970-01-01"))
str(post_OSI_first_test)

##create 5 min epochs
post_OSI_first_5 <- post_OSI_first_test %>% group_by(project_id,
by5=cut(osi_time, "5 min")) %>%
  summarise(median=median(osi), across())
str(post_OSI_first_5)
head(post_OSI_first_5)

##remove repeated rows 'by 5'
post_OSI_first_5a <- post_OSI_first_5 %>% group_by(project_id, by5) %>%
  filter(row_number()==1) %>%
  ungroup()
str(post_OSI_first_5a)

###check how many values for each
table(post_OSI_first_5a$project_id)

###check distrubution

ggplot(pre_OSI_first_5a, aes(x=osi)) + geom_histogram()
ggplot(post_OSI_first_5a, aes(x=osi)) + geom_histogram()

##check log
##pre
pre_OSI_first_5a$osi_log <- log(pre_OSI_first_5a$osi)
str(pre_OSI_first_5a)

ggplot(pre_OSI_first_5a, aes(x=osi_log)) + geom_histogram()

##post
post_OSI_first_5a$osi_log <- log(post_OSI_first_5a$osi)
str(post_OSI_first_5a)

ggplot(post_OSI_first_5a, aes(x=osi_log)) + geom_histogram()

#####
## draw graph of 5 min medians pre/post
#####

#need to change by into POSIXct from factor
pre_OSI_first_5a$by5 <- as.POSIXct(pre_OSI_first_5a$by5,format='%Y-%m-%d
%H:%M:%S')
post_OSI_first_5a$by5 <- as.POSIXct(post_OSI_first_5a$by5,format='%Y-%m-
%d %H:%M:%S')

```

```

### pre-physio
pre_plot <- ggplot(pre_OSI_first_5a, aes(x=diff_secs, y=median, colour =
project_id)) +
  geom_point(aes(color = project_id), size = 1) +
  geom_line() +
  ggtitle("OSI pre-physiotherapy") + # add a title
  xlab('Time (seconds)') + ylab('Median OSI') + # add axis names
  scale_y_continuous(expand = c(0, 0), limits = c(0, 26)) +
  scale_x_continuous(expand = c(0, 0), limits = c(0,1700)) +
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none")+
  scale_color_manual(values=my_colors)

## plot median SpO2
post_plot <- ggplot(post_OSI_first_5a, aes(x=diff_secs, y=median, colour =
project_id)) +
  geom_point(aes(color = project_id), size = 1) +
  geom_line() +
  ggtitle("OSI post-physiotherapy") + # add a title
  xlab('Time (seconds)') + ylab('Median OSI') + # add axis names
  scale_y_continuous(expand = c(0, 0), limits = c(0, 26)) +
  scale_x_continuous(expand = c(0, 0), limits = c(0,3600)) +
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none")+
  scale_color_manual(values=my_colors)

grid.arrange(pre_plot, post_plot, ncol=2)

#####
###5 mins pre and post add extra column
#####

str(pre_OSI_first_5a)
str(post_OSI_first_5a)

##select columns want
preOSI <- select(pre_OSI_first_5a, project_id, by5, median)
postOSI <- select(post_OSI_first_5a, project_id, by5, median)

##rename medians for clarity
names(preOSI)[names(preOSI) == 'median'] <- 'premedian'
names(postOSI)[names(postOSI) == 'median'] <- 'postmedian'

##add extra column
preOSI1 <- preOSI %>%
group_by(project_id) %>%
mutate(label1 = LETTERS[row_number()]) %>%
ungroup()

```

```

postOSI1 <- postOSI %>%
group_by(project_id) %>%
mutate(label = LETTERS[row_number()]) %>%
ungroup()

##Reverse preOSI letters
preOSI2 <- preOSI1 %>%
group_by(project_id) %>%
mutate(label = rev(label1)) %>%
ungroup()

#####
#####
###analysis 1 5 min pre vs 5 min post
#####
#####

#####
##subset pre for just 5min immediately pre "A"
#####

preOSI3 <- select(preOSI2, project_id, by5, premedian, label)
preOSI4 <- subset(preOSI3, label == "A")
str(preOSI4)
preOSI5 <- select(preOSI4, project_id, by5, premedian)
str(preOSI5)

###remove row if by5 time not 00:25:00
preOSI6 <- preOSI5[preOSI5$by5 == "1970-01-01 00:25:00",]

#####
##subset post for 5 min imm post A
#####

postOSI2 <- subset(postOSI1, label == "A")
str(postOSI2)
###remove rows if by5 time not 00:00:00
postOSI3 <- postOSI2[postOSI2$by5 == "1970-01-01 00:00:00",]
str(postOSI3)

#####
##join pre and post together
#####

osi_prepost_5 <- inner_join(postOSI3, preOSI6, by="project_id")
str(osi_prepost_5)
unique(osi_prepost_5$project_id)

#####
##calculate differences in 5 mins medians

```

```
#####

osi_prepost_5$OSI_diff <- osi_prepost_5$postmedian -
osi_prepost_5$premedian
str(osi_prepost_5)

#### create new variable for above or below threshold
osi_prepost_5$OSI_threshold <- ifelse(osi_prepost_5$OSI_diff >= 0.3, "yes",
"no")

str(osi_prepost_5)

t.OSI <- table(osi_prepost_5$OSI_threshold)

addmargins(t.OSI)
round(prop.table(t.OSI)*100, 2) #to give percentage

plot1 <- ggplot(osi_prepost_5, aes(x = premedian, y=OSI_diff)) +
  geom_point(colour="deepskyblue4") +
  ggtitle(" 0-5 mins post physiotherapy") + # add a title
  ylab('Difference in 5 minute medians of OSI') + xlab(NULL) +
  ylim(-6,15)+ # add axis names
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none")+
  geom_hline(yintercept = 0.3, color = "red")

####create new variable above, isq, below
osi_prepost_5$OSI_result <- ifelse(osi_prepost_5$OSI_diff < 0, 'Improved',
  ifelse(osi_prepost_5$OSI_diff == 0, 'ISQ',
  ifelse(osi_prepost_5$OSI_diff > 0 & osi_prepost_5$OSI_diff <
0.3, 'Worse', 'AE')))
str(osi_prepost_5)

result1 <- table(osi_prepost_5$OSI_result)
addmargins(result1)
round(prop.table(result1)*100, 2) #to give percentage

#####graph

plot5x <- ggplot(osi_prepost_5, aes(x = premedian, y=OSI_diff,
colour=OSI_result)) +
  geom_point() +
  ggtitle("0-5 minutes post-physiotherapy") + # add a title
  ylab('Change in median OSI') + xlab(NULL) +
  ylim(-6,15)+
  scale_x_continuous(expand = c(0, 0), limits = c(0,17)) +
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none")+
  scale_color_manual(breaks = c("AE", "Worse", "ISQ", "Improved"),
  values=c("red", "red4", "chartreuse4", "chartreuse3")) +
```

```
geom_hline(yintercept = 0.3, color = "red") +
geom_hline(yintercept = 0, color = "black")
```

```
#####
#####
##analysis 2 5 mins pre vs 15 mins post
#####
#####
```

```
#####
##subset post for 15 min imm post C
#####
```

```
postOSI_15 <- subset(postOSI1, label == "C")
str(postOSI_15)
```

```
###remove rows if by5 time not 00:10:00
```

```
postOSI_15a <- postOSI_15[postOSI_15$by5 == "1970-01-01 00:10:00",]
```

```
#####
##join pre and post together
#####
```

```
osi_prepost_15 <- inner_join(postOSI_15a, preOSI6, by="project_id")
str(osi_prepost_15)
```

```
#####
##calculate differences in 5 mins medians
#####
```

```
osi_prepost_15$OSI_diff <- osi_prepost_15$postmedian -
osi_prepost_15$premedian
str(osi_prepost_15)
```

```
#### create new variable for above or below threshold
osi_prepost_15$OSI_threshold <- ifelse(osi_prepost_15$OSI_diff >= 0.3, "yes",
"no")
```

```
str(osi_prepost_15)
```

```
t.OSI <- table(osi_prepost_15$OSI_threshold)
```

```
addmargins(t.OSI)
round(prop.table(t.OSI)*100, 2) #to give percentage
```

```
####create new variable above, isq, below
osi_prepost_15$OSI_result <- ifelse(osi_prepost_15$OSI_diff < 0, 'Improved',
ifelse(osi_prepost_15$OSI_diff == 0, 'ISQ',
```

```

        ifelse(osi_prepost_15$OSI_diff > 0 & osi_prepost_15$OSI_diff <
0.3, 'Worse', 'AE'))
str(osi_prepost_15)

```

```

result2 <- table(osi_prepost_15$OSI_result)
addmargins(result2)
round(prop.table(result2)*100, 2) #to give percentage

```

```
#####graph
```

```

plot15x <- ggplot(osi_prepost_15, aes(x = premedian, y=OSI_diff,
colour=OSI_result)) +
  geom_point() +
  ggtitle("10-15 minutes post-physiotherapy") + # add a title
  ylab(NULL) + xlab(NULL) +
  ylim(-6,15) +
  scale_x_continuous(expand = c(0, 0), limits = c(0,17)) +
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none")+
  scale_color_manual(breaks = c("AE", "Worse", "ISQ", "Improved"),
  values=c("red", "red4", "chartreuse4", "chartreuse3")) +
  geom_hline(yintercept = 0.3, color = "red") +
  geom_hline(yintercept = 0, color = "black")

```

```
#####
#####
### analysis 3 5 min pre vs 30 mins post
#####
#####

```

```
#####
##subset post for 30 min post F
#####

```

```

postOSI_30 <- subset(postOSI1, label == "F")
str(postOSI_30)

```

```

###remove rows if by5 time not 00:25:00
postOSI_30a <- postOSI_30[postOSI_30$by5 == "1970-01-01 00:25:00",]

```

```
#####
##join pre and post together
#####

```

```

osi_prepost_30 <- inner_join(postOSI_30a, preOSI6, by="project_id")
str(osi_prepost_30)

```

```
#####
##calculate differences in 5 mins medians
#####

```



```

osi_prepost_30$OSI_diff <- osi_prepost_30$postmedian -
osi_prepost_30$premedian
str(osi_prepost_30)

#### create new variable for above or below threshold
osi_prepost_30$OSI_threshold <- ifelse(osi_prepost_30$OSI_diff >= 0.3, "yes",
"no")

str(osi_prepost_30)

t.OSI <- table(osi_prepost_30$OSI_threshold)
addmargins(t.OSI)
round(prop.table(t.OSI)*100, 2) #to give percentage

####create new variable above, isq, below

osi_prepost_30$OSI_result <- ifelse(osi_prepost_30$OSI_diff < 0, 'Improved',
ifelse(osi_prepost_30$OSI_diff == 0, 'ISQ',
ifelse(osi_prepost_30$OSI_diff > 0 & osi_prepost_30$OSI_diff <
0.3, 'Worse', 'AE')))
str(osi_prepost_30)

result3 <- table(osi_prepost_30$OSI_result)
addmargins(result3)
round(prop.table(result3)*100, 2) #to give percentage

#####graph

plot30x <- ggplot(osi_prepost_30, aes(x = premedian, y=OSI_diff,
colour=OSI_result)) +
  geom_point() +
  ggtitle("25-30 minutes post-physiotherapy") + # add a title
  ylab('Change in median OSI') + xlab('Median OSI 5 minutes pre-
physiotherapy') +
  ylim(-6,15) +
  scale_x_continuous(expand = c(0, 0), limits = c(0,17)) +
  theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
legend.position = "none")+
  scale_color_manual(breaks = c("AE", "Worse", "ISQ", "Improved"),
  values=c("red", "red4", "chartreuse4", "chartreuse3")) +
  geom_hline(yintercept = 0.3, color = "red") +
  geom_hline(yintercept = 0, color = "black")

#####
#####
##analysis 4 5mins pre vs 60 mins
#####
#####

```

```

#####
##subset post for 60 min post
#####

postOSI_60 <- subset(postOSI1, label == "L")
str(postOSI_60)

###remove rows if by5 time not 00:60:00
postOSI_60a <- postOSI_60[postOSI_60$by5 == "1970-01-01 00:55:00",]
str(postOSI_60a)

#####
##join pre and post together
#####

osi_prepost_60 <- inner_join(postOSI_60a, preOSI6, by="project_id")
str(osi_prepost_60)
#####
##calculate differences in 5 mins medians
#####

osi_prepost_60$OSI_diff <- osi_prepost_60$postmedian -
osi_prepost_60$premedian
str(osi_prepost_60)

#### create new variable for above or below threshold
osi_prepost_60$OSI_threshold <- ifelse(osi_prepost_60$OSI_diff >= 0.3, "yes",
"no")

str(osi_prepost_60)

t.OSI <- table(osi_prepost_60$OSI_threshold)
addmargins(t.OSI)
round(prop.table(t.OSI)*100, 2) #to give percentage

####create new variable above, isq, below
osi_prepost_60$OSI_result <- ifelse(osi_prepost_60$OSI_diff < 0, 'Improved',
ifelse(osi_prepost_60$OSI_diff == 0, 'ISQ',
ifelse(osi_prepost_60$OSI_diff > 0 & osi_prepost_60$OSI_diff <
0.3, 'Worse', 'AE'))))
str(osi_prepost_60)

result4 <- table(osi_prepost_60$OSI_result)
addmargins(result4)
round(prop.table(result4)*100, 2) #to give percentage

#####graph

plot60x <- ggplot(osi_prepost_60, aes(x = premedian, y=OSI_diff,
colour=OSI_result)) +

```

```

    geom_point() +
    ggtitle("55-60 minutes post-physiotherapy") + # add a title
    ylab(NULL) + xlab('Median OSI 5 minutes pre-physiotherapy') +
    ylim(-6,15) +
    scale_x_continuous(expand = c(0, 0), limits = c(0,17)) +
    theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
    legend.position = "none")+
    scale_color_manual(breaks = c("AE", "Worse", "ISQ", "Improved"),
    values=c("red", "red4", "chartreuse4", "chartreuse3")) +
    geom_hline(yintercept = 0.3, color = "red") +
    geom_hline(yintercept = 0, color = "black")

```

```
##combine plots
```

```
grid.arrange(plot5x, plot15x, plot30x, plot60x, ncol=2, nrow=2)
```

```
#####
###Prepare data for univariable and multi-level regression
#####
```

```
#####get individual datasets
```

```
##5 min
```

```
str(osi_prepost_5)
osi_5 <- select(osi_prepost_5, project_id, postmedian, premedian)
str(osi_5)
names(osi_5)[names(osi_5) == "postmedian"] <- "postmedian5"
str(osi_5)
```

```
###15mins
```

```
str(osi_prepost_15)
osi_15 <- select(osi_prepost_15, project_id, postmedian)
str(osi_15)
names(osi_15)[names(osi_15) == "postmedian"] <- "postmedian15"
str(osi_15)
```

```
##30mins
```

```
osi_30 <- select(osi_prepost_30, project_id, postmedian)
str(osi_30)
names(osi_30)[names(osi_30) == "postmedian"] <- "postmedian30"
str(osi_30)
```

```
##60mins
```

```
osi_60 <- select(osi_prepost_60, project_id, postmedian)
str(osi_60)
names(osi_60)[names(osi_60) == "postmedian"] <- "postmedian60"
str(osi_60)
```

```
###join together
```

```

osi_change <- inner_join(osi_5, osi_15, by="project_id")
str(osi_change)
osi_change1 <- inner_join(osi_change, osi_30, by="project_id")
str(osi_change1)
osi_change2 <- inner_join(osi_change1, osi_60, by="project_id")
str(osi_change2)

###change order of columns
osi_change3 <- osi_change2[, c(1, 3, 2, 4, 5, 6)]
str(osi_change3)

####change to long format

osi_change4 <- tidyr::gather(osi_change3, key=time, value=medianosi,
premedian:postmedian60) %>%
  arrange(project_id)

str(osi_change4)

##wilcoxon test
test3 <- osi_change4 %>% wilcox_test(medianosi ~ time, paired = TRUE,
p.adjust.method = "bonferroni")
test3

#####
#####
####multilevel regression
#####
#####

#####
####convert to factor
#####

osi_change4$time <- as.factor(osi_change4$time)
str(osi_change4)

levels(osi_change4$time)

#####
####need to bring in other variables
#####

####GENDER
#####gender from Demo explor 1.1
str(demographic_data)
osi_gender <- select(demographic_data, project_id, sex)
str(osi_gender)

```

```

####join to osi_change4
osi_change5 <- left_join(osi_change4, osi_gender, by="project_id")
str(osi_change5)
unique(osi_change5$project_id)

#####AGE
#####age from Demo explor 1.1
str(age_OSIgroup)
osi_age <- select(age_OSIgroup, project_id, age_in_months)
str(osi_age)

####join to osi_change5
osi_change6 <- left_join(osi_change5, osi_age, by="project_id")
str(osi_change6)
unique(osi_change6$project_id)

#####WEIGHT
#####weight from Demo explor 1.1
str(weightosi)
osi_weight <- select(weightosi, project_id, weight)
str(osi_weight)

####join to osi_change6
osi_change7 <- left_join(osi_change6, osi_weight, by="project_id")
str(osi_change7)
unique(osi_change7$project_id)

#####ADMSSION TYPE
#####type from Demo explor 1.1
str(admission_osi)
osi_admission <- select(admission_osi, project_id, admission.type)
str(osi_admission)

####join to osi_change7
osi_change8 <- left_join(osi_change7, osi_admission, by="project_id")
str(osi_change8)
unique(osi_change8$project_id)

#####PELOD
#####pelod from Demo explor 1.1
str(pelod_osi)
osi_pelod <- select(pelod_osi, project_id, pelod_score)
str(osi_pelod)

####join to osi_change8
osi_change9 <- left_join(osi_change8, osi_pelod, by="project_id")
str(osi_change9)

```

```

###rename for regression and change reference to premedian

osi_change9$time <- relevel(osi_change9$time, "postmedian60")
osi_change9$time <- relevel(osi_change9$time, "postmedian30")
osi_change9$time <- relevel(osi_change9$time, "postmedian15")
osi_change9$time <- relevel(osi_change9$time, "postmedian5")
osi_change9$time <- relevel(osi_change9$time, "premedian")

str(osi_change9)

levels(osi_change9$time) <- c("5 pre", "0-5 post", "10-15 post", "25-30 post", "55-
60 post")

#graph
beanplot(osi_change9$medianosi ~ osi_change9$time,
         col = list("steelblue1", "steelblue2", "steelblue3", "steelblue",
"steelblue4"), border = c("steelblue1", "steelblue2", "steelblue3", "steelblue",
"steelblue4"),
         xlab = "Time point in relation to physiotherapy treatment (minutes)", ylab =
"Median Oxygen saturation index")

#####
###multi level models
#####

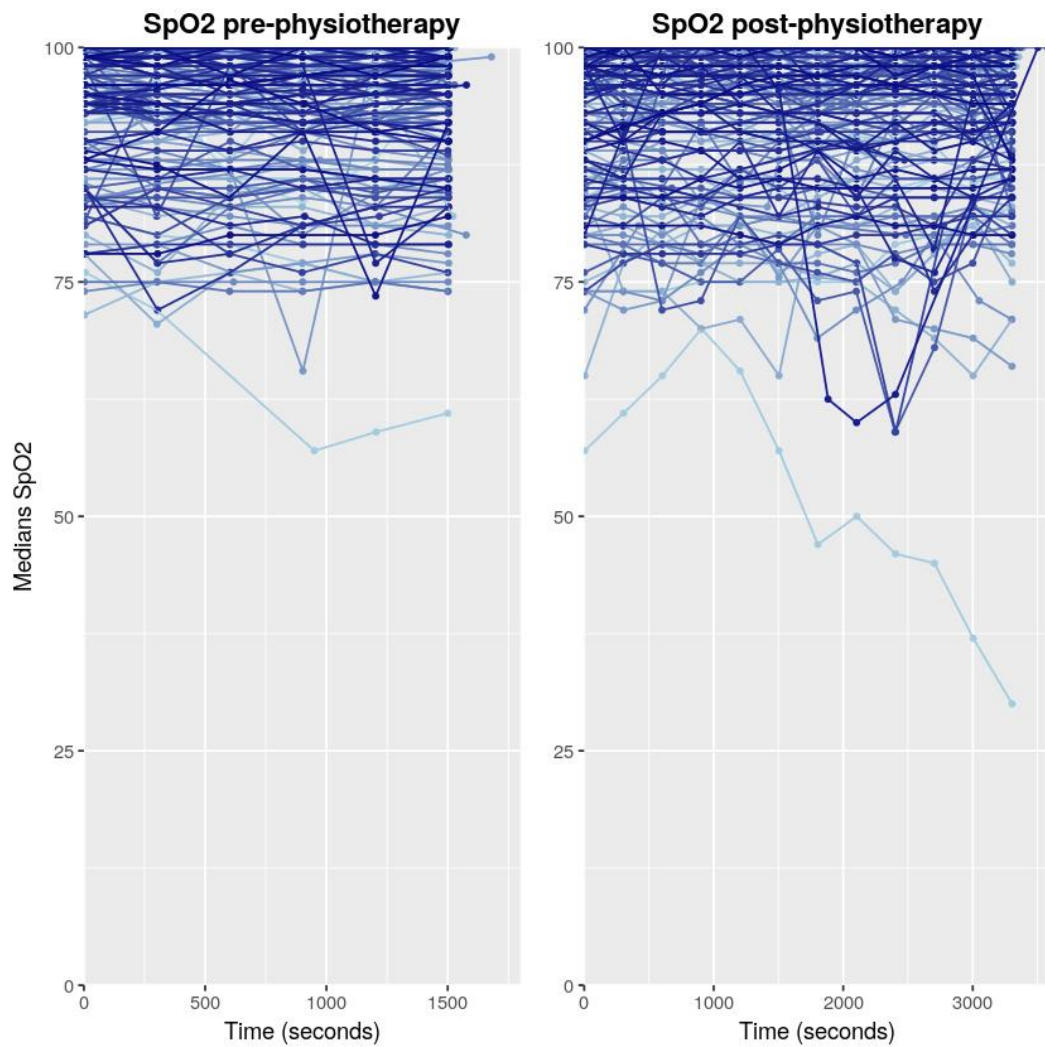
model1 <- glmer(medianosi ~ time + weight + admission.type + pelod_score +
(1|project_id), data=osi_change9, family=Gamma(link="log"))
summary(model1)

#####get confidence intervals

confint(model1,parm="beta_",method="Wald")

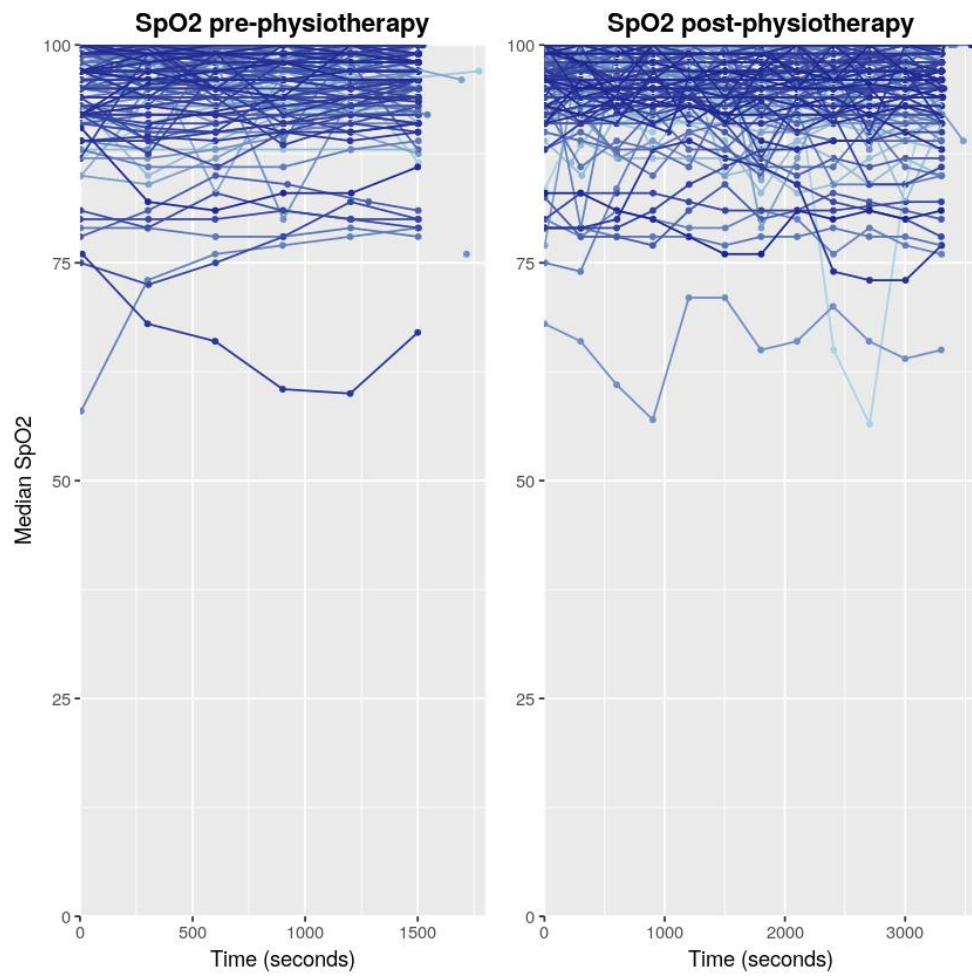
```

Appendix 29 – Five-minute summary SpO<sub>2</sub> medians for individual patients pre- and post-physiotherapy



(n=250, SpO<sub>2</sub> – Peripheral oxygen saturations)

Appendix 30 - Five-minute summary SpO<sub>2</sub> medians for individual patients pre- and post-physiotherapy, subgroup with only SpO<sub>2</sub> data available



(n=205, SpO<sub>2</sub> – Peripheral oxygen saturations)

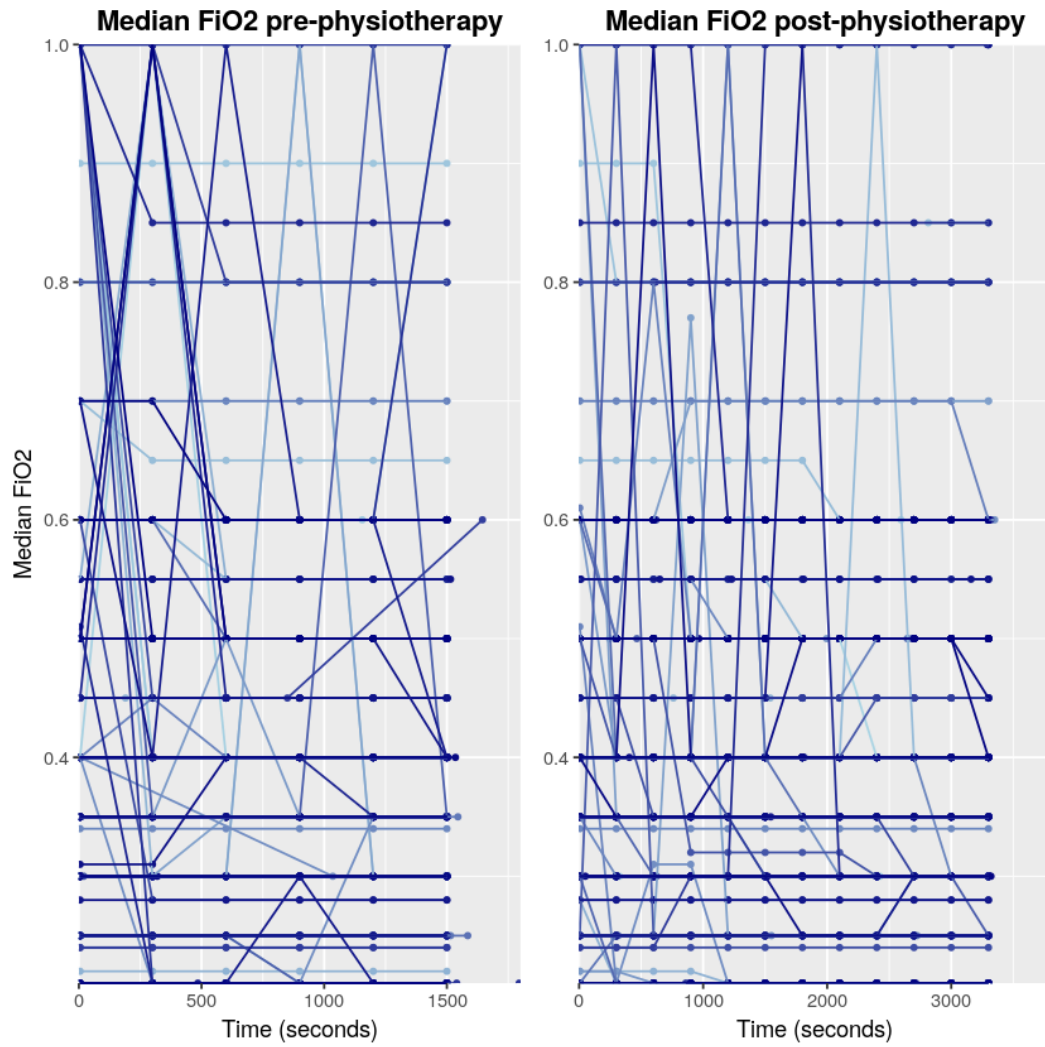


Appendix 31 - Wilcoxon signed-rank test with Bonferroni adjustment comparing median SpO<sub>2</sub> pre- and post-physiotherapy

<b>Time point 1</b>	<b>Time point 2</b>	<b>Median of SpO<sub>2</sub> paired differences (IQR)</b>	<b>Wilcoxon signed rank test (p.adjust)</b>
Pre-physiotherapy	5 minutes post	0 (-1-1)	p=1.0
Pre-physiotherapy	15 minutes post	0 (-2-1)	p=1.0
Pre-physiotherapy	30 minutes post	0 (-2-1)	p=1.0
Pre-physiotherapy	60 minutes post	0 (-2-1)	p=1.0
5 minutes post	15 minutes post	0 (-1-0)	p=0.762
5 minutes post	30 minutes post	0 (-1-1)	p=1.0
5 minutes post	60 minutes post	0 (-2-1)	p=0.747
15 minutes post	30 minutes post	0 (-1-1)	p=1.0
15 minutes post	60 minutes post	0 (-1-1)	p=1.0
30 minutes post	60 minutes post	0 (-1-1)	p=1.0

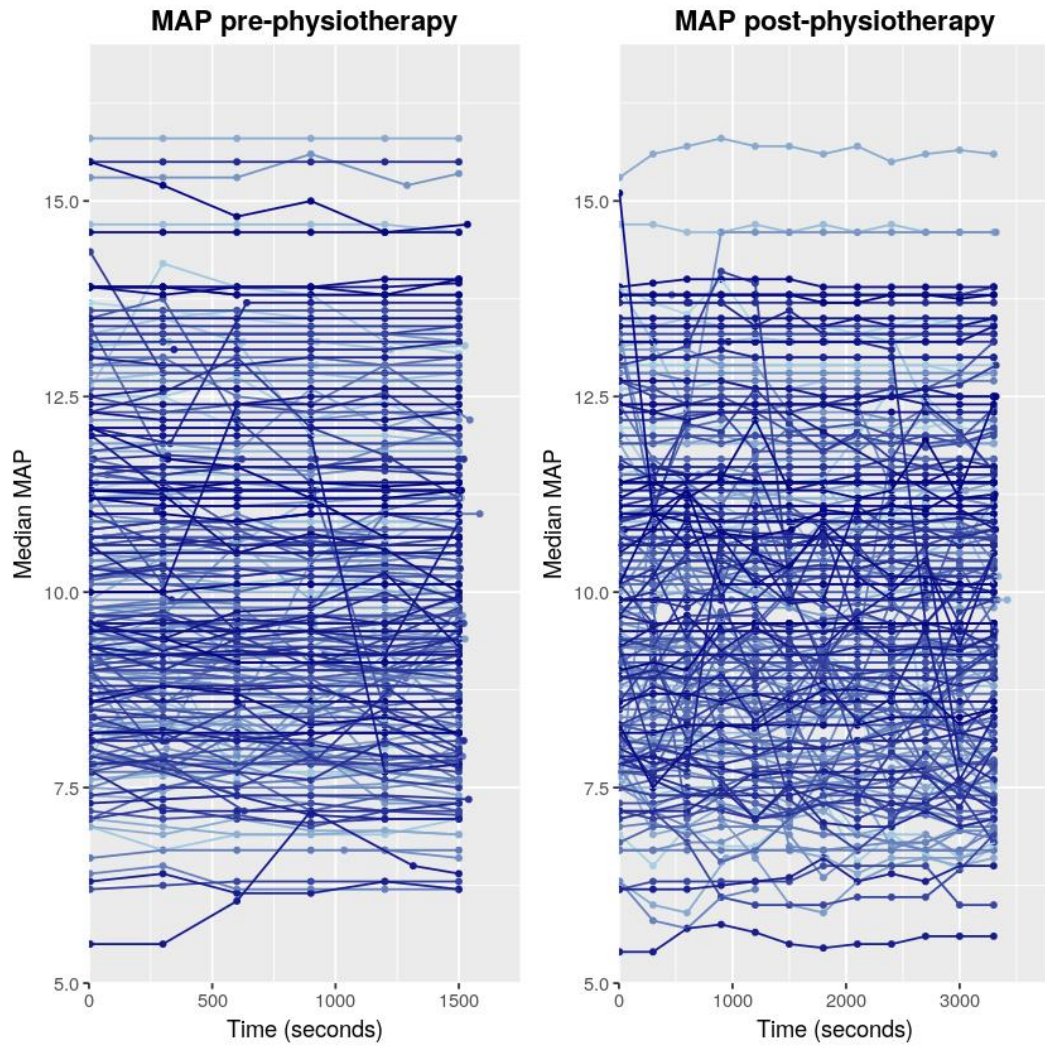
(p.adjust – adjusted p-value for multiple comparisons, n=205)

Appendix 32 - Five-minute summary FiO<sub>2</sub> medians for individual patients pre- and post-physiotherapy



(n=251, FiO<sub>2</sub> – Fraction of inspired oxygen)

Appendix 33 - Five-minute summary MAP medians for individual patients pre- and post-physiotherapy



(n=247, MAP – Mean airway pressure)

## Appendix 34 - Oxygen saturation index first session demographic exploration R script

```
#####  
# load in data sets  
#####  
  
##load in complete 01  
demographic01_data <-  
xap.read_table("complete01_caboodle_patient_demographics") # read in  
variables table for all patients  
# check data has loaded  
head(demographic01_data)  
dim(demographic01_data)  
tail(demographic01_data)  
  
##load in complete 02  
demographic02_data <-  
xap.read_table("complete02_caboodle_patient_demographics") # read in  
variables table for all patients  
# check data has loaded  
head(demographic02_data)  
dim(demographic02_data)  
tail(demographic02_data)  
  
##load in partial  
demographic_partial <-  
xap.read_table("partial_caboodle_patient_demographics") # read in variables  
table for all patients  
# check data has loaded  
head(demographic_partial)  
dim(demographic_partial)  
tail(demographic_partial)  
  
##join datasets together  
demographic_data1 <- rbind(demographic01_data, demographic02_data)  
demographic_dataa <- rbind(demographic_data1, demographic_partial)  
str(demographic_dataa)  
  
####bring in OSI group  
OSIgroup <- xap.read_table("osi_ae_1_1")  
str(OSIgroup)  
  
##get rid of id column  
OSIgroup1 <- select(OSIgroup, project_id, osi_ae)  
str(OSIgroup1)  
  
###join OSI group to full demo  
demographic_data <- inner_join(demographic_dataa, OSIgroup1,  
by="project_id")
```

```

str(demographic_data)

t.OSI <- table(demographic_data$osi_ae)

#####
#####
###explore AE vs no AE
#####
#####

#####
# explore gender
#####

t.gender <- table(demographic_data$sex , demographic_data$osi_ae)
addmargins(t.gender)
round(prop.table(t.gender)*100, 2) #to give percentage

###stats difference
chisq <- chisq.test( demographic_data$sex ,demographic_data$osi_ae)
chisq

#####
# exploring age
#####

##load in data set complete 01
age01_data <- xap.read_table("complete01_wp2_physio_details_check")
str(age01_data)

##load in data set complete 02
age02_data <- xap.read_table("complete02_wp2_physio_details_check")
str(age02_data)

##load in partial
age_partial <- xap.read_table("partial_wp2_physio_details_check")
str(age_partial)

#### join age data sets
age_data1 <- rbind(age01_data, age02_data)
head(age_data1)
str(age_data1)

age_dataa <- rbind(age_data1, age_partial)
str(age_dataa)

class (age_dataa$age_in_months) #this is a character needs to be integer
age_dataa[c(3,4,6)] <- lapply(age_dataa[c(3,4,6)], as.numeric)

```

```

str(age_dataa)

###join OSI group to full age

age_OSIGroup <- inner_join(age_dataa, OSIGroup1, by="project_id")
str(age_OSIGroup)

osimedian_age <- age_OSIGroup %>%
group_by(osi_ae) %>%
  summarize(median = median(age_in_months))

osiage_quant <- age_OSIGroup %>%
group_by(osi_ae) %>% summarize(age_in_months = quantile(age_in_months,
c(0.25, 0.5, 0.75)))

t.test(age_OSIGroup$age_in_months ~ age_OSIGroup$osi_ae, var.equal =
FALSE)

#####
### weight
#####

## load in data set 1
weight01_data <-
xap.read_table("complete01w_caboodle_patient_selected_flowsheetrows_clin_p
ivot")
str(weight01_data)

weight01_data <- select(weight01_data, project_id, taken_datetime,
R.DRUG.CALCULATION.WEIGHT_grams, WEIGHT.SCALE_grams)
weight01_data[c(3,4)] <- lapply(weight01_data[c(3,4)], as.integer)
str(weight01_data)

## load in data set 2
weight02_data <-
xap.read_table("complete02w_caboodle_patient_selected_flowsheetrows_clin_p
ivot")
str(weight02_data)

weight02_data <- select(weight02_data, project_id, taken_datetime,
R.DRUG.CALCULATION.WEIGHT_grams, WEIGHT.SCALE_grams)
weight02_data[c(3,4)] <- lapply(weight02_data[c(3,4)], as.integer)
str(weight02_data)

##load in partial
weight_p <-
xap.read_table("partialw_caboodle_patient_selected_flowsheetrows_clin_pivot")
str(weight_p)

```

```

weight_p <- select(weight_p, project_id, taken_datetime,
R.DRUG.CALCULATION.WEIGHT_grams, WEIGHT.SCALE_grams)
weight_p[c(3,4)] <- lapply(weight_p[c(3,4)], as.integer)
str(weight_p)

##cominbe data sets
weight_dataa <- rbind(weight01_data, weight02_data)
weight_data <- rbind(weight_dataa, weight_p)

str(weight_data)

## combine to one column
weight_data1 <- weight_data %>%
  mutate(weight = ifelse(is.na(weight_data$WEIGHT.SCALE_grams),
weight_data$R.DRUG.CALCULATION.WEIGHT_grams,
weight_data$WEIGHT.SCALE_grams))
str(weight_data1)

#####
### link weight to date of first physio
#####
#load in physio dates data set 1
physiotimes1_data <- xap.read_table("complete01_wp2_physio_times_check")

##load in physio times data set 2
physiotimes2_data <- xap.read_table("complete02_wp2_physio_times_check")

##load partial
physiotimes_p<- xap.read_table("partial_wp2_physio_times_check")

##combine data sets
physio_firsta <- rbind(physiotimes1_data, physiotimes2_data)
physio_first <- rbind(physio_firsta, physiotimes_p)
str(physio_first)

##pick first session
physio_first <- subset(physio_first, day == 1 & session == 1)
str(physio_first)

# join datasets
weight_data2 <- select(weight_data1, project_id, taken_datetime, weight)
weight_data3 <- left_join(physio_first, weight_data2, by = "project_id")
str(weight_data3)

#find difference between dates/times

weight_data4 <- weight_data3 %>%
  mutate(dateDiff = (weight_data3$datetime - weight_data3$taken_datetime))
str(weight_data4)

```

```

## filter to 2 weeks prior to physio only
weight_data5 <- filter(weight_data4, weight_data4$dateDiff %in% (0:1209600))
str(weight_data5)

#filter dates to keep only closest (min) datediff with a value (not NA), grouped by
id and index datetime

weight_data5 <- weight_data5[complete.cases(weight_data5), ]
weight_data6 <- weight_data5 %>%
group_by(weight_data5$project_id) %>%
filter(dateDiff == min(dateDiff))
weight_data6 <- weight_data6 %>%
  ungroup()

str(weight_data6)

###remove duplicates
unique(weight_data6$project_id)
weight_data7 <- weight_data6[!duplicated(weight_data6$project_id), ]
str(weight_data7)

weightosi <- inner_join(weight_data7, OSIgroup1, by="project_id")
str(weightosi)

###stats diff

osimedian_weight <- weightosi %>%
group_by(osi_ae) %>%
  summarize(median = median(weight))

osiweight_quant <- weightosi %>%
group_by(osi_ae) %>% summarize(weight = quantile(weight, c(0.25, 0.5, 0.75)))

t.test(weightosi$weight ~ weightosi$osi_ae, var.equal = FALSE)

#####
##admission type
#####

##load in data set 1
admission01_data <-
xap.read_table("complete01_caboodle_patient_hospital_admissions")
str(admission01_data)

##load in data set 2
admission02_data <-
xap.read_table("complete02_caboodle_patient_hospital_admissions")
str(admission02_data)

###load in partial

```



```

admission_p <- xap.read_table("partial_caboodle_patient_hospital_admissions")

##combine datasets

admission_dataa <- rbind(admission01_data, admission02_data)
admission_data <- rbind(admission_dataa, admission_p)
str(admission_data)

# create 2 variables

admission_data1 <- admission_data %>%
mutate(Emergency = ifelse(admission_data$admission_type == "Emergency -
A&E, Casualty, or Dental Casualty Department" |
admission_data$admission_type == "Emergency Transfer" |
admission_data$admission_type == "Emergency - Consultant Clinic" |
admission_data$admission_type == "Emergency - Bed Bureau" |
admission_data$admission_type == "Emergency - Other" |
admission_data$admission_type == "Baby Born Elsewhere" |
admission_data$admission_type == "Emergency - via A&E of another Health
Care Provider", 1, 0),
      Elective = ifelse(admission_data$admission_type == "Elective - Planned" |
admission_data$admission_type == "Elective - Booked" |
admission_data$admission_type == "Non-Emergency Transfer" |
admission_data$admission_type == "Elective - Waiting List", 1, 0))

str(admission_data1)

admission_data1$Emergency = ifelse(admission_data1$Emergency==1,
"Emergency", NA)
admission_data1$Elective = ifelse(admission_data1$Elective==1, "Elective", NA)

admission_data1 <- admission_data1 %>%
  unite("admission.type", Emergency:Elective, na.rm = TRUE)

#####join to osi group

admission_osi <- inner_join(admission_data1, OSigroup1, by="project_id")
str(admission_osi)

#####explore type of admission

t.admission <- table(admission_osi$admission.type, admission_osi$osi_ae)
t.admission

chisq <- chisq.test(admission_osi$admission.type, admission_osi$osi_ae)
chisq

#####
## iNO
#####

```

```

####use vent_first and join to osi

vent_osi <- inner_join(vent_first, OSGroup1, by="project_id")
str(vent_osi)

####remove duplicates
unique(vent_osi$project_id)
vent_osi[duplicated(vent_osi$project_id),]

####413 repeated
vent_osi[170:200,]

####keep second row of 413
vent_osi1 <- vent_osi %>% group_by(project_id) %>%
filter(n() == 1 |      # always keep if only one row in group
      row_number() > 1) %>%
      ungroup()

str(vent_osi1)

####compare iNO and osi threshold

t.iNO_osi <- table(vent_osi1$iNO, vent_osi1$osi_ae)
t.iNO_osi

fisher.test(vent_osi1$iNO, vent_osi1$osi_ae)

#####
####time of day
#####

str(physio_first)

physio_first1 <- physio_first %>%
  mutate(hour = hour(physio_first$datetime),
         Physio_time = case_when(hour %in% 9:16 ~ "day",
                                TRUE ~ "Oncall"))

str(physio_first1)

#####join session times to osi group
times_osi <- inner_join(physio_first1, OSGroup1, by="project_id")
str(times_osi)

####explore time
t.osi_time <- table(times_osi$Physio_time, times_osi$osi_ae)

fisher.test(times_osi$Physio_time, times_osi$osi_ae)

```

```

#####
##pelod
#####

###read in pelod data
pelod_first <- xap.read_table("firstpelod")

#####join session times to osi group
pelod_osi <- inner_join(pelod_first, OSIgroup1, by="project_id")
str(pelod_osi)

####explore

osimedian_pelod <- pelod_osi %>%
group_by(osi_ae) %>%
  summarize(median = median(pelod_score))

osipelod_quant <- pelod_osi %>%
group_by(osi_ae) %>% summarize(pelod_score = quantile(pelod_score, c(0.25,
0.5, 0.75)))

t.test(pelod_osi$pelod_score ~ pelod_osi$osi_ae, var.equal = FALSE)
table(pelod_osi$osi_ae)

#####
##COVID
#####

str(OSIgroup)
lab1_data <-
xap.read_table("complete01_caboodle_patient_selected_lab_components_all_pi
vot")
str(lab1_data)

lab1_data1 <- select(lab1_data, project_id, collected_datetime,
COVID19RES_SARS.CoV.2.by.PCR.Result)
str(lab1_data1)

lab2_data <-
xap.read_table("complete02_caboodle_patient_selected_lab_components_all_pi
vot")
str(lab2_data)

lab2_data1 <- select(lab2_data, project_id, collected_datetime,
COVID19RES_SARS.CoV.2.by.PCR.Result)
str(lab2_data1)

labpart <-
xap.read_table("partial_caboodle_patient_selected_lab_components_all_pivot")
str(labpart)

```

```

labpart1 <- select(labpart, project_id, collected_datetime,
COVID19RES_SARS.CoV.2.by.PCR.Result)
str(labpart1)

###join together

lab_covid <- rbind(lab1_data1, lab2_data1)
lab_covid1 <- rbind(lab_covid, labpart1)
str(lab_covid1)

####find results during admission

str(admission_data)
adm_1 <- select(admission_data, project_id, start_datetime, end_datetime)
str(adm_1)

###join and filter between dates
covid_all <- inner_join(lab_covid1, adm_1, by="project_id")
str(covid_all)

covid_all1 <- filter(covid_all, collected_datetime >= start_datetime &
collected_datetime <= end_datetime)
str(covid_all1)

table(covid_all1$project_id,
covid_all1$COVID19RES_SARS.CoV.2.by.PCR.Result)

###create new variable
covid_all1$covid <-
ifelse(covid_all1$COVID19RES_SARS.CoV.2.by.PCR.Result == "RNA
Detected", "Yes", "No")
str(covid_all1)

###change NAs to no
covid_all1$covid[is.na(covid_all1$covid)] <- 'No'
unique(covid_all1$project_id)

####join to OSI group
covid_osi <- inner_join(OSIgroup, covid_all1, by="project_id")
str(covid_osi)

###subset those with yes

covid_positive<- subset(covid_osi, covid == 'Yes')
str(covid_positive)

####no covid cases in osi 1.1

#####

```

```

####diagnosis
#####

## load in data set complete 01
episode01_data <- xap.read_table("complete01_caboodle_patient_episodes") #
read in variables table for all patients

# check data has loaded
head(episode01_data)
dim(episode01_data)
tail(episode01_data)

##load in data set complete 02
episode02_data <- xap.read_table("complete02_caboodle_patient_episodes") #
read in variables table for all patients

# check data has loaded
head(episode02_data)
dim(episode02_data)
tail(episode02_data)

##load in partial
episode_partial <- xap.read_table("partial_caboodle_patient_episodes") # read in
variables table for all patients

# check data has loaded
str(episode_partial)

##join complete data sets

episode_data1 <- rbind(episode01_data, episode02_data)
dim(episode_data1)
str(episode_data1)
episode_data <- rbind(episode_data1, episode_partial)
str(episode_data)

# need to remove duplicates
episode_data <- distinct(episode_data, episode_data$project_id, .keep_all =
TRUE)
dim(episode_data)
str(episode_data)

##select only columns want
episode_data1 <- select(episode_data, project_id, start_datetime, end_datetime,
primary_diagnosis_code, primary_diagnosis_name)

unique(episode_data1$primary_diagnosis_name)
str(episode_data1)

```

```

##change NA's to unknown
episode_data1[is.na(episode_data1)] <- 'unknown'
is.na(episode_data1)

#####
# create individual diagnosis variables
#####

diagnosis_data <- episode_data1 %>% #seperates out and changes diagnosis
groups
mutate(Respiratory= ifelse(grepl('^J1', episode_data1$primary_diagnosis_code) |
grepl('^J2', episode_data1$primary_diagnosis_code) | grepl('^J4',
episode_data1$primary_diagnosis_code) | grepl('^J6',
episode_data1$primary_diagnosis_code) | grepl('^J8',
episode_data1$primary_diagnosis_code) | grepl('^J9',
episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "P271" |
episode_data1$primary_diagnosis_code == "P240" |
episode_data1$primary_diagnosis_code == "P229" |
episode_data1$primary_diagnosis_code == "P285" |
episode_data1$primary_diagnosis_code == "Q330" |
episode_data1$primary_diagnosis_code == "R068" |
episode_data1$primary_diagnosis_code == "R092" |
episode_data1$primary_diagnosis_code == "P284" |
episode_data1$primary_diagnosis_code == "P288", 1, 0),
  Renal= ifelse(episode_data1$primary_diagnosis_code == "N10X" |
episode_data1$primary_diagnosis_code == "Q641", 1, 0),
  Musculoskeletal= ifelse(grepl('^M', episode_data1$primary_diagnosis_code),
1, 0),
  Hepatic= ifelse(episode_data1$primary_diagnosis_code == "K270", 1, 0),
  Endocrine= ifelse(grepl('^E', episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "P748", 1, 0),
  Haematology_oncology= ifelse(grepl('^C',
episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "D151" |
episode_data1$primary_diagnosis_code == "D761" |
episode_data1$primary_diagnosis_code == "D487" |
episode_data1$primary_diagnosis_code == "D71X", 1, 0),
  Cardiovascular = ifelse(grepl('^Q2', episode_data1$primary_diagnosis_code) |
grepl('^I2', episode_data1$primary_diagnosis_code) | grepl('^I3',
episode_data1$primary_diagnosis_code) | grepl('^I4',
episode_data1$primary_diagnosis_code) | grepl('^I7',
episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "I500" |
episode_data1$primary_diagnosis_code == "I971" |
episode_data1$primary_diagnosis_code == "T828" |
episode_data1$primary_diagnosis_code == "P291" |
episode_data1$primary_diagnosis_code == "P293" |
episode_data1$primary_diagnosis_code == "P298", 1, 0),

```

```

Neurology_neurosurgery= ifelse(grepl('^G',
episode_data1$primary_diagnosis_code) | grepl('^S',
episode_data1$primary_diagnosis_code) | grepl('^P9',
episode_data1$primary_diagnosis_code) | grepl('^I6',
episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "T850" |
episode_data1$primary_diagnosis_code == "P525" |
episode_data1$primary_diagnosis_code == "Q858" |
episode_data1$primary_diagnosis_code == "R568" |
episode_data1$primary_diagnosis_code == "R55X" |
episode_data1$primary_diagnosis_code == "P252" |
episode_data1$primary_diagnosis_code == "P219", 1, 0),
Gastroenterology= ifelse(grepl('^K', episode_data1$primary_diagnosis_code) |
grepl('^Q7', episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "R633" |
episode_data1$primary_diagnosis_code == "A081" |
episode_data1$primary_diagnosis_code == "Q423" |
episode_data1$primary_diagnosis_code == "R11X" |
episode_data1$primary_diagnosis_code == "Q390" |
episode_data1$primary_diagnosis_code == "Q393" |
episode_data1$primary_diagnosis_code == "Q411" |
episode_data1$primary_diagnosis_code == "T286" |
episode_data1$primary_diagnosis_code == "T855" |
episode_data1$primary_diagnosis_code == "Q391" |
episode_data1$primary_diagnosis_code == "Q392" |
episode_data1$primary_diagnosis_code == "P540", 1, 0),
Airway= ifelse(grepl('^J3', episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "Q318" |
episode_data1$primary_diagnosis_code == "Q320" |
episode_data1$primary_diagnosis_code == "Q321" |
episode_data1$primary_diagnosis_code == "Q310" |
episode_data1$primary_diagnosis_code == "Q311" |
episode_data1$primary_diagnosis_code == "R061", 1, 0),
Sepsis= ifelse(grepl('^A4', episode_data1$primary_diagnosis_code) |
episode_data1$primary_diagnosis_code == "P360", 1, 0),
Other= ifelse(episode_data1$primary_diagnosis_code == "D821" |
episode_data1$primary_diagnosis_code == "D180" |
episode_data1$primary_diagnosis_code == "U071" |
episode_data1$primary_diagnosis_code == "T810" |
episode_data1$primary_diagnosis_code == "P398" |
episode_data1$primary_diagnosis_code == "T823" |
episode_data1$primary_diagnosis_code == "T818" |
episode_data1$primary_diagnosis_code == "R560" |
episode_data1$primary_diagnosis_code == "T741" |
episode_data1$primary_diagnosis_code == "A199" |
episode_data1$primary_diagnosis_code == "B349" |
episode_data1$primary_diagnosis_code == "T856" |
episode_data1$primary_diagnosis_code == "T543" |
episode_data1$primary_diagnosis_code == "T813", 1, 0),

```

```
Unknown= ifelse(episode_data1$primary_diagnosis_code == "unknown", 1, 0))
```

```
str(diagnosis_data)
### rename so can merge
diagnosis_data$Respiratory <- ifelse(diagnosis_data$Respiratory==1,
"Respiratory", NA)
diagnosis_data$Renal <- ifelse(diagnosis_data$Renal==1, "Renal", NA)
diagnosis_data$Musculoskeletal <- ifelse(diagnosis_data$Musculoskeletal==1,
"Musculoskeletal", NA)
diagnosis_data$Hepatic <- ifelse(diagnosis_data$Hepatic==1, "Hepatic", NA)
diagnosis_data$Endocrine <- ifelse(diagnosis_data$Endocrine==1, "Endocrine",
NA)
diagnosis_data$Haematology_oncology <-
ifelse(diagnosis_data$Haematology_oncology==1, "Haematology/oncology", NA)
diagnosis_data$Cardiovascular <- ifelse(diagnosis_data$Cardiovascular==1,
"Cardiovascular", NA)
diagnosis_data$Neurology_neurosurgery <-
ifelse(diagnosis_data$Neurology_neurosurgery==1, "Neurology/neurosurgery",
NA)
diagnosis_data$Gastroenterology <-
ifelse(diagnosis_data$Gastroenterology==1, "Gastroenterology", NA)
diagnosis_data$Airway <- ifelse(diagnosis_data$Airway==1, "Airway", NA)
diagnosis_data$Sepsis <- ifelse(diagnosis_data$Sepsis==1, "Sepsis", NA)
diagnosis_data$Other <- ifelse(diagnosis_data$Other==1, "Other", NA)
diagnosis_data$Unknown <- ifelse(diagnosis_data$Unknown==1, "Unknown",
NA)
```

```
### need to merge the columns
diagnosis_data1 <- diagnosis_data %>%
  unite("diagnosis", Respiratory:Unknown, na.rm = TRUE)
str(diagnosis_data1)
unique(diagnosis_data1$project_id)
```

```
### create table
t.diagnosis <- table(diagnosis_data1$diagnosis)
addmargins(t.diagnosis)
round(prop.table(t.diagnosis)*100, 2)
```

```
# graph
ggplot(diagnosis_data1, aes(x=diagnosis_data1$diagnosis,
fill=diagnosis_data1$diagnosis)) +
geom_bar() + # add a title
  xlab('Diagnosis group') + ylab('Number of patients') + # add axis names
  scale_y_continuous(expand = c(0, 0), limits = c(0, 310)) +
theme(plot.title=element_text( hjust=0.5, vjust=0.5, face='bold'),
axis.text.x=element_text(angle=45, hjust=1), legend.position="none") +
```



```
scale_fill_manual(breaks = c("Airway", "Cardiovascular", "Endocrine",
"Gastroenterology", "Haematology/oncology", "Musculoskeletal",
"Neurology/neurosurgery", "Other", "Renal", "Respiratory", "Sepsis"),
values=c("lightblue1", "lightskyblue1", "skyblue1", "skyblue2",
"steelblue1", "steelblue3", "steelblue", "royalblue1", "royalblue3", "mediumblue",
"royalblue4", "navy"))
```

```
#####
#####create diagnosis subgroups
#####
```

```
diagnosis_data2 <- diagnosis_data %>%
mutate(Congenitalcardiac= ifelse(grepl('^Q2',
diagnosis_data$primary_diagnosis_code) |
diagnosis_data$primary_diagnosis_code == "T828" |
diagnosis_data$primary_diagnosis_code == "I288" |
diagnosis_data$primary_diagnosis_code == "I370", 1, 0),
Cardiomyopathy= ifelse(diagnosis_data$primary_diagnosis_code == "I420"
| diagnosis_data$primary_diagnosis_code == "I422", 1, 0),
Endo_myocarditis= ifelse(diagnosis_data$primary_diagnosis_code ==
"I400" | diagnosis_data$primary_diagnosis_code == "I330", 1, 0),
Cardiother= ifelse(diagnosis_data$primary_diagnosis_code == "P291" |
diagnosis_data$primary_diagnosis_code == "I313" |
diagnosis_data$primary_diagnosis_code == "I460" |
diagnosis_data$primary_diagnosis_code == "I251" |
diagnosis_data$primary_diagnosis_code == "P298" |
diagnosis_data$primary_diagnosis_code == "I971" |
diagnosis_data$primary_diagnosis_code == "I712" |
diagnosis_data$primary_diagnosis_code == "I710" |
diagnosis_data$primary_diagnosis_code == "P293" |
diagnosis_data$primary_diagnosis_code == "I460" |
diagnosis_data$primary_diagnosis_code == "I272" |
diagnosis_data$primary_diagnosis_code == "I500", 1, 0),
Airway1= ifelse(grepl('^J3', diagnosis_data$primary_diagnosis_code) |
diagnosis_data$primary_diagnosis_code == "Q318" |
diagnosis_data$primary_diagnosis_code == "Q320" |
diagnosis_data$primary_diagnosis_code == "Q321" |
diagnosis_data$primary_diagnosis_code == "Q310" |
diagnosis_data$primary_diagnosis_code == "Q311" |
diagnosis_data$primary_diagnosis_code == "R061", 1, 0),
Asthma= ifelse(diagnosis_data$primary_diagnosis_code == "J46X", 1, 0),
Pneumonia= ifelse(diagnosis_data$primary_diagnosis_code == "J181" |
diagnosis_data$primary_diagnosis_code == "J122" |
diagnosis_data$primary_diagnosis_code == "J22X" |
diagnosis_data$primary_diagnosis_code == "J690" |
diagnosis_data$primary_diagnosis_code == "J189", 1, 0),
ARDS= ifelse(diagnosis_data$primary_diagnosis_code == "J80X", 1, 0),
Bronchiolitis= ifelse(diagnosis_data$primary_diagnosis_code == "J210" |
diagnosis_data$primary_diagnosis_code == "J218", 1, 0),
MAS= ifelse(diagnosis_data$primary_diagnosis_code == "P240", 1, 0),
```

```

    Respfailure= ifelse(diagnosis_data$primary_diagnosis_code == "J9690" |
diagnosis_data$primary_diagnosis_code == "P229" |
diagnosis_data$primary_diagnosis_code == "P285" |
diagnosis_data$primary_diagnosis_code == "J9600" |
diagnosis_data$primary_diagnosis_code == "J9601" |
diagnosis_data$primary_diagnosis_code == "J9699", 1, 0),
    Respothter= ifelse(diagnosis_data$primary_diagnosis_code == "J860" |
diagnosis_data$primary_diagnosis_code == "J980" |
diagnosis_data$primary_diagnosis_code == "J869" |
diagnosis_data$primary_diagnosis_code == "J930" |
diagnosis_data$primary_diagnosis_code == "R092" |
diagnosis_data$primary_diagnosis_code == "J948" |
diagnosis_data$primary_diagnosis_code == "Q330" |
diagnosis_data$primary_diagnosis_code == "P284" |
diagnosis_data$primary_diagnosis_code == "J848" |
diagnosis_data$primary_diagnosis_code == "P271" |
diagnosis_data$primary_diagnosis_code == "R068" |
diagnosis_data$primary_diagnosis_code == "J985" |
diagnosis_data$primary_diagnosis_code == "P288" |
diagnosis_data$primary_diagnosis_code == "J988", 1, 0))

str(diagnosis_data2)

```

```
##remane so can merge
```

```

diagnosis_data2$Congenitalcardiac <-
ifelse(diagnosis_data2$Congenitalcardiac==1, "Congenitalcardiac", NA)
diagnosis_data2$Cardiomyopathy <-
ifelse(diagnosis_data2$Cardiomyopathy==1, "Cardiomyopathy", NA)
diagnosis_data2$Endo_myocarditis <-
ifelse(diagnosis_data2$Endo_myocarditis==1, "Endo_myocarditis", NA)
diagnosis_data2$Cardiacother <- ifelse(diagnosis_data2$Cardiacother==1,
"Cardiacother", NA)
diagnosis_data2$Airway1 <- ifelse(diagnosis_data2$Airway1==1, "Airway", NA)
diagnosis_data2$Asthma <- ifelse(diagnosis_data2$Asthma==1, "Asthmatic",
NA)
diagnosis_data2$Pneumonia <- ifelse(diagnosis_data2$Pneumonia==1,
"Pneumonia", NA)
diagnosis_data2$ARDS <- ifelse(diagnosis_data2$ARDS==1, "ARDS", NA)
diagnosis_data2$Bronchiolitis <- ifelse(diagnosis_data2$Bronchiolitis==1,
"Bronchiolitis", NA)
diagnosis_data2$MAS <- ifelse(diagnosis_data2$MAS==1, "MAS", NA)
diagnosis_data2$Respfailure <- ifelse(diagnosis_data2$Respfailure==1,
"Respfailure", NA)
diagnosis_data2$Respothter <- ifelse(diagnosis_data2$Respothter==1,
"Respothter", NA)

```

```
###merge new columns
```

```

diagnosis_data3 <- diagnosis_data2 %>%
  unite("Cardiac_diagnosis", Congenitalcardiac:Airway1, na.rm = TRUE)
str(diagnosis_data3)

diagnosis_data4 <- diagnosis_data3 %>%
  unite("Respiratory_diagnosis", Asthma:Respothor, na.rm = TRUE)
str(diagnosis_data4)

diagnosis_resp_cardiac <- select(diagnosis_data4, project_id,
Cardiac_diagnosis, Respiratory_diagnosis)
str(diagnosis_resp_cardiac)

##join to OSI group
cardiac_osi <- inner_join(diagnosis_resp_cardiac, OSIGroup1, by="project_id")
str(cardiac_osi)

unique(cardiac_osi$Cardiac_diagnosis)

####explore diagnosis
t.diag <- table(cardiac_osi$Cardiac_diagnosis, cardiac_osi$osi_ae)
t.diag

####merge cardiac and resp
cardiac_osi1 <- cardiac_osi %>%
  unite("diagnosis", Cardiac_diagnosis:Respiratory_diagnosis , na.rm = TRUE)
str(cardiac_osi1)

t.diag <- table(cardiac_osi1$diagnosis, cardiac_osi1$osi_ae)
t.diag

fisher.test(cardiac_osi1$diagnosis, cardiac_osi1$osi_ae)

```

## Appendix 35 – Oxygen saturation index first session physiotherapy exploration R script

```
#####  
###bring in OSI group  
#####  
  
OSIgroup <- xap.read_table("osi_ae_1_1")  
str(OSIgroup)  
  
#####  
## load in times of sessions  
#####  
  
##load in part 1  
physio_times01 <- xap.read_table("complete01_wp2_physio_times_check")  
str(physio_times01)  
  
##load in part 2  
physio_times02 <- xap.read_table("complete02_wp2_physio_times_check")  
str(physio_times02)  
  
##load in partial  
physio_times_partial <- xap.read_table("partial_wp2_physio_times_check")  
str(physio_times_partial)  
  
###join data sets  
physio_timesa <- rbind(physio_times01, physio_times02)  
physio_times <- rbind(physio_timesa, physio_times_partial)  
str(physio_times)  
  
#####  
####select first session only  
#####  
  
physio_times_first <- subset(physio_times, day == 1 & session == 1)  
str(physio_times_first)  
  
#####  
##### prepare data to explore physio treatments  
#####  
  
##load in data set 1  
treatment01_data <-  
xap.read_table("complete01_caboodle_patient_selected_flowsheetrows_phys_pi  
vot")  
str(treatment01_data)  
  
##load in data set 2
```

```

treatment02_data <-
xap.read_table("complete02_caboodle_patient_selected_flowsheetrows_phys_pi
vot")
str(treatment02_data)

##load in partial
treatment_p <-
xap.read_table("partial_caboodle_patient_selected_flowsheetrows_phys_pivot")
str(treatment_p)

##combine data sets
treatment_dataa <- rbind(treatment01_data, treatment02_data)
treatment_data <-rbind(treatment_dataa, treatment_p)
str(treatment_data)

#####
#manipulate variables
#####

# combine 2 same suction variables

treatment_data <- treatment_data %>%
mutate(suctiontype =
coalesce(treatment_data$RETIRED.R.AIRWAY.SUCTION.TYPE.OLD,
treatment_data$R.GOSH.AIRWAY.SUCTION.TYPE))

str(treatment_data)
head(treatment_data)

## select only columns need

treatment_data1 <- select(treatment_data, project_id, taken_datetime,
R.AIRWAY.SUCTION.TOLERANCE, R.AIRWAY.SUCTION.DEVICE,
R.GOSH.IP.PHSYIO.VIBRATION, R.GOSH.IP.PHYSIO.DECOMPRESSION,
R.GOSH.IP.SALINE.INSTALLATION,
R.GOSH.IP.PHYSIO.BAG, R.GOSH.IP.PHYSIO.CHEST.PERCUSSION,
R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION, suctiontype)

str(treatment_data1)

#####
## join data frames for times and keep treatments with matching times time
#####

physio_data <- left_join(physio_times,treatment_data1 , by = "project_id")
str(physio_data)
head(physio_data)
unique(physio_data$project_id)

physio_data1 <- physio_data %>%

```

```

mutate(dateDiff = abs(physio_data$datetime - physio_data$taken_date)) %>%
  group_by(project_id, physio_data$datetime) %>%
  filter(dateDiff == 0)
str(physio_data1)

physio_data1 <- physio_data1 %>%
  ungroup()
str(physio_data1)

range(physio_data1$dateDiff)

#####
### describe physio sessions
#####

###explore saline
t.saline <- table(physio_data1$R.GOSH.IP.SALINE.INSTALLATION)
addmargins(t.saline)
round(prop.table(t.saline)*100, 2)

# change variables into yes no and remove NA
physio_data1$R.GOSH.IP.PHYSIO.BAG <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.BAG=="No",0 , 1)
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=="No",0,1)
physio_data1$R.GOSH.IP.PHYSIO.VIBRATION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=="No", 0, 1)
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=="No", 0, 1)
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=="No", 0, 1)
physio_data1$R.GOSH.IP.SALINE.INSTALLATION <-
ifelse(physio_data1$R.GOSH.IP.SALINE.INSTALLATION=="No", 0, 1)

physio_data1 <- mutate_if(physio_data1, is.numeric, ~replace(., is.na(.), 0))

physio_data1$R.GOSH.IP.PHYSIO.BAG <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.BAG=="0",'No' , 'Yes')
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=="0",'No','Yes')
physio_data1$R.GOSH.IP.PHYSIO.VIBRATION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=="0", 'No', 'Yes')
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=="0", 'No', 'Yes')
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION <-
ifelse(physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=="0", 'No',
'Yes')

```

```

physio_data1$R.GOSH.IP.SALINE.INSTALLATION <-
ifelse(physio_data1$R.GOSH.IP.SALINE.INSTALLATION=="0", 'No', 'Yes')

str(physio_data1)
#####
## explore suction in more detail just get open vs closed
#####
unique(physio_data1$suctiontype)

physio_data1 <- physio_data1 %>%
mutate(suctionopen = ifelse(physio_data1$suctiontype == 'Endotracheal Tube -
Open' | physio_data1$suctiontype == 'Endotracheal Tube - Open;Nasal' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Nasal;Oral' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Nasopharyngeal' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Nasopharyngeal;Oral' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;NPA' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Oral' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Oral;Nasal' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Oral;Nasopharyngeal' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Other (Comment)' |
physio_data1$suctiontype == 'Oral;Endotracheal Tube - Open' |
physio_data1$suctiontype == 'Oral;Nasal Prong;Endotracheal Tube - Open' |
physio_data1$suctiontype == 'Oral;Nasal;Endotracheal Tube - Open', "Yes",
"No"),
  suctionclosed = ifelse(physio_data1$suctiontype == 'Endotracheal Tube -
Closed' | physio_data1$suctiontype == 'Endotracheal Tube - Closed;Oral' |
physio_data1$suctiontype == 'Endotracheal Tube - Closed;Oral;Nasal', "Yes",
"No"),
  both = ifelse(physio_data1$suctiontype == 'Endotracheal Tube -
Closed;Endotracheal Tube - Open' | physio_data1$suctiontype == 'Endotracheal
Tube - Closed;Endotracheal Tube - Open;Oral' | physio_data1$suctiontype ==
'Endotracheal Tube - Closed;Endotracheal Tube - Open;Oral;Nasal' |
physio_data1$suctiontype == 'Endotracheal Tube - Open;Endotracheal Tube -
Closed' | physio_data1$suctiontype == 'Oral;Nasal;Endotracheal Tube -
Open;Endotracheal Tube - Closed', "Yes", "No"),
  unknown = ifelse(physio_data1$suctiontype == 'Nasal' |
physio_data1$suctiontype == 'Nasal Prong' | physio_data1$suctiontype ==
'Trache'| physio_data1$suctiontype == 'NA', "Yes", "No"))

str(physio_data1)

##create one suction variable

physio_data1$suctionopen <- ifelse(physio_data1$suctionopen == 'Yes', "Open",
NA)
physio_data1$suctionclosed <- ifelse(physio_data1$suctionclosed == 'Yes',
"Closed", NA)
physio_data1$both <- ifelse(physio_data1$both == 'Yes', "Both", NA)
physio_data1$unknown <- ifelse(physio_data1$unknown == 'Yes', "Unknown",
NA)

```

```

physio_data1 <- physio_data1 %>%
  unite("Suction", suctionopen:unknown, na.rm = TRUE)

str(physio_data1)
unique(physio_data1$Suction)

t.suction <- table(physio_data1$Suction)
addmargins(t.suction)
round(prop.table(t.suction)*100, 2)

#####
##create variable for MHI and CWV
#####

physio_data1$MHLvibs <-
ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes', "Yes",
"No")
str(physio_data1)

physio_data1$MHICWV <- ifelse(physio_data1$R.GOSH.IP.PHYSIO.BAG ==
'Yes' | physio_data1$MHLvibs == 'Yes', "Yes", "No")
str(physio_data1)

#####
# create new combination of treatment variables without suction
#####

physio_data_comb1 <- physio_data1 %>%
  mutate(saline.MHICWV.perc.decomp=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$MHICWV == 'Yes', "saline.MHICWV.perc.decomp", NA),
    saline.MHICWV.perc=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes'&
physio_data1$MHICWV == 'Yes', "saline.MHICWV.perc", NA),
    saline.MHICWV.decomp=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$MHICWV == 'Yes', "saline.MHICWV.decomp", NA),
    saline.MHICWV=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$MHICWV == 'Yes', "saline.MHICWV", NA),

```



```

        saline.vibs.perc.decomp=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
    physio_data1$MHICWV == 'No', "saline.vibs.perc.deomp", NA),
        saline.vibs.perc=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
    physio_data1$MHICWV == 'No', "saline.vibs.perc", NA),
        saline.vibs=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
    physio_data1$MHICWV == 'No', "saline.vibs", NA),
        saline.perc.decomp=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
    physio_data1$MHICWV == 'No', "saline.perc.decomp", NA),
        saline.perc=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
    physio_data1$MHICWV == 'No', "saline.perc", NA),
        saline.decomp=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
    physio_data1$MHICWV == 'No', "saline.decomp", NA),
        saline.MHI.perc.decomp=
    ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No' &
    physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
    physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
    physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
    physio_data1$MHICWV == 'No', "saline.MHI.perc.decomp", NA),

```

```

        saline.MHI.perc=
ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "saline.MHI.perc", NA),
        saline.MHI.decomp=
ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "saline.MHI.decomp", NA),
        saline.MHI= ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='No'
& physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "saline.MHI", NA),
        MHICWV.perc.decomp=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$MHICWV == 'Yes', "MHICWV.perc.decomp", NA),
        MHICWV.perc=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$MHICWV == 'Yes', "MHICWV.perc", NA),
        MHICWV.decomp=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$MHICWV == 'Yes', "MHICWV.decomp", NA),
        vibs.perc.decomp=
ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "vibs.perc.decomp", NA),
        vibs.perc= ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes'
& physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "vibs.perc", NA),
        vibs.decomp=
ifelse(physio_data1$R.GOSH.IP.PHSYIO.VIBRATION=='Yes' &

```

```

physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "vibs.decomp", NA),
  MHI.perc.decomp=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "MHI.perc.decomp", NA),
  MHI.perc= ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No'
& physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "MHI.perc", NA),
  MHI.decomp=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "MHI.decomp", NA),
  MHIonly= ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='Yes' &
physio_data1$MHICWV == 'No', "MHIonly", NA),
  CWVonly= ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='Yes'
& physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "CWVonly", NA),
  MHI.CWV=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$MHICWV == 'Yes', "MHICWV", NA),
  perconly= ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "perconly", NA),
  decomponly=
ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No' &

```

```

physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='Yes' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "decomponly", NA),
  salineonly= ifelse(physio_data1$R.GOSH.IP.PHYSIO.VIBRATION=='No'
& physio_data1$R.GOSH.IP.PHYSIO.DECOMPRESSION=='No' &
physio_data1$R.GOSH.IP.SALINE.INSTALLATION=='Yes' &
physio_data1$R.GOSH.IP.PHYSIO.CHEST.PERCUSSION=='No' &
physio_data1$R.GOSH.IP.PHYSIO.MAN.HYPERINFLATION=='No' &
physio_data1$MHICWV == 'No', "salineonly", NA))

str(physio_data_comb1)

# need to merge the columns to creat one treatment variable
physio_data_comb2 <- physio_data_comb1 %>%
  unite("Treatment", saline.MHICWV.perc.decomp:salineonly, na.rm = TRUE)

str(physio_data_comb2)

##change "" to NA
physio_data_comb2$Treatment[physio_data_comb2$Treatment==""]<-NA
unique(physio_data_comb2$Treatment)

t.Treatment <- table(physio_data_comb2$Treatment)
addmargins(t.Treatment)
round(prop.table(t.Treatment)*100, 2)

####create suction only column
str(physio_data_comb2)

physio_data_comb2$Treatment[is.na(physio_data_comb2$Treatment)] <-
'unknown'

t.Treatment <- table(physio_data_comb2$Treatment)
addmargins(t.Treatment)
round(prop.table(t.Treatment)*100, 2)

physio_data_comb2$suctioned <- ifelse(physio_data_comb2$Suction == 'Open' |
physio_data_comb2$Suction =='Closed'|physio_data_comb2$Suction == 'Both',
'Yes', 'No')
physio_data_comb2$suctiononly <- ifelse(physio_data_comb2$Treatment ==
'unknown' & physio_data_comb2$suctioned == 'Yes', 'suctiononly', NA)

t.suctiononly <- table(physio_data_comb2$suctiononly)

###change unknown treatment back to NA
physio_data_comb2$Treatment[physio_data_comb2$Treatment=="unknown"]<-
NA

```

```

unique(physio_data_comb2$Treatment)

## join and remove suctioned column
physio_data_comb2a <- subset(physio_data_comb2, select = -suctioned)

str(physio_data_comb2a)

physio_data_comb3 <- physio_data_comb2a %>%
  unite("Treatmentnew", Treatment:suctiononly, na.rm = TRUE)

str(physio_data_comb3)
unique(physio_data_comb3$Treatmentnew)

physio_data_comb3$Treatmentnew[physio_data_comb3$Treatmentnew==""] <-
NA
unique(physio_data_comb3$Treatmentnew)

t.Treatmentnew <- table(physio_data_comb3$Treatmentnew)
addmargins(t.Treatmentnew)
round(prop.table(t.Treatmentnew)*100, 2)

####subset for day 1 session1
physio_data_comb1_1 <- subset(physio_data_comb3, day == 1 & session == 1)
str(physio_data_comb1_1)

###join to osi data
physio_osi <- inner_join(physio_data_comb1_1, OSIgroup, by="project_id")
str(physio_osi)
unique(physio_osi$project_id)

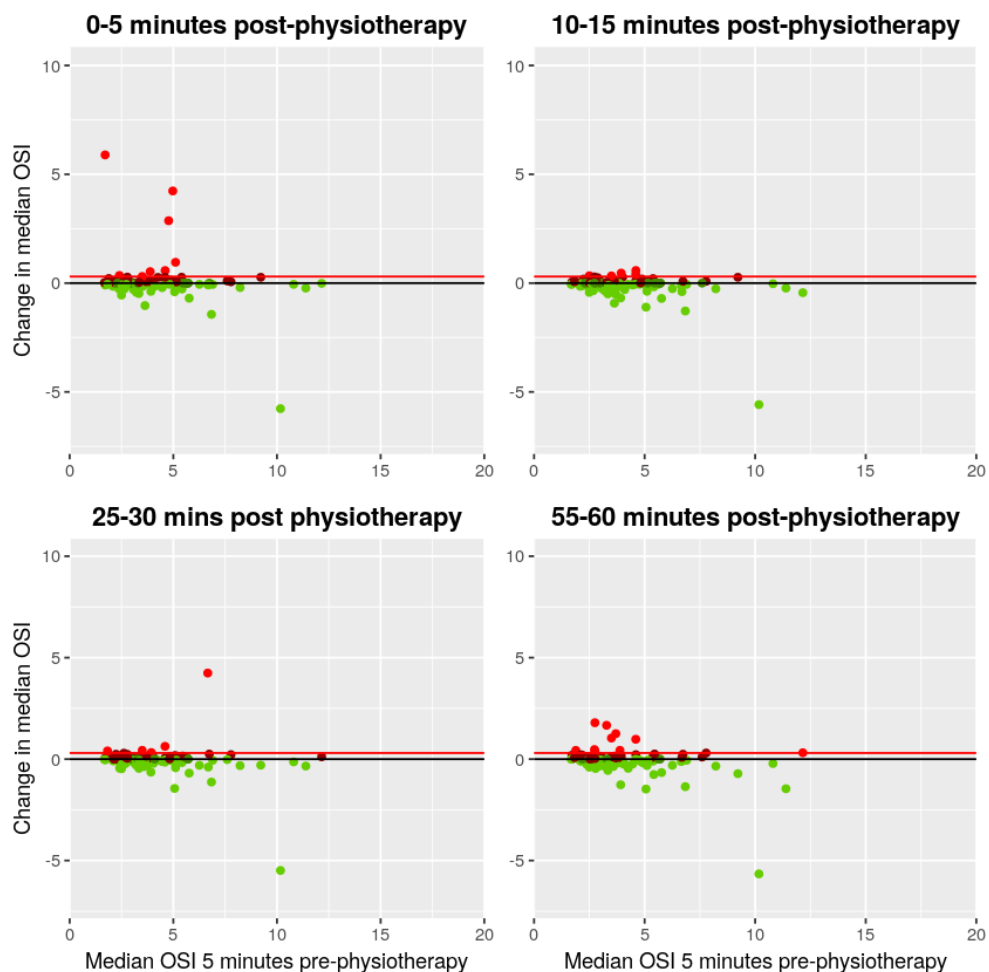
t.physio <- table(physio_osi$Treatmentnew, physio_osi$osi_ae)
t.physio

fisher.test(physio_osi$Treatmentnew, physio_osi$osi_ae)

```

Appendix 36 – Oxygen saturation index results first session day 3 and 4

Day 3, Session 1

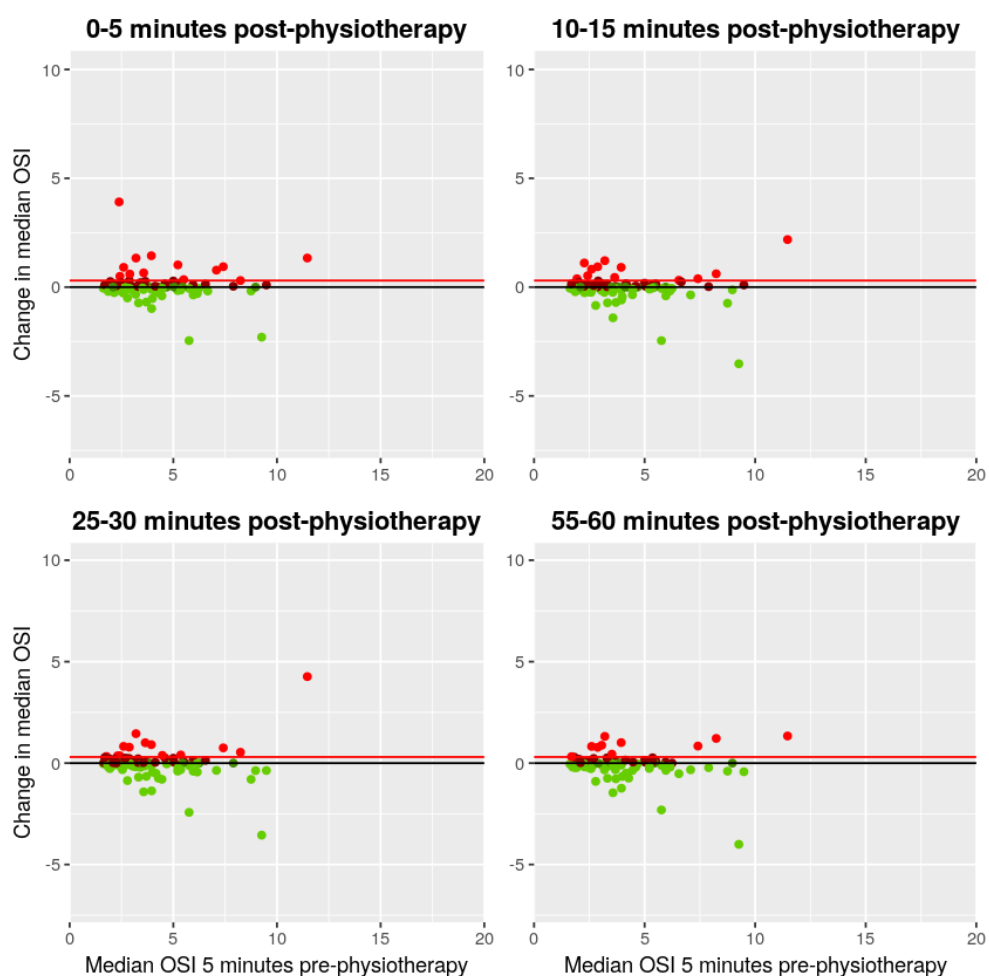


Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - in-status-quo, green - improved. OSI – oxygen saturation index)

Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=115)	8 (7.0)	42 (36.5)	12 (10.4)	53 (46.0)
15 minutes, n (%) (n=114)	5 (4.4)	31 (27.2)	16 (14.0)	62 (54.4)
30 minutes, n (%) (n=112)	5 (4.5)	42 (37.5)	10 (8.9)	55 (49.1)
60 minutes, n (%) (n=107)	10 (9.3)	30 (28.0)	6 (5.6)	61 (57.0)

## Day 4, Session 1



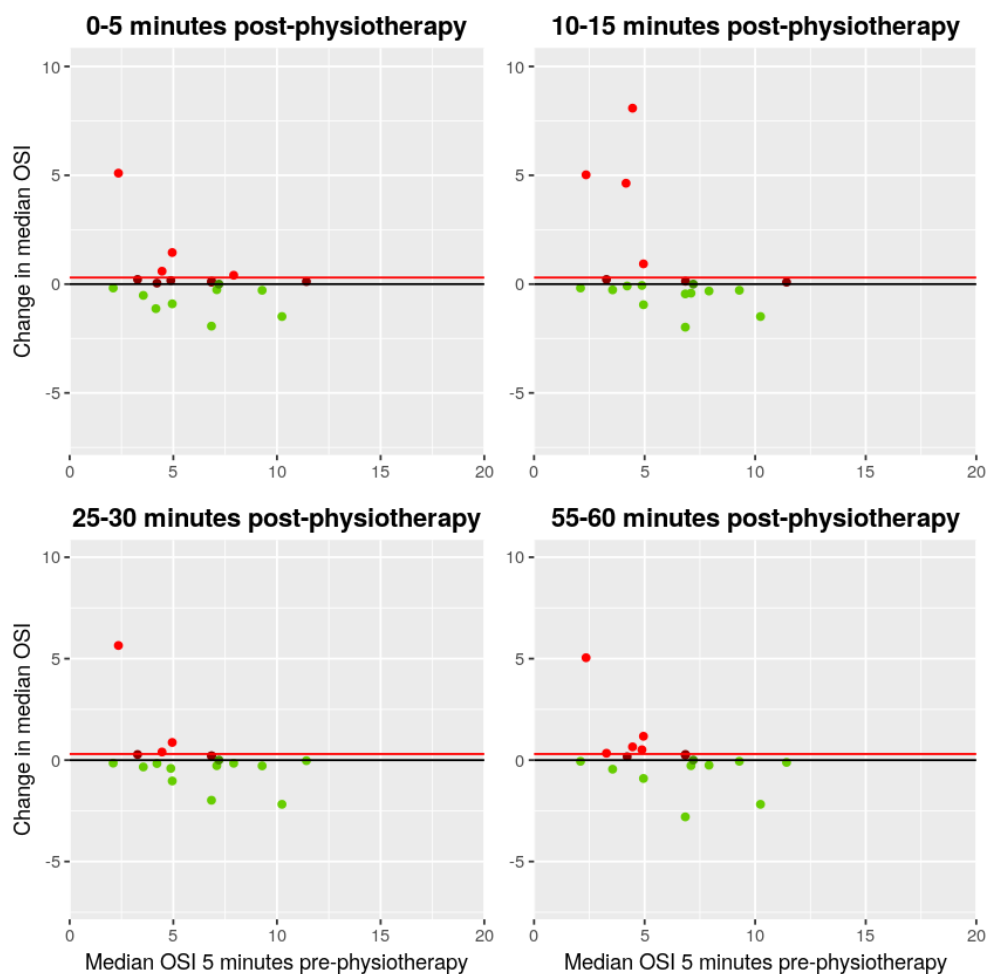
Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - in-status-quo, green - improved. OSI – oxygen saturation index)

Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=104)	13 (12.5)	30 (28.8)	10 (9.6)	51 (49.0)
15 minutes, n (%) (n=102)	12 (11.8)	32 (31.4)	9 (8.8)	49 (48.0)
30 minutes, n (%) (n=99)	13 (13.1)	28 (28.3)	8 (8.1)	50 (50.5)
60 minutes, n (%) (n=92)	10 (10.9)	23 (25.0)	6 (6.5)	53 (57.6)

Appendix 37 – Oxygen saturation index results subsequent sessions days 1-4

Day 1, Session 2



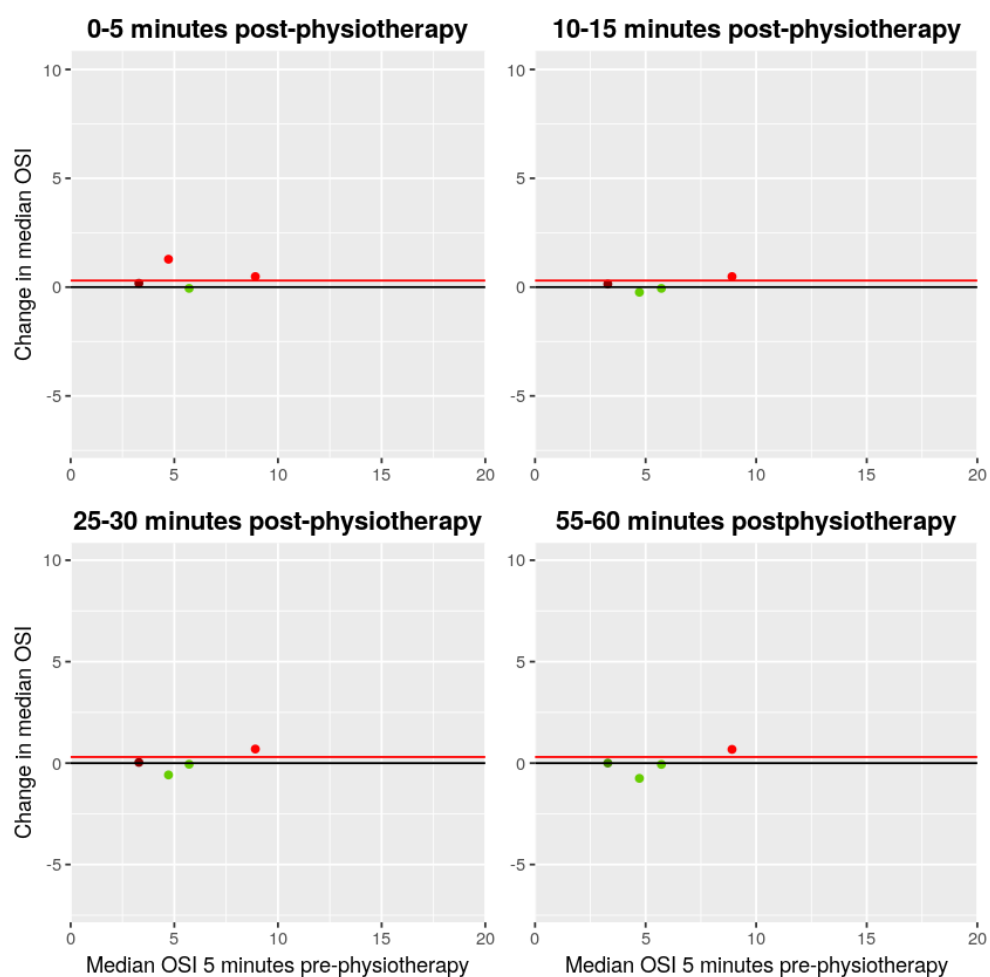
Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - in-status-quo, green - improved. OSI – oxygen saturation index)

Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=19)	4 (21.1)	6 (31.6)	1 (5.3)	8 (42.1)
15 minutes, n (%) (n=19)	4 (21.1)	3 (15.8)	1 (5.3)	11 (57.9)
30 minutes, n (%) (n=18)	3 (16.7)	3 (16.7)	1 (5.6)	11 (61.1)
60 minutes, n (%) (n=18)	5 (27.8)	3 (16.7)	1 (5.6)	9 (50.0)



## Day 2, Session 2

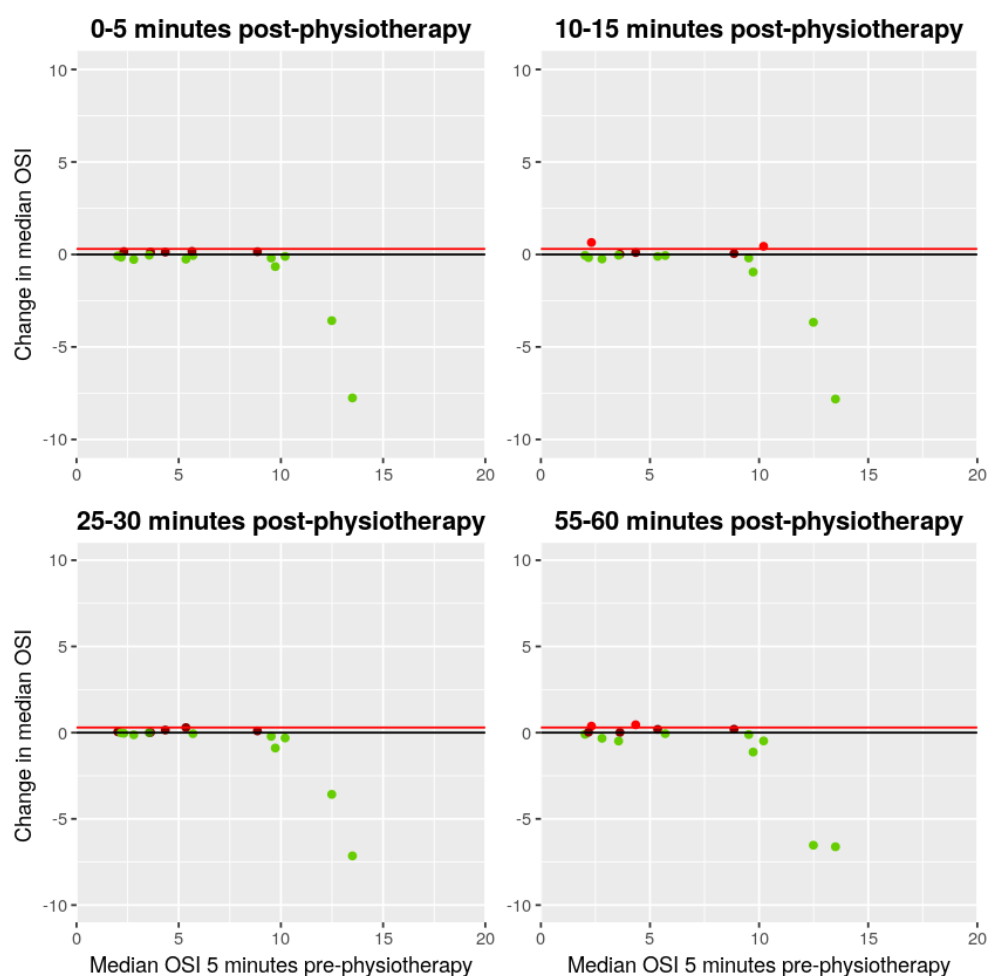


Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - in-status-quo, green - improved. OSI – oxygen saturation index)

Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=4)	2 (50.0)	1 (25.0)	0	1 (25.0)
15 minutes, n (%) (n=4)	1 (25.0)	1 (25.0)	0	2 (50.0)
30 minutes, n (%) (n=4)	1 (25.0)	1 (25.0)	0	2 (50.0)
60 minutes, n (%) (n=4)	1 (25.0)	0	1 (25.0)	2 (50.0)

## Day 3, Session 2

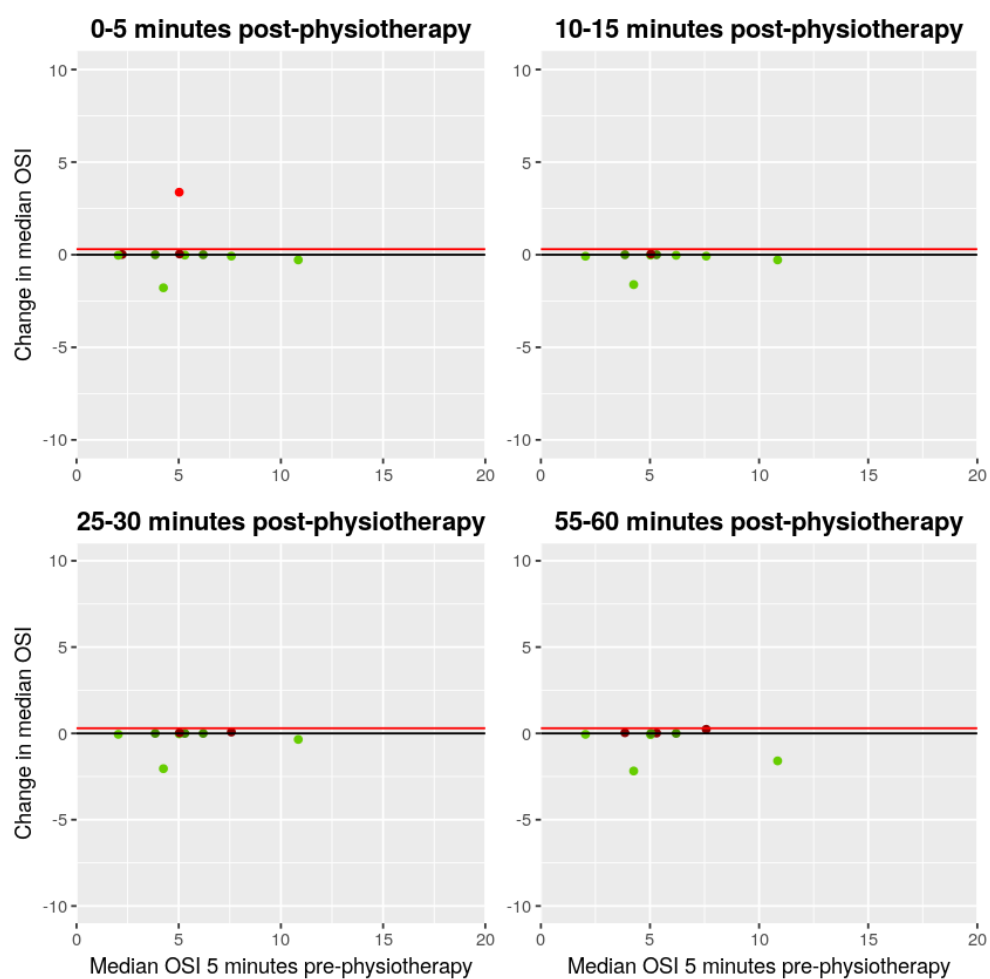


Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - in-status-quo, green - improved. OSI – oxygen saturation index)

Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=16)	0	5 (31.3)	0	11 (68.8)
15 minutes, n (%) (n=15)	2 (13.3)	3 (20.0)	0	10 (66.7)
30 minutes, n (%) (n=15)	0	5 (33.3)	1 (6.7)	9 (60.0)
60 minutes, n (%) (n=15)	2 (13.3)	4 (26.7)	0	9 (60.0)

## Day 4. Session 2



Change in median oxygen saturation index post-physiotherapy plotted against pre-physiotherapy median (The horizontal red line indicates the adverse event threshold of 0.3. Patients identified as having an adverse event are highlighted in red. Dark red points indicate patients with a worse OSI, dark green - in-status-quo, green - improved. OSI – oxygen saturation index)

Description of change in median oxygen saturation index post-physiotherapy

Post-physiotherapy time point	Adverse events	Worse (<threshold)	ISQ	Improvement
5 minutes, n (%) (n=10)	1 (10.0)	2 (20.0)	2 (20.0)	5 (50.0)
15 minutes, n (%) (n=9)	0	1 (11.1)	2 (22.2)	6 (66.7)
30 minutes, n (%) (n=9)	0	2 (22.2)	3 (33.3)	4 (44.4)
60 minutes, n (%) (n=9)	0	3 (33.3)	2 (22.2)	4 (44.4)

## Appendix 38 – Oxygen saturation index long-term analysis R script

```
#####  
##load in osi AE files and rename  
#####  
  
##1.1  
osi_AE_1.1 <- xap.read_table("osi_ae_1_1")  
names(osi_AE_1.1)[names(osi_AE_1.1) == 'osi_ae'] <- 'osi_ae1.1'  
str(osi_AE_1.1)  
  
##2.1  
osi_AE_2.1 <- xap.read_table("osi_ae_2_1")  
names(osi_AE_2.1)[names(osi_AE_2.1) == 'osi_ae'] <- 'osi_ae2.1'  
str(osi_AE_2.1)  
  
##3.1  
osi_AE_3.1 <- xap.read_table("osi_ae_3_1")  
names(osi_AE_3.1)[names(osi_AE_3.1) == 'osi_ae'] <- 'osi_ae3.1'  
str(osi_AE_3.1)  
  
##4.1  
osi_AE_4.1 <- xap.read_table("osi_ae_4_1")  
names(osi_AE_4.1)[names(osi_AE_4.1) == 'osi_ae'] <- 'osi_ae4.1'  
str(osi_AE_4.1)  
  
##1.2  
osi_AE_1.2 <- xap.read_table("osi_ae_1_2")  
names(osi_AE_1.2)[names(osi_AE_1.2) == 'osi_ae'] <- 'osi_ae1.2'  
str(osi_AE_1.2)  
  
##2.2  
  
osi_AE_2.2 <- xap.read_table("osi_ae_2_2")  
names(osi_AE_2.2)[names(osi_AE_2.2) == 'osi_ae'] <- 'osi_ae2.2'  
str(osi_AE_2.2)  
  
##3.2  
  
osi_AE_3.2 <- xap.read_table("osi_ae_3_2")  
names(osi_AE_3.2)[names(osi_AE_3.2) == 'osi_ae'] <- 'osi_ae3.2'  
str(osi_AE_3.2)  
  
##4.2  
  
osi_AE_4.2 <- xap.read_table("osi_ae_4_2")  
names(osi_AE_4.2)[names(osi_AE_4.2) == 'osi_ae'] <- 'osi_ae4.2'  
str(osi_AE_4.2)
```

```

#####
####combine sessions to compare
#####

osi_first_sessions <- left_join(osi_AE_1.1, osi_AE_2.1, by = "project_id")
str(osi_first_sessions)

osi_first_sessions1 <- left_join(osi_first_sessions, osi_AE_3.1, by = "project_id")
osi_first_sessions2 <- left_join(osi_first_sessions1, osi_AE_4.1, by =
"project_id")
osi_first_sessions3 <- left_join(osi_first_sessions2, osi_AE_1.2, by =
"project_id")
osi_first_sessions4 <- left_join(osi_first_sessions3, osi_AE_2.2, by =
"project_id")
osi_first_sessions5 <- left_join(osi_first_sessions4, osi_AE_3.2, by =
"project_id")
osi_first_sessions6 <- left_join(osi_first_sessions5, osi_AE_4.2, by =
"project_id")
str(osi_first_sessions6)

osi_first_sessions7 <- select(osi_first_sessions6, project_id, osi_ae1.1,
osi_ae2.1, osi_ae3.1, osi_ae4.1, osi_ae1.2, osi_ae2.2, osi_ae3.2, osi_ae4.2)
str(osi_first_sessions7)

unique(osi_first_sessions7$project_id)

#####take out partial data patients as only have session 1.1 for these
##load in partial patients

partial_patients <- xap.read_table("partial_wp2_physio_times_check")
str(partial_patients)

partial <- select(partial_patients, project_id)

#####remove partial patients

osi_first_session8 <- osi_first_sessions7[!(osi_first_sessions7$project_id %in%
partial$project_id),]
str(osi_first_session8)
unique(osi_first_session8$project_id)

#####
####number AE in all sessions
#####
###change TRUE to 1 and False to 0

osi_first_session8$osi_ae1.1 <- as.integer(osi_first_session8$osi_ae1.1)
osi_first_session8$osi_ae2.1 <- as.integer(osi_first_session8$osi_ae2.1)
osi_first_session8$osi_ae3.1 <- as.integer(osi_first_session8$osi_ae3.1)
osi_first_session8$osi_ae4.1 <- as.integer(osi_first_session8$osi_ae4.1)

```

```

osi_first_session8$osi_ae1.2 <- as.integer(osi_first_session8$osi_ae1.2)
osi_first_session8$osi_ae2.2 <- as.integer(osi_first_session8$osi_ae2.2)
osi_first_session8$osi_ae3.2 <- as.integer(osi_first_session8$osi_ae3.2)
osi_first_session8$osi_ae4.2 <- as.integer(osi_first_session8$osi_ae4.2)

str(osi_first_session8)

####sum rows

osi_first_session8$num_ae <- rowSums(osi_first_session8[2:9], na.rm = TRUE)

table(osi_first_session8$num_ae)
str(osi_first_session8)
unique(osi_first_session8$num_ae)

##create new variable

osi_first_session8$NumAE <- ifelse(osi_first_session8$num_ae ==0, 0,
                                ifelse(osi_first_session8$num_ae ==1, 1, 2 ))

str(osi_first_session8)
table(osi_first_session8$NumAE)

osi_AE <- osi_first_session8[, c(1,2,6,3,7,4,8,5,9,10,11)]
str(osi_AE)

#####
#####
#####compare demographics
#####
#####

##load in complete 01

demographic01_data <-
xap.read_table("complete01_caboodle_patient_demographics") # read in
variables table for all patients

# check data has loaded
head(demographic01_data)
dim(demographic01_data)
tail(demographic01_data)

##load in complete 02

demographic02_data <-
xap.read_table("complete02_caboodle_patient_demographics") # read in
variables table for all patients

# check data has loaded

```

```

head(demographic02_data)
dim(demographic02_data)
tail(demographic02_data)

#####
##join datasets together
#####

demographic_data1 <- rbind(demographic01_data, demographic02_data)

###join OSI group to full demo

demographic_data1 <- inner_join(demographic_data1, osi_AE, by="project_id")
str(demographic_data1)

t.OSI <- table(demographic_data1$NumAE)

#####
# explore gender
#####

t.gender <- table(demographic_data1$sex , demographic_data1$NumAE)

addmargins(t.gender)
round(prop.table(t.gender)*100, 2) #to give percentage

###stats difference

chisq <- chisq.test( demographic_data1$sex ,demographic_data1$NumAE)
chisq

#####
# exploring age
#####

##load in data set complete 01
age01_data <- xap.read_table("complete01_wp2_physio_details_check")
str(age01_data)

##load in data set complete 02
age02_data <- xap.read_table("complete02_wp2_physio_details_check")
str(age02_data)

#### join age data sets

age_data1 <- rbind(age01_data, age02_data)
head(age_data1)
str(age_data1)

```

```

class (age_data1$age_in_months) #this is a character needs to be integer
age_data1[c(3,4,6)] <- lapply(age_data1[c(3,4,6)], as.numeric)
str(age_data1)

###join OSI group to full age

age_OSIGroup <- inner_join(age_data1, osi_AE, by="project_id")
str(age_OSIGroup)

osimedian_age <- age_OSIGroup %>%
group_by(NumAE) %>%
  summarize(median = median(age_in_months))

osiage_quant <- age_OSIGroup %>%
group_by(NumAE) %>% summarize(age_in_months = quantile(age_in_months,
c(0.25, 0.5, 0.75)))

kruskal.test(age_in_months ~ NumAE, data = age_OSIGroup)

#####
### weight
#####

## load in data set 1
weight01_data <-
xap.read_table("complete01w_caboodle_patient_selected_flowsheetrows_clin_p
ivot")
str(weight01_data)

weight01_data <- select(weight01_data, project_id, taken_datetime,
R.DRUG.CALCULATION.WEIGHT_grams, WEIGHT.SCALE_grams)
weight01_data[c(3,4)] <- lapply(weight01_data[c(3,4)], as.integer)
str(weight01_data)

## load in data set 2

weight02_data <-
xap.read_table("complete02w_caboodle_patient_selected_flowsheetrows_clin_p
ivot")
str(weight02_data)

weight02_data <- select(weight02_data, project_id, taken_datetime,
R.DRUG.CALCULATION.WEIGHT_grams, WEIGHT.SCALE_grams)
weight02_data[c(3,4)] <- lapply(weight02_data[c(3,4)], as.integer)
str(weight02_data)

##cominbe data sets

weight_data <- rbind(weight01_data, weight02_data)

```



```

str(weight_data)

# combine to one column
weight_data1 <- weight_data %>%
  mutate(weight = ifelse(is.na(weight_data$WEIGHT.SCALE_grams),
weight_data$R.DRUG.CALCULATION.WEIGHT_grams,
weight_data$WEIGHT.SCALE_grams))
str(weight_data1)

###load in physio times

physiotimes1_data <- xap.read_table("complete01_wp2_physio_times_check")
str(physiotimes1_data)
head(physiotimes1_data)
unique(physiotimes1_data$project_id)

physiotimes2_data <- xap.read_table("complete02_wp2_physio_times_check")
str(physiotimes2_data)
head(physiotimes2_data)
unique(physiotimes2_data$project_id)

###join

physio_first <- rbind(physiotimes1_data, physiotimes2_data)
str(physio_first)

##pick first session
physio_first <- subset(physio_first, day == 1 & session == 1)
str(physio_first)

# join datasets

weight_data2 <- select(weight_data1, project_id, taken_datetime, weight)
weight_data3 <- left_join(physio_first, weight_data2, by = "project_id")
str(weight_data3)

##find difference between dates/times

weight_data4 <- weight_data3 %>%
  mutate(dateDiff = (weight_data3$datetime - weight_data3$taken_datetime))
str(weight_data4)

## filter to 2 weeks prior to physio only (doesnt work with negative numbers)

weight_data5 <- filter(weight_data4, weight_data4$dateDiff %in% (0:1209600))
str(weight_data5)

##filter dates to keep only closest (min) datediff with a value (not NA), grouped
by id and index datetime

```

```

weight_data5 <- weight_data5[complete.cases(weight_data5), ]

weight_data6 <- weight_data5 %>%
  group_by(weight_data5$project_id) %>%
  filter(dateDiff == min(dateDiff))

weight_data6 <- weight_data6 %>%
  ungroup()

str(weight_data6)
head(weight_data6)

unique(weight_data6$project_id)
weight_data7 <- weight_data6[!duplicated(weight_data6$project_id), ]
str(weight_data7)

weightosi <- inner_join(weight_data7, osi_AE, by="project_id")
str(weightosi)

unique(weightosi$project_id)

###stats diff

osimedian_weight <- weightosi %>%
  group_by(NumAE) %>%
  summarize(median = median(weight))

osiweight_quant <- weightosi %>%
  group_by(NumAE) %>% summarize(weight = quantile(weight, c(0.25, 0.5,
0.75)))

kruskal.test(weight ~ NumAE, data = weightosi)

#####
#### admission type
#####

##load in data set 1
admission01_data <-
xap.read_table("complete01_caboodle_patient_hospital_admissions")

dim(admission01_data)
str(admission01_data)

##load in data set 2
admission02_data <-
xap.read_table("complete02_caboodle_patient_hospital_admissions")

dim(admission02_data)
str(admission02_data)

```

```

##combine datasets

admission_data <- rbind(admission01_data, admission02_data)

str(admission_data)

# create 2 variables

admission_data1 <- admission_data %>%
mutate(Emergency = ifelse(admission_data$admission_type == "Emergency -
A&E, Casualty, or Dental Casualty Department" |
admission_data$admission_type == "Emergency Transfer" |
admission_data$admission_type == "Emergency - Consultant Clinic" |
admission_data$admission_type == "Emergency - Bed Bureau" |
admission_data$admission_type == "Emergency - Other" |
admission_data$admission_type == "Baby Born Elsewhere" |
admission_data$admission_type == "Emergency - via A&E of another Health
Care Provider", 1, 0),
      Elective = ifelse(admission_data$admission_type == "Elective - Planned" |
admission_data$admission_type == "Elective - Booked" |
admission_data$admission_type == "Non-Emergency Transfer" |
admission_data$admission_type == "Elective - Waiting List", 1, 0))

str(admission_data1)

admission_data1$Emergency = ifelse(admission_data1$Emergency==1,
"Emergency", NA)
admission_data1$Elective = ifelse(admission_data1$Elective==1, "Elective", NA)

admission_data1 <- admission_data1 %>%
  unite("admission.type", Emergency:Elective, na.rm = TRUE)

#####join to osi group

admission_osi <- inner_join(admission_data1, osi_AE, by="project_id")
str(admission_osi)

#####explore type of admission

t.admission <- table(admission_osi$admission.type, admission_osi$NumAE)
t.admission

chisq <- chisq.test(admission_osi$admission.type, admission_osi$NumAE)
chisq

#####
##pelod
#####

###read in pelod data

```

```

pelod_first <- xap.read_table("firstpelod")
str(pelod_first)

###join session times to osi group

pelod_osi <- inner_join(pelod_first, osi_AE, by="project_id")
str(pelod_osi)
table(pelod_osi$NumAE)

###explore

osimedian_pelod <- pelod_osi %>%
group_by(NumAE) %>%
  summarize(median = median(pelod_score))

osipelod_quant <- pelod_osi %>%
group_by(NumAE) %>% summarize(pelod_score = quantile(pelod_score,
c(0.25, 0.5, 0.75)))

kruskal.test(pelod_score ~ NumAE, data = pelod_osi)

#####
##COVID
#####

str(osi_AE)

lab1_data <-
xap.read_table("complete01_caboodle_patient_selected_lab_components_all_pi
vot")
str(lab1_data)

lab1_data1 <- select(lab1_data, project_id, collected_datetime,
COVID19RES_SARS.CoV.2.by.PCR.Result)
str(lab1_data1)

lab2_data <-
xap.read_table("complete02_caboodle_patient_selected_lab_components_all_pi
vot")
str(lab2_data)

lab2_data1 <- select(lab2_data, project_id, collected_datetime,
COVID19RES_SARS.CoV.2.by.PCR.Result)
str(lab2_data1)

labpart <-
xap.read_table("partial_caboodle_patient_selected_lab_components_all_pivot")
str(labpart)

```

```

labpart1 <- select(labpart, project_id, collected_datetime,
COVID19RES_SARS.CoV.2.by.PCR.Result)
str(labpart1)

###join together

lab_covid <- rbind(lab1_data1, lab2_data1)
lab_covid1 <- rbind(lab_covid, labpart1)
str(lab_covid1)

####find results during admission

str(admission_data)
adm_1 <- select(admission_data, project_id, start_datetime, end_datetime)
str(adm_1)

###join and filter between dates

covid_all <- inner_join(lab_covid1, adm_1, by="project_id")
str(covid_all)

covid_all1 <- filter(covid_all, collected_datetime >= start_datetime &
collected_datetime <= end_datetime)
str(covid_all1)

table(covid_all1$project_id,
covid_all1$COVID19RES_SARS.CoV.2.by.PCR.Result)

###create new variable
covid_all1$covid <-
ifelse(covid_all1$COVID19RES_SARS.CoV.2.by.PCR.Result == "RNA
Detected", "Yes", "No")
str(covid_all1)

###change NAs to no

covid_all1$covid[is.na(covid_all1$covid)] <- 'No'

unique(covid_all1$project_id)

###join to OSI group

covid_osi <- inner_join(osi_AE, covid_all1, by="project_id")
str(covid_osi)

unique(covid_osi$project_id)

###subset those with yes

covid_positive<- subset(covid_osi, covid == 'Yes')

```

```

str(covid_positive)
table(covid_positive$covid, covid_positive$NumAE)

#####
#####gestation
#####

full_longterm <- xap.read_table("full_longterm")
str(full_longterm)

osi_longterm1 <- inner_join(full_longterm, osi_AE, by="project_id")
str(osi_longterm1)

t.gest <- table(osi_longterm1$gest_group, osi_longterm1$NumAE)
t.gest
fisher.test(osi_longterm1$gest_group, osi_longterm1$NumAE)

#####
#####pim3
#####

median_pim <- osi_longterm1 %>%
group_by(NumAE) %>%
  summarize(median = median(pim3, na.rm = TRUE))

pim_quant <- osi_longterm1 %>%
group_by(NumAE) %>% summarize(pim3 = quantile(pim3, c(0.25, 0.5, 0.75),
na.rm = TRUE))

kruskal.test(pim3 ~ NumAE, data = osi_longterm1)

osi_longterm1$NumAE <- as.factor(osi_longterm1$NumAE)

#####
#####
#####investigate those with multiple admissions
#####

str(osi_first_session8)

osi_first_session9 <- osi_first_session8[order(osi_first_session8$project_id),]
str(osi_first_session9)

osi_first_session9[is.na(osi_first_session9)] <- FALSE

```

```

write.csv(osi_first_session8, "~/files/datafiles/osi_multiplesessions1new.csv")

osi_AE <- osi_AE[order(osi_AE$project_id),]
str(osi_AE)
write.csv(osi_AE, "~/files/datafiles/osi_numAE1.csv")
unique(osi_AE$NumAE)

#####
####compare number of physio sessions to num AE
#####

###join osi_AE and physiosessions_data

AE <- inner_join(osi_first_session8, physiosessions_data, by ="project_id")

str(AE)

ggplot(AE, aes(x=AE, y=number_of_physiotherapy_treatments))

ggplot(AE, aes(x=number_of_physiotherapy_treatments, y=num_ae)) +
  geom_bar()

ggplot(data=AE, aes(x=number_of_physiotherapy_treatments, y=num_ae,
fill=project_id)) +
geom_bar(stat="identity", position=position_dodge()) +

ggscatter(AE, x = "number_of_physiotherapy_treatments", y = "num_ae",
color="steelblue", add.params = list(color = "steelblue4", fill = "steelblue1"),size =
1, position = position_jitter(width = .1, height = 0.1),
  add = "reg.line", conf.int = TRUE,
  cor.coef = TRUE, cor.method = "spearman",
  xlab = "Number of physiotherapy treatments", ylab = "Number of
treatments with an OSI adverse event")

res2 <-cor.test(AE$num_ae, AE$number_of_physiotherapy_treatments, method
= "spearman", exact = FALSE)
res2

ci=1.96/(sqrt(length(ae$project_id)-3))
ci
> ci
uci=tanh(atanh(sp$estimate)+ci)
uci
> uci
  rho
lci=tanh(atanh(sp$estimate)-ci)
lci
> lci
  rho

```

```

#####
#####
####Long term outcome comparison
#####
#####

####pull all baseline characteristics together
str(demographic_data1)
str(age_OSIgroup)
str(weightosi)
str(admission_osi)
str(pelod_osi)

demo <- select(demographic_data1, project_id, sex, NumAE)
age <- select(age_OSIgroup, project_id, age_in_months)
weight <- select(weightosi, project_id, weight)
admission <- select(admission_osi, project_id, admission.type)
pelod <- select(pelod_osi, project_id, pelod_score)

osi_demo <- inner_join(demo, age, by="project_id")
osi_demo1 <- inner_join(osi_demo, weight, by="project_id")
osi_demo2<- inner_join(osi_demo1, admission, by="project_id")
osi_demo3 <- full_join(osi_demo2, pelod, by="project_id")
str(osi_demo3)

#####join to long term

osi_demo4 <- inner_join(osi_demo3, osi_longterm1, by = "project_id")
str(osi_demo4)

unique(osi_demo4$NumAE)

osi_demo4$NumAE.y <- as.factor(osi_demo4$NumAE.y)
osi_demo4$gest_group <- as.factor(osi_demo4$gest_group)

#####
#####dataframe for effects of multiple AEs
#####

##### select what need
osi_demo5 <- select(osi_demo4, project_id, age_in_months, weight,
admission.type, pim3, disstatus, lov, NumAE.y)
str(osi_demo5)

#####bring in number of physio sessions

##load in part 1
physio_details01 <- xap.read_table("complete01_wp2_physio_details_check")

```



```

str(physio_details01)

physio_details01[c(3,4,6,9,10)] <- lapply(physio_details01[c(3,4,6,9,10)],
as.integer)
str(physio_details01)

##load in part 2
physio_details02 <- xap.read_table("complete02_wp2_physio_details_check")

str(physio_details02)

physio_details02[c(3,4,6,9,10)] <- lapply(physio_details02[c(3,4,6,9,10)],
as.integer)
str(physio_details02)

##load in partial
physio_details_partial <- xap.read_table("partial_wp2_physio_details_check")

str(physio_details_partial)

physio_details_partial[c(3,4,6,9,10)] <-
lapply(physio_details_partial[c(3,4,6,9,10)], as.integer)
str(physio_details_partial)

##join complete data sets

physiosessions_dataa <- rbind(physio_details01, physio_details02)
physiosessions_data <- rbind(physiosessions_dataa, physio_details_partial)
str(physiosessions_data)

physio_sessions <- select(physiosessions_data, project_id,
number_of_physiotherapy_treatments)
str(physio_sessions)

#####join dataframes

osi_demo6 <- inner_join(osi_demo5, physio_sessions, by="project_id")
str(osi_demo6)

#####
###dataframe for effects of 1 AE
#####

#####select what need

osi_lov <- select(osi_demo4, project_id, weight, pim3, lov, osi_ae1.1, osi_ae1.2,
osi_ae2.1, osi_ae2.2, osi_ae3.1, osi_ae3.2, osi_ae4.1, osi_ae4.2, )
str(osi_lov)

```

```

#####change to long format

osi_lov1 <- tidyr::gather(osi_lov, key=physio_session, value=AE,
osi_ae1.1:osi_ae4.2) %>%
  arrange(project_id)

str(osi_lov1)
osi_lov1$physio_session <- as.factor(osi_lov1$physio_session)

###re-label physio_session

levels(osi_lov1$physio_session) <- c(1, 2, 3, 4, 5, 6, 7, 8)

###change to integer

osi_lov1$physio_session <- as.integer(osi_lov1$physio_session)
str(osi_lov1)

#####
###load in day of vent
#####

day_vent <- xap.read_table("day_of_vent1")
str(day_vent)

day_vent1 <- select(day_vent, project_id, day_ventilation, physio_session)
str(day_vent1)

###combine

osi_lov2 <- left_join(osi_lov1, day_vent1, by=c("project_id", "physio_session"))
str(osi_lov2)

osi_lov2$physio_session <- as.integer(osi_lov2$physio_session)
osi_lov2$day_ventilation <- as.integer(osi_lov2$day_ventilation)
osi_lov2$AE <- as.factor(osi_lov2$AE)

#####
#####basic comparison variables
#####

table(osi_demo6$disstatus, osi_demo6$NumAE.y)

fisher.test(osi_demo6$disstatus, osi_demo6$NumAE.y)

lov_quant <- osi_demo6 %>%
group_by(NumAE.y) %>%
  summarise(lov = quantile(lov, c(0.25, 0.5, 0.75)))

```

```
median(osi_demo6$lov)
table(osi_demo6$disstatus)
##check distribution of lov
```

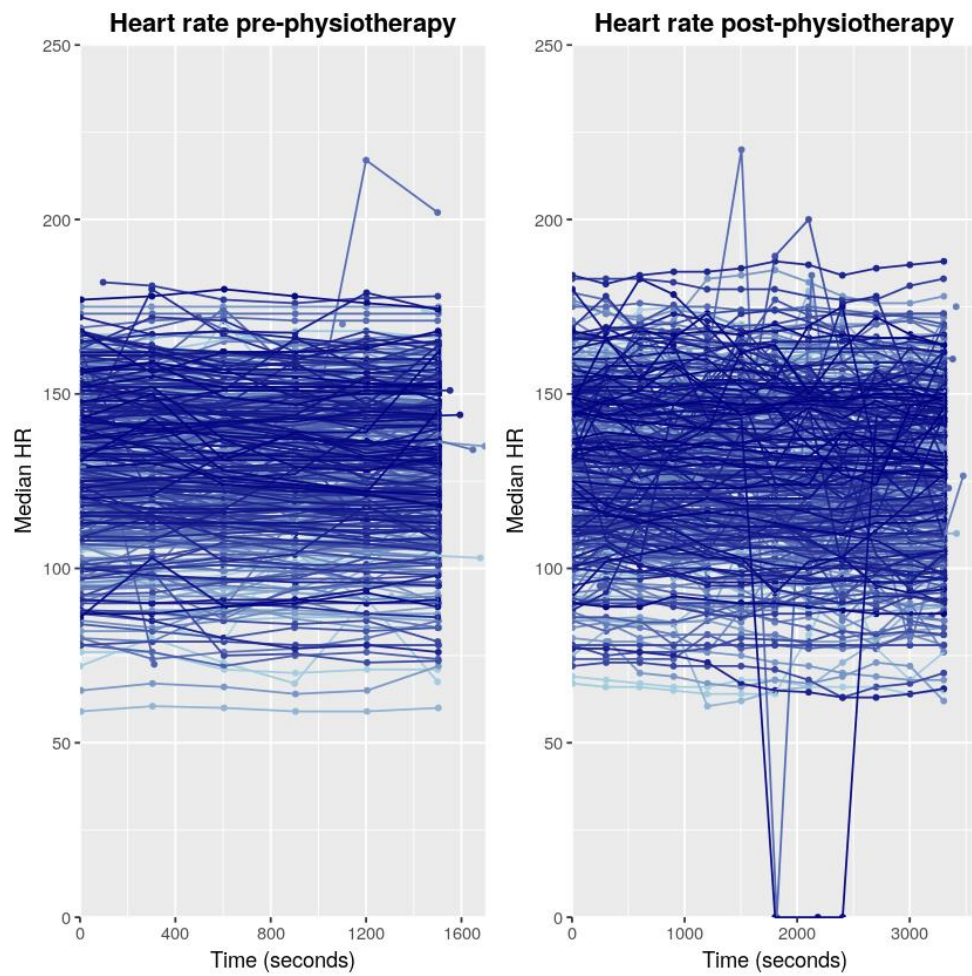
```
hist(osi_demo4$lov)
```

```
#####
###multilevel regression lov and ae
#####
```

```
model1 <- glm((lov+0.0001)~NumAE.y + weight + pim3 +
number_of_physiotherapy_treatments, data=osi_demo6,
family=Gamma(link="log"))
summary(model1)
confint(model1)
```

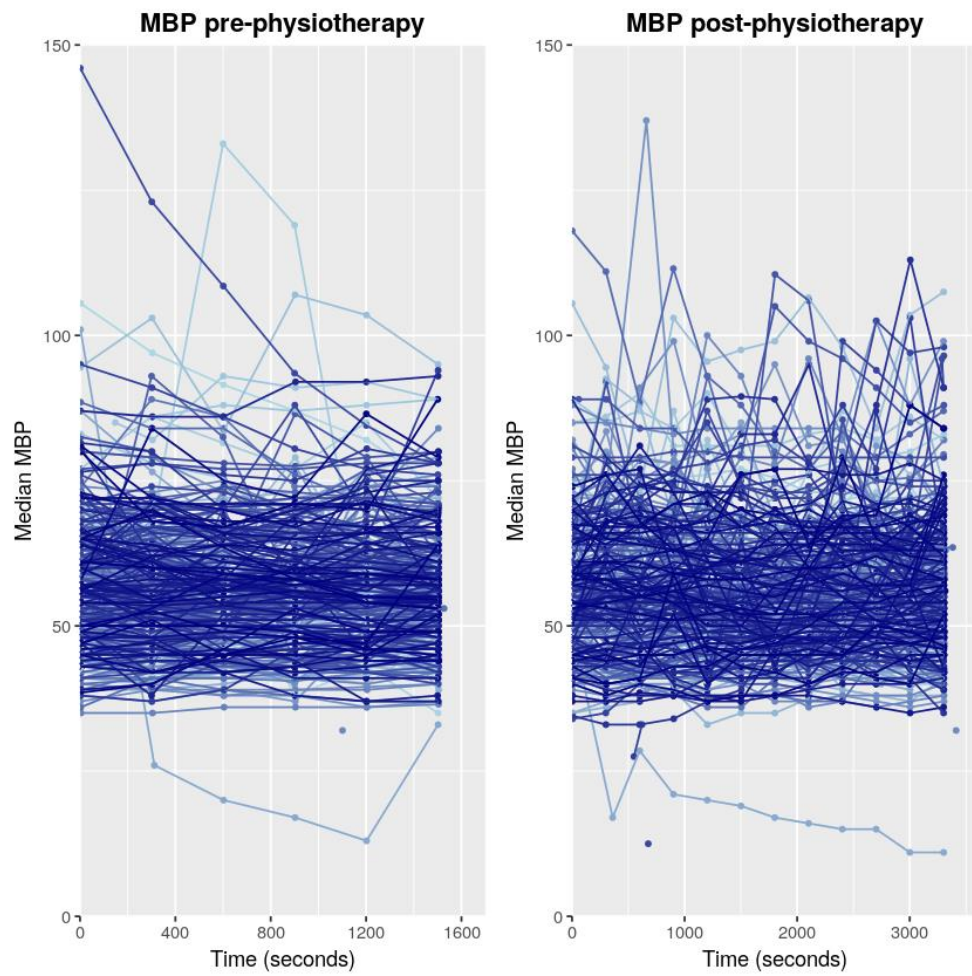
```
model2 <- glmer((lov+0.0001)~AE + weight + pim3 + physio_session +
(1|project_id), data=osi_lov2, family=Gamma(link="log"))
summary(model2)
confint(model2,parm="beta_",method="Wald")
```

Appendix 39 – Five-minute summary heart rate medians for individual patients pre- and post-physiotherapy



(n=425)

Appendix 40 – Five-minute summary mean arterial blood pressure medians for individual patients pre- and post-physiotherapy



(n=340, MBP – Mean arterial blood pressure)

Appendix 41 - Wilcoxon signed-rank test with Bonferroni adjustment comparing median mean arterial blood pressure pre- and post-physiotherapy

<b>Time point 1</b>	<b>Time point 2</b>	<b>Median of MBP paired differences (IQR)</b>	<b>Wilcoxon signed rank test (p.adjust)</b>
Pre-physiotherapy	5 minutes post	0 (-3-3.5)	p=1.0
Pre-physiotherapy	15 minutes post	0 (-3-4)	p=1.0
Pre-physiotherapy	30 minutes post	-0.5 (-4.5-3)	p=0.762
Pre-physiotherapy	60 minutes post	-0.5 (-5-4)	p=1.0
5 minutes post	15 minutes post	0 (-2-2)	p=1.0
5 minutes post	30 minutes post	0 (-4-3)	p=1.0
5 minutes post	60 minutes post	0 (-5-5)	p=1.0
15 minutes post	30 minutes post	0 (-3-2)	p=1.964
15 minutes post	60 minutes post	-0.5 (-5-4)	p=1.0
30 minutes post	60 minutes post	0 (-3-3.5)	p=1.0

(MBP – Mean blood pressure, p.adjust – adjusted p-value for multiple comparisons, n=340)