

***Investigating physiotherapy management  
of patients undergoing upper abdominal  
surgery at Waitematā District Health Board***

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## Abstract

**Objectives.** Post-operative pulmonary complications (PPCs) are one of the most prevalent complications following abdominal surgery. These complications increase hospital length of stay and mortality rates, imposing a significant financial burden on healthcare resources and patient recovery. In patients undergoing major abdominal surgery, physiotherapy aims to prevent and remediate post-operative complications, provide rehabilitation, and maintain and/or improve function. This study took place at North Shore Hospital, a publicly funded 600 bed metropolitan hospital within Waitematā District Health Board, Auckland, New Zealand. Data were collected to investigate the prevalence of PPCs, post-operative management, post-operative outcomes, as well as the provision of physiotherapy. Data were also collected to identify those participants at risk of complications amenable to physiotherapy interventions.

**Design.** Nested as part of a large, multicentre, international observational study.

**Setting.** Intensive care unit/high dependency unit and surgical wards at North Shore Hospital, Waitematā District Health Board, Auckland, New Zealand.

**Participants.** 100 consecutive patients between June and October 2018 undergoing abdominal surgery that was advanced laparoscopic, laparoscopic assisted, or open.

**Outcome measures.** Incidence of PPCs as diagnosed using the Melbourne Group Score Version 3. Secondary outcomes included length of stay and a diagnosis of pneumonia. Additionally, physiotherapy interventions for all participants were audited.

**Results.** The incidence rate of PPCs was 4%. The majority of surgeries (85%) were upper abdominal. Colorectal surgery was the most common surgery undertaken. There were fewer numbers of open (41%) to laparoscopic surgeries (59%). Most surgery was elective and 59% of surgeries were more than three hours in duration. The total median post-operative hospital length of stay for the whole cohort was 6.0 days (IQR 6.0 /range 2.0-30.0). Those who developed a PPC had a longer hospital length of stay compared with those who did not; median 20 days (IQR 18.0, range 11.0-29.0) versus 6.0 (IQR 5.0, range 2.0-30.0).

**Conclusion** This study provides participant demographic and surgical demographic data from North Shore Hospital. Whilst the sample size was small, the PPC rate in our centre is below that found in several other studies. Reasons for this require

further investigation in a larger cohort in our centre and comparison of abdominal surgery patient management at North Shore Hospital to elsewhere. The audit of physiotherapy interventions demonstrates less physiotherapy involvement at our centre compared with other centres in New Zealand; however, the type of physiotherapy interventions was similar to those supported by evidence-based practice.

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## Contents

Abstract.....	i
Acknowledgements.....	iii
Contents .....	iv
List of Tables.....	vi
List of Figures .....	vii
Author's Role.....	viii
Attestation of Authorship .....	ix
Abbreviations .....	x
Chapter One: Introduction.....	1
1.1 Introduction .....	1
1.2 Practice Project Aims .....	2
1.3 Structure of Report .....	3
Chapter Two: Background .....	4
2.1 Abdominal Surgery.....	4
2.2 Post-Operative Pulmonary Complications Definition and Prevalence .....	4
2.3 The Impact of PPCs on Clinical Outcome .....	5
2.4 Aetiology of PPCs .....	6
2.5 Risk Factors for PPC Development.....	7
2.6 Diagnosis of a PPC – Tools.....	9
2.7 Established Physiotherapy Practice at NSH .....	10
2.8 Background to CHESTY Trial.....	11
Chapter Three: Methods for Observational Study .....	13
3.1 Introduction .....	13
3.2 Study Aims .....	13
3.3 Method .....	13
3.3.1 Study design .....	13
3.3.2 Study setting .....	13
3.3.4 Participants .....	14
3.3.5 Data collection procedure.....	15
3.3.6 Primary and secondary outcomes .....	15
3.3.6 a. Primary outcomes .....	15
3.3.6 b. Secondary outcomes.....	17
3.4 Data Entry .....	17
3.5 Data Analysis.....	18
3.6 Ethics .....	18

Chapter Four: Results .....	19
4.1 Details of the Cohort.....	19
4.2 Primary Outcome: Post-Operative Pulmonary Complications .....	21
4.3 Secondary Outcome: Pneumonia .....	24
4.4 Length of Stay .....	24
4.5 Details of Respiratory Physiotherapy Intervention.....	26
4.6 Details of Rehabilitation Physiotherapy Intervention.....	28
4.7 Risk Factors .....	28
Chapter Five: Discussion .....	31
5.1 Discussion.....	31
5.2 Recommendations for Clinical Practice and Research.....	36
Chapter Six: Conclusion.....	38
References .....	39
Bibliography .....	46
Appendices.....	48
Appendix A: The CHESTY Study.....	48
Appendix B: Data Fields .....	49
Appendix C: Ethics Approval .....	52

## List of Tables

TABLE 1. <i>DEMOGRAPHIC/PARTICIPANT CHARACTERISTICS</i> .....	20
TABLE 2. <i>SURGICAL/OPERATIVE CHARACTERISTICS</i> .....	21
TABLE 3. <i>PROFILE OF PARTICIPANTS WHO DEVELOPED A PPC</i> .....	23
TABLE 4. <i>LENGTH OF STAY</i> .....	25
TABLE 5. <i>PHYSIOTHERAPY RESPIRATORY INPUT BY DAY</i> .....	27
TABLE 6. <i>PHYSIOTHERAPY REHABILITATION INPUT BY DAY</i> .....	29

## List of Figures

FIGURE 1: <i>AMERICAN SOCIETY OF ANAESTHESIOLOGISTS SCORE</i> .....	9
FIGURE 2: <i>MELBOURNE GROUP SCALE VERSION 3 (BODEN ET AL., 2018)</i> .....	16



## Author's Role

At the time of this research study, the author was employed by North Shore Hospital as a senior surgical physiotherapist, primarily working on the surgical wards and within the intensive care unit. The author was offered the opportunity to participate in the CHESTY study as the Waitematā District Health Board (WDHB) site investigator with support from Dr Julie Reeve, who was the principal investigator for the New Zealand sites.

As the site investigator, the author was involved in the application for funding and locality approval at WDHB, as well as liaising with the lead researcher at the University of Melbourne. Following locality and ethics approval, the author was responsible for the assessment of patients against the eligibility criteria, collection and inputting of data for secure storage, analysis of data, and consideration of the relevance of the findings to practice at WDHB.

## Attestation of Authorship

In submitting this work, I declare that:

- This assessment has been produced by me and represents my own work
- Any work of another person is appropriately acknowledged/or referenced
- This work did not involve any unauthorised collaboration
- This work has not previously been submitted by me or any other person/author, unless authorised
- I did not use any unfair means to complete this work
- I understand that the above obligations form a part of the University's regulations and that breaching them may result in disciplinary action

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Victoria Lai

Date: 20.03.2021

## Abbreviations

<b>ASA</b>	The American Society of Anaesthesiologists
<b>BBS</b>	Brooks-Brunn Score
<b>CHESTY</b>	CHEST infection prevalence following surgery
<b>CO<sub>2</sub></b>	Carbon Dioxide
<b>COPD</b>	Chronic obstructive pulmonary disease
<b>CT</b>	Computerised tomography
<b>ERAS</b>	Enhanced Recovery After Surgery
<b>FiO<sub>2</sub></b>	Fraction of inspired oxygen
<b>FRC</b>	Functional residual capacity
<b>GS</b>	Gosselink score
<b>HDU</b>	High Dependency Unit
<b>IBM</b>	International Business Machines Corporation
<b>ICU</b>	Intensive care unit
<b>IQR</b>	Interquartile range
<b>LOS</b>	Length of stay
<b>mg/dL</b>	milligrams per decilitre
<b>MGS</b>	Melbourne Group Score
<b>ml</b>	Milliliters
<b>mL/d</b>	Megalitres per day
<b>NSH</b>	North Shore Hospital
<b>PaO<sub>2</sub></b>	Partial pressure of arterial oxygen
<b>PEEP</b>	Positive end expiratory pressure
<b>POD</b>	Post-operative day
<b>PPC</b>	Post-operative pulmonary complication(s)
<b>REDCap</b>	Research Electronic Data Capture
<b>SD</b>	Standard deviation
<b>UAS</b>	Upper abdominal surgery
<b>µL</b>	Microlitre
<b>VC</b>	Vital capacity
<b>WCC</b>	White cell count
<b>WDHB</b>	Waitematā District Health Board

## Chapter One: Introduction

### 1.1 Introduction

Abdominal surgery is a procedure which involves opening the abdomen, most frequently to remove cancerous tissue; and is the most common type of surgery performed in both New Zealand and Australia (Reeve & Boden, 2016). Over recent years the number of abdominal surgeries performed annually has continued to increase, to approximately 234 million surgeries worldwide. This number is increasing due to a growth in population size as well as more patients being considered for surgery due to the progression of surgical techniques and imaging ability (Weiser et al., 2008).

Waitematā District Health Board (WDHB) is one of 20 District Health Boards within New Zealand, and covers North Shore City, Waitakere City, and the Rodney District in Auckland (Ministry of Health, 2020a). There are three hospital sites within WDHB; Waitakere Hospital, which does not provide tertiary services for general surgery, North Shore Hospital (NSH), and the Elective Surgical Centre (ESC), a second surgical facility based at NSH primarily utilised for day stay or overnight routine abdominal or orthopaedic surgery. North Shore Hospital is a publicly funded 600 bed metropolitan hospital with three surgical wards consisting of 98 general surgical beds. In addition, it has an intensive care unit (ICU) which has a total of six beds and a high dependency unit (HDU) with eight beds. Over 3000 abdominal surgeries are performed each year at NSH (Ministry of Health, 2019a). Between July 2018 and March 2019, 8552 patients were discharged from the general surgical service at NSH (Ministry of Health, 2019b).

Many patients undergoing abdominal surgery have an uncomplicated post-operative course and can be discharged within 14 days post-operatively (Haines, Skinner, & Berney, 2013). However, a proportion of patients develop complications post-operatively; the most prevalent being post-operative pulmonary complications (PPCs) (Hemmes, de Abreu, Pelosi, & Schultz, 2014; Miskovic & Lumb, 2017). Other common complications include cardiac and vascular complications and wound infections (Simoes et al., 2018). Despite the serious nature of PPCs, the prevalence rates vary widely in current literature. This is partly due to the heterogeneity of the type of abdominal surgery, surgery protocols, and the different populations being

investigated, as well as the diagnostic criteria/ tools and the sensitivity of such tools used to determine PPC.

Physiotherapy aims to prevent PPCs and treat any that do occur (Agostini et al., 2020), which makes it important to have up to date data regarding interventions and associated outcomes to accurately plan for ongoing services. Understanding the utilisation of physiotherapy resources will enable physiotherapists and researchers to determine the impact of interventions on such outcomes as PPCs and other complications, length of stay, and mobilisation.

Chest infection prevalence following surgery (CHESTY) is an international, multicentre, observational study involving a large group of international physiotherapy researchers and clinicians. This study includes data collected in 30 different international centres including Australia, New Zealand, United Kingdom, United States of America, Canada, Malaysia, and Singapore. The CHESTY study will examine the impact of physiotherapy interventions on post-operative outcomes by determining what interventions are delivered, as well as the timing and frequency of such interventions. As a nested part of the CHESTY study, this practice project will focus on the data collected at NSH which will enable the author to investigate local surgical data, PPC (and other complication) prevalence rates, and compare physiotherapy service/outcomes with other studies to determine at risk populations.

## 1.2 Practice Project Aims

1. Investigate prevalence of PPCs following abdominal surgery at NSH.
2. Investigate post-operative length of stay following abdominal surgery at NSH.
3. Investigate demographics of patients undergoing abdominal surgery at NSH.
4. Audit the physiotherapy service provision for patients undergoing abdominal surgery.
5. Determine risk factors that contribute towards the development of PPCs in patients undergoing abdominal surgery at NSH.

### 1.3 Structure of Report

- Chapter One provides an overview of the practice project.
- Chapter Two provides an overview of abdominal surgery, the prevalence and pathogenesis of PPCs, the use of PPC diagnostic tools, and the impact PPCs have on clinical outcomes.
- Chapter Three outlines the study methodology.
- Chapter Four presents the results of the study nested within the context of current physiotherapy practice at NSH, Auckland, New Zealand.
- Chapter Five provides an in-depth discussion around each of the study aims and any limitations identified. Research and practice recommendations and reflections for this study are presented.
- Chapter Six will provide a summary of the results and main findings.

## Chapter Two: Background

### 2.1 Abdominal Surgery

Abdominal surgery can be categorised by the location of the incision, extent of incision, the region of the abdomen being operated on (i.e., colorectal, upper gastrointestinal), and by the name of the specific procedure. The location of the incision determines whether the surgery is classified as upper or lower abdominal surgery. Upper abdominal surgery refers to incisions above, or extending above, the umbilicus, compared with lower abdominal surgeries where the incision is below the umbilicus. These surgeries can be performed via a laparotomy, which is an incision (usually midline abdominal) measuring greater than 5cm; or laparoscopically, also known as keyhole surgery. Over the last decade, laparoscopic surgery or hand assisted laparoscopic surgery (an incision smaller than 5cm) has become more frequent (Kulkarni & Arulampalam, 2020; National Bowel Cancer Audit, 2019). The use of laparoscopic techniques has been shown to improve short term outcomes following surgery such as reduced hospital length of stay (LOS), reduced pain, lower rates of ileus and earlier mobilisation (Biondi et al., 2013; Veldkamp et al., 2005).

Abdominal surgery is most frequently performed to remove cancerous tissue (Reeve & Boden, 2016), but also to remove infections, obstructions, or for bariatric weight loss surgery. The main types of abdominal surgery are performed for colorectal cancers as well as cancer of the pancreas, bladder, stomach, and kidney, which make up 50% of the 10 most common cancers in New Zealand (Ministry of Health, 2019a). Most patients have an uneventful recovery following abdominal surgery; however, a proportion of patients undergoing abdominal surgery go on to develop complications, the most common being a PPC (Haines et al., 2013; Miskovic & Lumb, 2017; Pasin et al., 2017). Improvements in surgical techniques and radiographic imaging has often led to earlier diagnosis and surgery being offered to higher risk patients such as those who are older or have multiple co-morbidities (Deng, Mitchell, Paine, & Kerse, 2020).

### 2.2 Post-Operative Pulmonary Complications Definition and Prevalence

A PPC is defined as a pulmonary complication that occurs in the post-operative period that causes respiratory illness or disease which has a negative impact on the patient's recovery (O'Donohue, 1992). The term PPC includes pneumonia,

atelectasis, acute respiratory failure, pleural effusions, pulmonary oedema, pulmonary embolus, bronchospasm, and exacerbation of previous lung disease (Kelkar, 2015), some of which are amenable to physiotherapy treatment. PPCs may require relatively simple ward-based care such as antibiotics and physiotherapy, or may escalate to require intensive care support, intubation, or result in increased morbidity and mortality. Post-operative pulmonary complications increase hospital LOS, morbidity, mortality, and use of hospital resources following upper abdominal surgery (Boden et al., 2015; Smetana, Lawrence & Cornell, 2006).

A PPC is the most common complication following abdominal surgery (Hemmes, de Abreu, Pelosi, & Schultz, 2014; Miskovic & Lumb, 2017; Simoes et al., 2018), however, the incidence of PPCs following upper abdominal surgery (UAS) has been found to vary from 2% (Burks et al., 2017) to 42% (Parry et al., 2014). The lower incidence rate may be due to under-reporting of some PPCs (particularly those that are minor and do not require significant change to the post-operative treatment plan) (Patel et al., 2016). The incidence of PPCs reported in the literature may also differ due to varying definitions and tools used within the literature to diagnose a PPC, as well as the different types of surgical groups, such as colorectal or gynaecological surgery, included in each study (Miskovic et al., 2017). Surgery involving the thorax and abdomen has been shown to have the highest rate of PPCs of all operative procedures due to the proximity of these incisions to the diaphragm, particularly procedures involving the upper gastrointestinal tract and hepatobiliary system (Jin et al., 2014; Parry et al., 2014; Scholes et al., 2009; Smetana et al., 2006).

### 2.3 The Impact of PPCs on Clinical Outcome

Post-operative pulmonary complications have differing levels of severity, ranging from minor atelectasis or requiring supplemental oxygen, to a severe pneumonia (Fernandez-Bustamante et al., 2017). Complications, such as severe atelectasis and pneumonia, can result in the need for mechanical ventilation or admission to the ICU, both of which increase PPC risk due to a range of factors such as hospital/ventilator associated pneumonia, reduced mobilisation, and sepsis resulting in multi-organ failure. These factors, combined with surgeries being performed on older patients who may be less fit (Deng, Mitchell, Paine, & Kerse, 2020), increase the risk of mortality (Endo, Kumamoto & Matsuyama, 2017).



Post-operative pulmonary complications are costly to the New Zealand health service; Sheikh, Croft and Harmston (2019) reported the average cost of a post-operative pulmonary complication to be NZ\$20,683.00 per patient. Thompson, Makary, Dorman and Pronovost (2006) demonstrated that patients who developed hospital acquired pneumonia had a ninefold increased risk of in-hospital mortality, a fourfold increased risk of discharge to an assisted living facility, and an average increased length of stay in hospital of 11 days. A PPC can result in a significant health burden, causing reduced physical function, reduced short term quality of life and increases the use of hospital resources (Boden et al., 2015; Boden et al., 2020; Miskovic & Lumb, 2017). With health needs and costs increasing, as well as an aging population, resources and the health dollar need to be utilised effectively. By understanding why, or in whom, PPCs occur, physiotherapy interventions can be targeted with the aim of reducing PPC prevalence.

## 2.4 Aetiology of PPCs

Abdominal surgery is usually performed under a general anaesthetic. The impacts of general anaesthesia include respiratory depression, and reductions in vital capacity (VC) and functional residual capacity (FRC). Additionally, patient related factors such as obesity, advanced age, smoking, and chronic lung disease can cause a reduction in the elastic recoil of the lungs, potentially perpetuating PPCs. With a decreased FRC or an increased closing capacity the small airways shut down. This results in reduced compliance of the lungs, hypoxaemia, and atelectasis. Post-operatively diaphragmatic excursion is reduced, further impaired by pain, with greater rib cage movement than abdominal movement resulting in a reduced VC (Wahba, 1991). The reduction in FRC and impairment to the respiratory muscles (including the diaphragm and abdominals) limits the ability to produce an effective cough and clear secretions. Vital capacity and FRC are reduced by up to 40% and 20% respectively post-operatively (Pryor & Prasad, 2008). The greatest reduction in FRC often occurs on post-operative day one (POD1) and post-operative day two (POD2) (Wahba 1991).

Normally, mucus is produced in small volumes within the lung and acts as a barrier to trap any toxins or debris. Clearance of mucus is achieved from the smaller airways by mucus attaching to the cilia (small hair like structures that have a

synchronous beat and transport mucus and any debris to the larger airways). Mucus is then cleared by a strong cough. Following surgery, the mucociliary escalator is compromised by a paralysis of the cilia and an increase in goblet cell activity. If the abdominal muscles have lost strength or if pain limits an effective cough, the patient may be unable to effectively clear pulmonary secretions. Reduced lung volumes can remain for several days post-operatively. Deep breathing exercises and early mobilisation are encouraged to reduce the impact that surgery has on the normal function of the lungs. Improving lung volumes and muscular strength enables effective clearance of secretions and a reduction in the amount of mucus remaining in the dependent airways by restarting the mucociliary escalator.

## 2.5 Risk Factors for PPC Development

There are well documented risk factors for the development of PPCs, some of which are related to the surgery and some of which are patient related. The pre-operative identification of risk factors for the development of PPCs facilitates management strategies in the pre, peri and post-operative stages.

Surgery that requires an incision above the umbilicus is considered a higher risk for the development of PPCs compared with some other surgeries (Smetana et al., 2006). Upper abdominal surgery increases the risk of a PPC due to several factors, including the proximity of the surgery to the diaphragm, which increases the impact on the respiratory system beyond the effect of general anaesthesia (Scholes et al., 2006). Respiratory function is affected by the reduction in FRC and VC from surgically induced decreased lung volumes during the operation (to improve visibility of the organ being operated on), and from impaired diaphragmatic excursion post-operatively, due to pain and the impact of anaesthesia. Furthermore, the combination of pain and impaired muscular function reduces the effectiveness of a cough, preventing effective secretion clearance.

Adequate pain management has been linked to improved patient outcomes and reduced PPC rates (Davies, Husain and Stephens., 2017). Considering the physiology of deep breathing and chest physiotherapy, and through clinical experience, it is often noted that patients who do not have optimal pain management do not achieve early or frequent ambulation, and can be unable to effectively participate in respiratory physiotherapy interventions (e.g., coughing) (Davies et al.,

2017). However, achieving the balance of adequate analgesia can be difficult, as opiates are known to suppress the cough mechanism, reduce FRC, and cause respiratory drive depression (Jordan, 1982). Therefore, effective pain management that results in the least disruption to respiratory mechanics is required to reduce the risk of PPCs. Nimmo (2004) discussed the benefit of epidurals to supplement a general anaesthetic and identified the benefits on pulmonary function by providing effective pain relief and reducing the need for strong opioids that would cause respiratory depression. Epidurals minimise the disruption to respiration by blocking reflexes that impair diaphragmatic function, as well as reducing the stress response that surgery has on the body, which, when heightened, may contribute towards immunosuppression and an increased risk of infection.

The risk of developing a PPC increases over the age of 60 and increases further over 80 years of age, and appears closely linked with measures of frailty and the presence of co-morbidities (Massarweh, Legner, Symons, McCormick, & Flum, 2009). The percentage of the patient population for WDHB over 60 years is 19.2%; similar to the national population average (Ministry of Health, 2020b). The impact of advancing age as a non-modifiable risk factor will become more apparent as patients with more co-morbidities are considered for surgical intervention (Hulzebos, Van Meeteren, De Bie, Dagnelie, & Helders, 2003). As surgical techniques continue to advance, surgery is now being performed on patients who would not previously have been considered a surgical candidate.

A history of smoking is both a contributing factor to the presence of respiratory illness, and a risk factor for PPCs (Gronkjaer et al., 2014). Smoking results in chronic lung changes, such as a reduced closing capacity which results in alveolar closure and reductions in gas exchange. Smoking also inhibits mucocilliary clearance (Moller, Villebro, Pedersen, & Tonnesen, 2002). Patients undergoing upper abdominal surgery that are current smokers are twice as likely to get a PPC compared to non-smokers (Bluman, Mosca, Newman, & Simon, 1998; Gronkjaer et al., 2014; Scholes et al., 2009).

The American Society of Anaesthesiologists Score (ASA) is often used in hospitals pre-operatively to quantify a patient's risk of a PPC. The ASA is a global score that measures the overall status of a patient prior to the surgery (Smetana et al., 2006). Figure 1 shows the classification description. Smetana et al. (2006) published a systematic review which suggested there is strong evidence for risk

factors which include an ASA score greater than two. Other findings from Smetana et al., (2006) demonstrated that increasing age, decrease in functional independence, longer surgery, or an albumin of less than 30g/l were all associated with increased risk of post-operative complications.

Classification	Description
1	Healthy patient
2	Patients with mild systemic disease
3	Patients with severe systemic disease
4	Patients with severe systemic disease that is a constant threat to life
5	A moribund patient not expected to survive 24 hours with or without operation
6	Declared brain-dead and organs are being removed for donor purposes

Figure 1: *American Society of Anaesthesiologists Score*

## 2.6 Diagnosis of a PPC – Tools

The definition of a PPC varies throughout the literature, as do the criteria used to diagnose a PPC. This results in a wide variation in the prevalence of PPCs reported in the literature, and difficulty with reliable diagnosis as there are no universally accepted criteria (Agostini et al., 2011). Often in the literature, objective measures of respiratory function (such as oxygen saturation, chest x-rays and, auscultation) are grouped to form a tool in an attempt to improve the reliable diagnosis of PPCs. Many of these criterion-based tools exist, however, this creates variability in the diagnosis and prevalence of PPCs, both across the literature and in clinical practice.

Furthermore, variability in the measurement/use of individual criterion, and in the differing way these criteria are combined, lend confusion to the accuracy in the prevalence of clinically significant PPCs.

The three main tools used in research studies similar to the CHESTY study are the Gosselink Score (GS), Brooks-Brunn Score (BBS) and the Melbourne Group Scale (MGS). Primarily, these are tools used by physiotherapists to diagnose PPCs amenable to physiotherapy interventions. The GS was designed for use following

thoracic surgery to identify clinically significant PPCs associated with respiratory infection. The criteria are based on pyrexia above 38°C, a white cell count greater than 12 <sup>9</sup>/L, and an author designed scoring system based on the results of a chest x-ray that indicate major atelectasis or infiltrations unilaterally or bilaterally. The BBS was developed to use following upper abdominal surgery to diagnose atelectasis and pneumonia. The criteria include pyrexia ≥38°C, physician and/or chest x-ray diagnosis of atelectasis or pneumonia, new cough/sputum and altered auscultation. A PPC is diagnosed using the BBS if a patient scores two of the criteria for two consecutive days (Brooks-Brunn, 1997). The MGS is the most recent of these tools and was designed by physiotherapists to diagnose those PPCs amenable to physiotherapy treatment such as atelectasis and pneumonia (Parry, Denehy, Berney, & Browning, 2014) and can be seen at Appendix A. The MGS confirms the diagnosis of a PPC if four or more of the identified criteria are present (e.g., auscultation or sputum changes, presence of sputum or pyrexia). Diagnostic changes include a raised white cell count, chest x-ray changes, or a sputum culture report; and a final 'other' category is for anti-biotics prescribed specifically for a chest infection or a physician's diagnosis of a PPC. The MGS has been shown to be a reliable and valid tool with good inter-rater reliability following thoracic surgery (Agostini et al., 2011). Despite there being no gold standard tool available in the diagnosis of a PPC, the MGS was chosen by the lead investigators of the wider CHESTY study due to its use in other similar trials (Boden et al., 2018) and its demonstrated clinimetric properties (Agostini, 2011).

## 2.7 Established Physiotherapy Practice at NSH

Established physiotherapy practice at NSH has typically been provided to all patients undergoing open, upper abdominal surgery post-operatively and, provided pre-operatively to patients undergoing upper gastrointestinal surgery. This pre-operative service was initiated during, and maintained following, the Lung Infection Prevention Post Surgery (Major Abdo) with Pre-Operative Physiotherapy (LiPPSMACK-POP) study, targeting the upper gastrointestinal surgical population due to the known increased risk of complications following this type of surgery (Boden et al., 2018).

Studies in New Zealand have determined that the majority of physiotherapists working in abdominal surgical centres prophylactically administer post-operative

physiotherapy to all patients following open, upper, abdominal surgery to prevent PPCs (Reeve et al., 2019). The same study reported that patients that develop PPCs following laparoscopic surgery are not normally treated by a physiotherapist but assessed by a physiotherapist once a PPC occurs. Physiotherapy aims to reduce the incidence of PPCs, reduce LOS, and improve quality of life (Agostini et al., 2020) using a range of techniques, including post-operative mobilisation and breathing exercises; ambulation with a focus on the frequency, intensity, and safety of mobilisation to improve and maintain lung volumes; aid secretion clearance; and encourage retention of strength and function.

With approximately 3000 abdominal surgeries performed each year at NSH (Ministry of Health, 2019a) it is important that physiotherapists evaluate their practice to determine the prevalence of complications amenable to their interventions, compare their prevalence to other providers both nationally and internationally, and evaluate service delivery to ensure they are providing cost effective, evidence-based interventions that are reflective of the developments with abdominal surgery techniques.

## 2.8 Background to CHESTY Trial

In 2017, NSH physiotherapy department participated in a large, international, multi-centre randomised controlled trial by Boden et al. (2018a); namely, the LIPPSMAck POP trial. This trial investigated whether a single pre-operative session with a physiotherapist was successful in reducing the number of PPCs following major open, upper abdominal surgery. It found that PPCs reduced from 27% to 12% when comparing pre-operative education to no pre-operative education with standard post-operative physiotherapy care, and PPCs reduced even further in high-risk participants undergoing abdominal surgery, with an absolute risk reduction of 21% observed (40% in control group to 19% in treatment group). The intervention, which has subsequently been demonstrated to be cost effective (Boden et al., 2020), was able to reduce PPCs, reduce length of stay by two days and to reduce pneumonia rates. The LIPPSMAck POP study also highlighted that the highest rate of PPCs occurred within participants undergoing colorectal surgery (Boden et al., 2018). However, in a subgroup analysis, the LIPPSMAck POP trial did not show a difference in PPC rates within the WDHB population; possibly due to the sample size being small at this centre. The CHESTY study, following on closely from the

LIPSMack POP study will allow for investigation into a more diverse range of surgical groups, including those undergoing laparoscopic surgery. The aim of this study is to enable us to identify patients that may be at risk of a PPC, including those who typically would not receive routine physiotherapy input, such as those undergoing laparoscopic surgery. The audit of respiratory and rehabilitation physiotherapy interventions will provide information on the current physiotherapy service provision, including for those who do and do not develop a PPC, and provide data to enable NSH to compare outcomes to that of other centres.

## Chapter Three: Methods for Observational Study

### 3.1 Introduction

This chapter will discuss the protocol followed for the study, outlining the methodology, study design, data analysis, and ethics approval.

### 3.2 Study Aims

The aims of this study were to:

1. Investigate the prevalence of PPCs following abdominal surgery at NSH.
2. Investigate the post-operative length of stay following abdominal surgery at NSH.
3. Investigate demographics of patients undergoing abdominal surgery at NSH.
4. Audit the physiotherapy service provision for patients undergoing abdominal surgery.
5. Determine risk factors that contribute towards the development of PPCs in patients undergoing abdominal surgery at NSH.

### 3.3 Method

#### 3.3.1 Study design

This research was conducted as a nested observational study within the larger CHESTY study, which was registered with the Australian New Zealand Clinical Trials Registry (ACTRN: 12616001020471). The study protocol used for this observational study was designed by the CHESTY steering committee comprising of senior clinical and academic physiotherapists. The data collected at NSH was a contribution to the wider CHESTY study which is being collected across 30 centres in 7 countries and is due for completion in 2021. NSH was one of four New Zealand centres involved in the CHESTY study; each centre has access to the data collected at their individual sites only.

#### 3.3.2 Study setting

This study was undertaken at NSH in Auckland, New Zealand. North Shore Hospital is a publicly funded, 600 bed metropolitan hospital with three surgical wards



consisting of 98 general surgical beds. In addition, the ICU has a total of six beds and the HDU has eight beds. Types of surgery undertaken range from laparoscopic to open incisions, and include surgery to the renal, colorectal, and upper gastrointestinal systems.

### 3.3.3 Recruitment procedure

One hundred participants admitted consecutively to NSH ICU/HDU or surgical wards from June to October 2018 were screened by the author (as the site investigator) for eligibility according to pre-specified inclusion criteria (see section 3.3.4). Data were collected daily by the author for each participant for seven consecutive post-operative days or until discharge, whichever came first. An a priori sample size of 100 participants was selected due to time and staffing constraints within the physiotherapy department restricting the amount of time able to be allocated to data collection.

### 3.3.4 Participants

All adults undergoing emergency or elective abdominal surgery with a minimum of a two-night hospital stay, and who fit the criteria below, were eligible to be included in the study.

#### *Inclusion criteria:*

1. All abdominal surgical patients admitted to ICU/HDU post-operatively regardless of surgery type/duration.
2. Patients admitted to a surgical ward undergoing the following operations:
  - Open upper abdominal surgery
  - Laparoscopic assisted or hand-assisted abdominal surgery
  - Advanced laparoscopic surgery (colorectal, upper gastrointestinal, bariatric surgery)
3. Anaesthetic time exceeded 180 minutes for either of the following operations:
  - Open lower abdominal surgery
  - Standard laparoscopic surgery

#### *Exclusion criteria:*

1. Gynaecological surgery
2. Inguinal hernia repairs
3. Peripheral elective orthopedic surgery
4. Patients whose surgery did not occur on-site
5. Patients admitted to day-surgery unit or short-stay surgical unit
6. Patients already recruited in the study who had repeat surgical procedure/s within the primary episode of care

### 3.3.5 Data collection procedure

During weekdays, the demographic, clinical information and an audit of physiotherapy input was collected prospectively daily by the author and entered into a standardised piloted electronic/paper-based case report form (Appendix B list of data collected). Data collection for weekend days were collected retrospectively by the author on the following Monday. Data were collected by reviewing Concerto (Orion Health), a computer software package that allows authorised clinicians to view participant demographic and clinical information. Additionally, the handwritten clinical notes for each participant were reviewed for further details on a daily basis. There were no additional assessments or deviation conducted on participants from standard patient care. When all data points were collected, the paper forms were entered into an electronic database REDCap (see section 3.4). Data were entered by the site investigator and one other physiotherapist. To ensure the data were accurate, after all data were entered, an audit of 20% of the entries was completed and the information verified to be accurate by the author with no data entry errors found.

### 3.3.6 Primary and secondary outcomes

#### 3.3.6 a. Primary outcomes

The primary outcome measure used to standardise the diagnosis of a PPC was the MGS Version 3 (Figure 2, p. 16) (Boden et al., 2018).

The presence of a PPC was calculated retrospectively via REDCap (see section 4.3.4) using the data as collected and recorded above for the first seven days post-operatively, or until discharge. No extra assessments or interventions beyond standard care were performed to gather this data.

PPC diagnostic criteria

When four (4) or more of the following criteria\* are present anytime in the 24hour period 00:01 to 24:00 on a single POD:

1. New abnormal breath sounds on auscultation different to preoperative assessment
2. Production of yellow, green, or brown sputum different to pre-morbid status
3. Pulse oximetry oxygen saturation ( $SpO_2$ ) <90% on room air or  $FiO_2$  0.21 on more than one consecutive post-operative day\*\*
4. Raised maximum tympanic temperature >38°C on more than one consecutive post-operative day
5. Chest radiograph report of collapse/consolidation\*\*\*
6. An otherwise unexplained white cell count greater than 11, or less than 3.
7. Presence of infection on sputum culture report\*\*\*
8. Physician's diagnosis of postoperative pulmonary complication (e.g. atelectasis, pneumonia, AECOPD, respiratory failure, upper respiratory tract infection) **OR** prescription of an antibiotic specific for respiratory infection

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*\*If a therapist, nurse or physician documents in the medical record the occurrence of a criterion at any time in the 24hr time period, this is taken as a default positive finding. If no documentation present, blinded assessor is required to assess this directly.*

*\*\*For ventilated patients, if  $FiO_2 \geq 0.5$  or  $PEEP \geq 8$ , assume criterion 3 is present (do not alter PEEP or  $FiO_2$ ), for all other patients set  $FiO_2$  to 0.21 and PEEP to 5 and observe  $SpO_2$  for two minutes. If  $SpO_2$  drops below 90% immediately reinstate previous PEEP and  $FiO_2$ . If not permissible to adjust ventilator settings assume +ve.*

*For spontaneously ventilating patients, assume +ve if  $O_2$  therapy delivery has an estimated  $FiO_2 \geq 0.4$*

*\*\*\*If daily measures are not made for CXR or sputum samples carry over a positive diagnosis for either of these criteria to the next consecutive postoperative day.*

Figure 2: *Melbourne Group Scale Version 3* (Boden et al., 2018)

On collection of the individual criteria for the MGS tool, a finding of new or abnormal breath sounds on auscultation were taken from the documentation by the doctor, nursing staff, or physiotherapists and compared to pre-operative assessment notes, if available. Sputum microbiology, white cell count, and the chest x-ray findings were located through Concerto where available. If these were not conducted on the following day, a positive result would be carried over to the following post-operative day. Oxygen saturation was measured percutaneously, and would be considered positive if the oxygen saturation dropped below 90% on room air for greater than two minutes, or was assumed to be positive if the participant was ventilated with a positive end expiratory pressure (PEEP) of greater or equal to eight, or if supplemental oxygen was greater than or equal to 50%. Participants who were self-ventilating but had supplemental oxygen greater than 40% were also assumed to be positive for the oxygen saturation criteria due to their additional oxygen requirements. The highest temperature for each 24-hour period was recorded, and

was positive if this was raised above 38°C on more than one consecutive day post-operatively. A doctor's diagnosis of a PPC required clear documentation that antibiotics were prescribed or a respiratory infection/complication was listed in the clinical notes, such as atelectasis or pneumonia. If such a finding was not assessed or documented, it was recorded as not recorded and scored as a negative on the MGS. A PPC is diagnosed on REDCap using the data entered if four or more of the criteria were positive on any one post-operative day.

### 3.3.6 b. Secondary outcomes

Length of hospital stay was calculated using the data recorded, including date of admission, date of surgery, and date of discharge. These data were used to calculate the post-operative length of stay, as well as the length of stay if the participant was admitted to ICU.

Physiotherapy intervention was considered across 2 domains of treatment—respiratory and rehabilitation interventions. These data were collected through the documentation of the ward physiotherapists treating each participant. A tick box sheet was completed to indicate all interventions carried out on a daily basis for seven days post-operatively or until discharge, whichever came sooner. If the physiotherapist completed an intervention that was not on the provided list this was added as “other” and detailed in the notes section.

Pneumonia was retrospectively diagnosed on REDCap using the data entered. REDCap calculated pneumonia using the results from a chest x-ray or computerised tomography (CT) scan showing infiltrates, and at least two of the following: a temperature of over 38°C, dyspnoea, a cough and sputum changes, auscultation changes and a white cell count >12,000/ml or leukopenia <3000/ml. These were documented as per the instructions for the MGS above.

## 3.4 Data Entry

Data were entered and securely stored in the REDCap Consortium database platform. This software belongs to the University of Melbourne, with password protected access permitted to the site investigator for NSH's data only. The paper data sheets were stored in a locked cabinet accessible only to the author. Upon data analysis, the data relating to participants from NSH were extracted from the REDCap

database into Microsoft Excel (Version 2019). Data were then transferred to the software IBM SPSS Statistics (version 23, 2015). Data were cleaned and coded to enable data analysis within this software.

### 3.5 Data Analysis

To establish if data were normally distributed, Shapiro-Wilk tests were performed and the p-value analysed. If the p-value was above 0.05, data were considered to be normally distributed. Descriptive results are presented in terms of mean (SD) or median (IQR, range) where data was skewed for continuous variables, counts are reported for categorical variables. As proportions and counts were exactly equal (i.e., n=100), either counts or proportions are presented throughout. As the primary outcome of interest had very low occurrences (n=4) no statistical testing was undertaken to examine bivariate associations, however, non-parametric (Mann Whitney U) testing was undertaken to compare the differences in LOS between those who did and did not develop a PPC.

### 3.6 Ethics

Ethics approval was received from the New Zealand Health and Disability Ethics Committee for all New Zealand centers' participation in the CHESTY study; reference 17/NTA/97, September 2017 (Appendix C). Locality approval for NSH was granted from WDHB's Awhina Research and Knowledge center in October 2017. The need for participant consent was waived as there was no divergence from each site's usual care. No extra-ordinary assessments or treatments were performed for this study outside of the usual care.

## Chapter Four: Results

This chapter presents the results from the data collected at NSH between June and October 2018. As determined a priori, data were collected on 100 consecutive participants.

### 4.1 Details of the Cohort

The mean age of participants was 60 years (SD 15.5), with a similar number of males (46%) to females (56%). The largest ethnic group was European, comprising 72% of the cohort. Participant demographic data are presented in Table 1 (p.20), and the surgical characteristics of participants are presented in Table 2 (p. 21), including comparison between participants who did and did not present with a PPC.

The majority of surgeries undertaken were upper abdominal operations (85%), with 41% of participants having an open laparotomy. The largest groups by surgical type were participants undergoing colorectal surgery (55%) and upper gastrointestinal surgery (37%). The majority of surgeries were elective (65%). The operation duration ranged from 1 hour 35 minutes to 8 hours 50 minutes. There were 19 participants admitted to ICU throughout the study; of these, 11 were unplanned admissions of which two developed a PPC. None of the admissions to ICU were due to PPCs.

The majority of participants were discharged from hospital to their home following surgery (94%), while two were discharged to other hospitals as they were admitted to NSH for the surgical expertise, despite living outside the usual catchment area. Rehabilitation as an inpatient was needed for three participants due to prolonged immobility. There was one death during the study period due to pre-existing comorbidities and surgical complications following a bowel obstruction.

Table 1. *Demographic/Participant Characteristics*

Participant Characteristics	All Participants (%) (n=100)	PPC (%) (n=4)	Non-PPC (%) (n=96)
<b>Age in years Mean (SD)</b>	60.6 (15.5)	67 (12.03)	60.38 (30.23)
<b>Gender (n)</b>			
Male	46	1	45
Female	54	3	51
<b>Ethnicity (n)</b>			
European	72	2	70
Asian	11	1	10
Māori	7	1	6
Pacific Islander/Oceania	5	0	5
Other	5	0	5
<b>BMI Median (IQR, range)</b>	28.1 (IQR 12.8, range 17.9-54.24)	26.7 (IQR 10.8 range 19.6-32.9)	28.2 (IQR 13.0 range 17.9-54.2)
<b>ASA score (n)</b>			
1	4	0	4
2	51	1	50
3	43	1	42
4	2	2	0
<b>Smoking history (n)</b>			
No	53	2	51
Yes	47	2	45
Current smoker	8	0	8
<b>Respiratory comorbidity present (n)</b>			
Asthma	6	1	5
COPD/ILD/Other	9	0	9
<b>Other comorbidities present (n)</b>			
Cancer in last 2 years	42	3	39
Neurological/CVA/MND/other)	9	0	9
Musculoskeletal (OA/back pain)	24	0	24
Cardiac Disease (CCF)	3	0	3
NSTEMI/AMI	3	0	3
Angina/CAD	6	1	5
Diabetes	14	1	13
Anxiety/ depression	10	0	10
No comorbidities	10	0	10

*Note:* ASA - American Society of Anaesthesiologists score; BMI – body mass index; CAD – coronary artery disease; CCF– congestive cardiac failure; COPD – chronic obstructive pulmonary disease; CVA – cerebral vascular accident; ILD – interstitial lung disease; MND – motor neurone disease. OA – osteoarthritis



Table 2. *Surgical/Operative Characteristics*

<b>Surgical Characteristics</b>	<b>All Participants (%) (n=100)</b>	<b>PPC (%) (n=4)</b>	<b>Non-PPC (%) (n=96)</b>
<b>Surgical urgency (n)</b>			
Elective	65	1	64
Emergency*	33	2	31
Expedited*	2	1	1
<b>Type of operation (n)</b>			
Renal	7	0	7
Colorectal	55	2	53
Urology	1	0	1
UGI	37	2	35
<b>Surgical quadrant (n)</b>			
Upper abdominal	85	4	81
Lower abdominal	15	0	15
<b>Incision (n)</b>			
Laparotomy	41	3	38
Laparoscopic	45	1	44
Laparoscopic-assisted	14	0	14
<b>Operation time (n)</b>			
1.5-3 hours	41	1	40
3-5 hours	36	1	35
5-7 hours	19	2	17
7+ hours	4	0	4
<b>Epidural post-op (n)</b>	17	1	16
<b>ICU/HDU admission (n)</b>	19	3	16
<b>ICU/HDU Unplanned admission (n)</b>	11	2	9
<b>ICU length of stay, mean (SD)</b>	1.68 (1.10)	1 (.00)	1.81 (1.167)
<b>Total post-operative hospital length of stay, median (IQR, range)</b>	6.0 (IQR 6.0, range 2.0-30.0)	20.0 (IQR 18.0, range 11.0-29.0)	6.0 (IQR 5.0 range 2.0-30.0)
<b>Discharge destination (n)</b>			
Home	94	3	91
Other hospital	2	0	3
Rehabilitation facility	3	1	3
Death	1	0	1

Note: ICU/HDU – intensive care unit/ high dependency unit; UGI – upper gastrointestinal

\*Emergency surgery refers to unplanned operations following an urgent admission, expedited surgery refers to when planned surgery is performed sooner than expected due to deterioration or acute admission

## 4.2 Primary Outcome: Post-Operative Pulmonary Complications

Of the 100 study participants, four developed PPCs. The characteristics of these participants are detailed in Table 3 (p. 23). Of the four participants who developed a PPC, three developed a PPC on POD2. The remaining participant developed a PPC on POD7; however, this was following a return to theatre and thus was POD1 for a subsequent surgery. All participants presenting with a PPC had undergone upper abdominal surgery and the incision type was via open laparotomy in the three of the four participants.



Of the four participants that developed a PPC, three required an ICU admission from theatre, two (50%) of which were unplanned due to hypotension post-operatively. One participant who required admission to ICU needed inpatient rehabilitation prior to discharge to improve mobility and exercise tolerance. None of the admissions to ICU were due to a respiratory problem and all four of the unplanned admissions to ICU were discharged to their usual home.

Whilst there were four participants that presented with a score of four on the MGS, only a further seven presented with a score of three on the MGS, with all other participants presenting with a score of two or less. This shows the low number of participants that were close to being diagnosed with a PPC (which requires a score of four), indicating there were few participants that had respiratory concerns.

Table 3. *Profile of Participants Who Developed a PPC*

Characteristic	Participant no. 38	Participant no. 68	Participant no. 85	Participant no. 99 Recorded after initial operation
<b>Age in years</b>	74	72	73	49
<b>Gender</b>	Female	Female	Female	Male
<b>Ethnicity</b>	European	European	Māori	Asian
<b>BMI</b>	20 Normal	25 Overweight	33 Obese	28 Overweight
<b>ASA score</b>	4E	4	3	2E
<b>Smoking history</b>	Non-smoker	Ex-smoker	Non-smoker	Ex-smoker
<b>Comorbidities</b>	Angina/CAD	Cancer, Asthma	Cancer, Diabetes	Cancer
<b>Surgical urgency</b>	Emergency	Emergency	Elective	Expedited
<b>Type of operation</b>	Bowel resection, washout	Formation of sigmoid colostomy	Liver resection, partial gastrectomy	Subtotal gastrectomy
<b>Operation indication</b>	Terminal ileal perforation and collection	Palliative decompression of ileum	Cancer	Cancer – expedited due to perforation during gastroscopy
<b>Surgical quadrant</b>	Upper abdominal	Upper abdominal	Upper abdominal	Upper Abdominal
<b>Incision</b>	Open Laparotomy	Open Laparotomy	Laparoscopic	Open Laparotomy
<b>Operation time</b>	3 hours, 47 minutes	2 hours, 5 minutes	6 hours, 5 minutes	5 hours, 27 minutes
<b>Epidural post-op</b>	No	No	No	Yes
<b>Day developed PPC according to MGS scoring</b>	Day 1	Day of surgery	Day 2	Day 6 (Day 1 post second surgery)
<b>Attended Pre- operative PT Clinic</b>	No	No	No	No
<b>1<sup>st</sup> PT assessment</b>	POD1	Pre-op (inpatient)	None	POD1
<b>Day first mobilised &gt;10m with PT</b>	1	Day 5	None	Not mobilised with PT during hospital stay
<b>PT input</b>	Education, Deep breathing, mobility	Mobility, ACBT Deep breathing	None	Deep breathing, ACBT, education
<b>ICU/HDU admission</b>	Yes – unplanned from theatre due to hypotension	Yes – unplanned from theatre Due to hypotension	No	Yes – unplanned Day 6 following second surgery
<b>ICU length of stay</b>	1 Day	2 Days	0 Days	1 Day
<b>Post-operative length of stay</b>	16 Days	21 Days	30 Days	32 Days
<b>Discharge destination</b>	Home	Rehabilitation	Home	Home
<b>NOTES:</b>	No PT POD2&3 (weekend) No PT day 4	Pre-op pneumonia Declined mobility POD1&4		Day 6: Returned to surgery for washout due to anastomotic leak, then transferred to HDU from theatre

*Note:* ACBT – Active cycle of breathing technique; ASA - American Society of Anaesthesiologists score; BMI – body mass index; CAD – Coronary artery disease; ICU/HDU – intensive care unit/ high dependency unit; POD – Post-operative day; PT – Physiotherapist

### 4.3 Secondary Outcome: Pneumonia

All participants presenting with a PPC were diagnosed with pneumonia according to the pneumonia criteria used for this study (see section 3.3.6b). There were no additional participants who presented with pneumonia as per the study definition.

### 4.4 Length of Stay

The total median, (IQR / range) post-operative LOS was 6 days (6.0/ 2.0-30.0).

The LOS by participant and surgical characteristics is reported in Table 4 (p. 25) and has been calculated from the day of the operation to the day the participant was discharged from acute care at NSH to home, a rehabilitation facility or another hospital.

Three participants were transferred from acute care to rehabilitation facilities, and two participants were transferred to another hospital. The participants who went to a rehabilitation facility had a total post-operative hospital LOS (including acute admission and rehabilitation) of 85 days, 39 days and 21 days respectively. The two participants who were transferred to their local hospital, which was outside of Auckland, had a total post-operative LOS of 15 days and 10 days.

As anticipated, length of stay was increased in participants undergoing an open laparotomy, upper abdominal surgery and emergency or expedited surgery (see Table 4, p. 25). Similarly, as the length of time of the operation increased, LOS also increased (see Table 4, p. 25). Nineteen participants were admitted to the ICU/HDU; these participants had an increased LOS which can be seen in Table 4 (p.25).

There was a significant difference found in LOS between participants who did and did not develop a PPC (  $U = 30.0$ ,  $z = -2.866$ ,  $p = 0.002$ ), with the median LOS for those with a PPC being 20.0 days (18.0/ 11.0-29.0) and for those without a PPC being 6 days (5.0/ 2.0-30.0).

Table 4. *Length of Stay*

Surgical Characteristics	Post-operative length of stay* (days) Median	Interquartile range	Range
<b>Age</b>			
19-40 years (n=12)	2.5	2.5	2.0-12.0
41-65 years (n=48)	4.5	6.0	2.0-30.0
66-84 years (n=36)	7.0	5.5	3.0-29.0
85-105 years (n=4)	5.5	2.5	4.0-7.0
<b>BMI</b>			
Obese (n=42)	4.0	5.3	2.0-30.0
Overweight (n=21)	9.0	10.0	3.0-29.0
Normal (n=35)	6.0	5.0	2.0-25.0
Underweight (n=2)	6.5	0.0	6.0-7.0
<b>ASA Score</b>			
1 (n=4)	6.0	8.5	2.0-12.0
2 (n=51)	5.0	6.0	2.0-30.0
3 (n=43)	6.0	4.0	2.0-29.0
4 (n=2)	11.0	0.0	11-11.0
<b>Surgical urgency</b>			
Elective (n=65)	4.0	5.0	2.0-30.0
Emergency (n=33)	8.0	5.5	3.0-26.0
Expedited (n=2)	21.0	0.0	13.0-29.0
<b>Type of operation</b>			
Renal (n=8)	8.0	9.0	2.0-30.0
Colorectal (n=55)	6.0	5.0	2.0-26.0
UGI (n=37)	4.0	5.5	2.0-29.0
<b>Surgical quadrant</b>			
Upper abdominal (n=85)	6.0	6.0	2.0-30.0
Lower abdominal (n=15)	5.0	3.0	2.0-20.0
<b>Incision</b>			
Laparotomy (n=41)	8.0	5.0	2.0-30.0
Laparoscopic (n=45)	4.0	4.5	2.0-29.0
Laparoscopic-assisted (n=14)	4.0	3.0	2.0-11.0
<b>Operation time</b>			
1.5-3 hours (n=41)	4.0	3.0	2.0-25.0
3-5 hours (n=36)	6.0	4.8	2.0-25.0
5-7 hours (n=19)	8.0	9.0	3.0-29.0
7+ hours (n=4)	12.0	19.3	5.0-30.0
<b>PPC</b>			
No PPC (n=96)	6.0	5.0	2.0-30.0
PPC (n=4)	20.0	18.0	11.0-29.0
<b>ICU/HDU admission (n=19)</b>	11.0	13.0	3.0-30.0
Unplanned (n=11)	11.0	18.0	6.0-29.0
Planned (n=8)	9.5	8.5	3.0-30.0

*Note:* \*post-operative length of stay is from the operation date to the acute discharge date to home, rehabilitation or another hospital.

#### 4.5 Details of Respiratory Physiotherapy Intervention

Respiratory physiotherapy interventions were always provided by a qualified physiotherapist, details of which can be viewed in Table 5 (p. 27). Pre-operative respiratory physiotherapy was provided to 2% of participants. One participant was seen by a physiotherapist on the day of surgery due to a pre-operative pneumonia and was taught ACBT for airway clearance and inspiratory holds. Respiratory physiotherapy was provided for two participants on POD0, which is not usual practice at NSH, but was most commonly provided on POD1 and POD2. On POD1, 34% of participants had respiratory physiotherapy interventions provided; of which the majority had surgery via an open laparotomy. Only 4% of participants undergoing laparoscopic or laparoscopic assisted surgery were deemed to require respiratory physiotherapy interventions at this time. All of the participants that had respiratory education, which involved verbally reminding participants why and how to correctly perform deep breathing exercises and mobilisation. On POD2, 18% of participants were seen by a physiotherapist for respiratory interventions, of whom 17% had undergone open laparotomies. Deep breathing exercises and respiratory education were the most common treatment options used overall on POD2. The total number of respiratory physiotherapy sessions varied between 0 and 6 per participant during the study period. The type and number of respiratory physiotherapy interventions per day are recorded in Table 5 (p. 27). Overall, 45% of all participants admitted for surgery had some sort of respiratory intervention with 43% of these being administered post-operatively.

Table 5. *Physiotherapy Respiratory Input by Day*

Respiratory Intervention	Pre-op n (%)	Day of surgery n (%)	POD1 n (%)	POD2 n (%)	POD3 n (%)	POD4 n (%)	POD5 n (%)	POD6 n (%)	POD7 n (%)
Respiratory Education	2	2	34	16	10	4	4	5	1
DB & C	0	1	20	10	5	2	5	4	1
ACBT	0	0	1	2	2	0	0	1	0
Inspiratory Holds	0	0	1	1	0	0	0	0	0
Total number of participants seen by PT/POD for respiratory interventions	2	1	34	18	11	5	7	6	1
Total number of participants seeing PT for first respiratory intervention/POD	2	1	34	6	1	0	0	1	0
<p><i>Note:</i> ACBT – Active cycle of breathing technique; DB &amp; C – Deep breathing and coughing; PT – Physiotherapist; POD – Post-operative day.  <b>Respiratory interventions listed in study and available at NSH but not utilised:</b> Airway recruitment; Bubble positive expiratory pressure (PEP); Cough assist machine; Hyperinflation via a ventilator or manually; Incentive spirometry; Intermittent positive pressure ventilation (IPPV); Manual techniques; Postural drainage/positioning for ventilation; Suctioning; Tubing/oscillating/non-oscillating PEP</p>									

## 4.6 Details of Rehabilitation Physiotherapy Intervention

A range of post-operative rehabilitation interventions were undertaken during the study period, the details of which can be viewed in Table 6 (p. 29). In total 37% of participants undergoing abdominal surgery required physiotherapy for rehabilitation interventions. Documentation of 'Education (general advice)' was deemed to refer to reminding or instructing participants about the role of physiotherapy and the benefits of mobilisation and exercise. 'Education (mobilisation)' was documented when the importance of mobilisation was specifically discussed with the participant. The majority of participants (63%) were deemed not to require physiotherapy input to assist with mobilisation post-operatively, however, the mobilisation interventions, when utilised by physiotherapists, varied from sitting on the edge of the bed, transferring into a chair, or walking with assistance/supervision.

Importantly, there were no adverse events reported during physiotherapy mobilisation interventions but rehabilitation was stopped once during the study due to a participant being too drowsy to continue following a post-operative stroke. The number of participants that ambulated with a physiotherapist on each post-operative day is displayed in Table 6 (p. 29). Rehabilitation was declined by participants on 12 occasions during the study, the reasons for this was not documented as it was not included as a data point in the audit.

## 4.7 Risk Factors

Due to the small number of PPCs in this study no inferences could be made regarding risk factors for the development of PPC's. It is anticipated that results from the wider CHESTY study will be able to provide more insight into the identification of risk factors in this population.

Table 6. *Physiotherapy Rehabilitation Input by Day*

Rehabilitation Intervention	Pre-op n (%)	Day of surgery n (%)	POD1 n (%)	POD2 n (%)	POD3 n (%)	POD4 n (%)	POD5 n (%)	POD6 n (%)	POD7 n (%)
Education - general advice	1	1	12	6	3	1	2	1	1
Education - early mobilisation	1	1	19	6	3	2	1	2	1
Ambulation assist or supervision	0	0	14	20	13	5	6	11	4
Supervised exercise therapy	0	0	0	0	0	0	2	0	0
Active assisted exercises	1	0	2	3	2	0	0	0	0
Passive range of motion exercises	0	0	0	0	0	0	1	0	0
SOEOB	0	0	7	4	1	1	2	1	0
Chair exercises	0	0	0	1	0	0	0	0	0
Sit to stand exercises	0	0	4	2	0	2	0	0	0
Marching on the spot	0	0	3	2	2	1	1	1	0



Rehabilitation Intervention	Pre-op n (%)	Day of surgery n (%)	POD1 n (%)	POD2 n (%)	POD3 n (%)	POD4 n (%)	POD5 n (%)	POD6 n (%)	POD7 n (%)
Transfer to chair	0	0	3	1	1	0	0	0	0
Stairs assessment	0	0	0	0	0	0	0	1	0
Participant declined input	0	0	2	0	1	1	4	3	1
Total number of participants mobilised with PT on each POD for rehabilitation	0	0	14	13	3	4	2	1	0
Total number of participants seen (Initial and follow ups combined) on each POD for rehabilitation	2	1	31	24	18	10	12	14	7
Provider	PT	PT	PT	PT	PT	PT	PT	PT	PT

*Note:* Exs – Exercises; Mob – Mobilised; Pt – Participant; PT – Physiotherapist; SOEOB – Sitting on edge of bed; Sup – Supervised; Rehab – Rehabilitation  
Physiotherapy assistants were not utilised during the study period

## Chapter Five: Discussion

### 5.1 Discussion

This chapter offers an analysis of the results presented in Chapter Four and considers the main aims of the study. These aims were to investigate the following in patients undergoing abdominal surgery at NSH; the prevalence of PPCs, the LOS following abdominal surgery, individual and surgical demographics of patients undergoing abdominal surgery, audit physiotherapy practice and identify any factors which may predict risk associated with the development of PPCs. The results and analysis will be compared to current evidence where possible.

The results from the current study show a PPC prevalence of 4%. A previous study (Boden et al., 2018) conducted in a higher risk population but at the same centre (NSH) showed a PPC prevalence of 10%. The difference between the prevalence in these two studies can likely be explained by the difference in population (whereby in the current study both low and high-risk participants were included) and in the study methodology, where Boden et al., (2018) used a more rigorous RCT design. Nonetheless, overall these two studies demonstrate that NSH has a low rate of PPCs compared with other studies, some of which have found PPC rates of up to 42% (Fernandes-Bustamante et al., 2017; Haines et al., 2013; Hemmes et al., 2014; Neto et al., 2014; Parry et al., 2014; Scholes et al., 2014).

The consistently low PPC rate at NSH raises the question of what is different between NSH and centres involved in other studies. One factor impacting upon the current study might be the lack of high-risk surgeries during the data collection period as, unpredictably during the time of data collection, a national nursing strike in New Zealand was undertaken resulting in fewer high-risk surgeries being performed during this time. As data collection for other centres involved in the CHESTY study has occurred at a time convenient to each centre, it is likely that other centres have not encountered the same alterations to their surgical routines. A further factor that may explain the difference in PPC rate between our centre and that of others may be the wide use of Enhanced Recovery After Surgery (ERAS) protocols for patients undergoing abdominal surgery at NSH. This, together with the nursing strike during data collection may explain the large number of (lower risk) laparoscopic and laparoscopic assisted operations compared to open laparotomy, whereby the higher

risk surgeries were cancelled and more laparoscopic surgeries undertaken instead. Enhanced Recovery After Surgery protocols include pre-, peri-, and post-operative procedures to reduce complications by preserving pre-operative organ function and alleviating the stress response on the body peri-operatively (Fearon et al., 2005). Protocols within ERAS programmes reduce prolonged periods nil by mouth pre-operatively and optimise nutrition and hydration post-operatively. Of particular relevance to physiotherapists, these protocols include ambulation targets for distance and frequency of mobilisation (Rawlinson, Kang, Evans, & Khanna, 2011). The change to more minimally invasive incisions and the implementation of ERAS protocols have been clearly demonstrated to reduce post-operative LOS and complications (Gustafsson et al., 2019; Melnyk, Casey, Black, & Koupparis, 2011). In the current study, colorectal surgery was the most common surgery performed, making up 55% of the cohort. It is usual that most of these participants would be treated under the ERAS protocol, which could account for our low PPC rate, however; unfortunately, the use of ERAS protocols for participants was not documented as part of this study and therefore the impact of ERAS protocols on outcomes cannot be specifically accounted for.

A further factor likely to influence the prevalence of PPCs in our observational study was the necessity to use the inclusion criteria for the CHESTY study as predetermined by the Chesty Steering Group. Patients undergoing laparoscopic surgery do not routinely receive physiotherapy input at our centre as they are considered low risk, for example laparoscopic bariatric surgery. Some literature suggests the PPC rate in those undergoing laparoscopic bariatric surgery to be less than 1.6% (Antoniou et al., 2005; Gupta et al., 2012), yet laparoscopic bariatric surgery made up 18% of our cohort. These patients are only seen by a physiotherapist if they develop a respiratory complication or if there are mobility concerns. Reasons for including such patients in the wider CHESTY study are to get more contemporary data on the prevalence of PPCs and other outcomes as surgery and surgical management continues to change. Indeed, open laparotomy was performed in only 41% of the participants in our study with the majority of our participants undergoing laparoscopic surgery. None of the participants undergoing laparoscopic surgery developed a PPC which appears to validate our ongoing decisions to not focus on these patients following surgery unless a PPC has developed or risk of likelihood of a PPC increases. It is possible that the PPC

prevalence determined at our centre may alter if data collection was repeated with an 'at risk' population or in those undergoing higher risk surgery. Comparing the NSH results with the results of the wider CHESTY centres will allow for comparison of groups with specific demographic factors e.g. those with COPD and in those undergoing specific surgical procedures. This will allow for identification of those who do and do not require routine physiotherapy and allow us to determine where physiotherapy resources could be allocated to best effect in our centre.

In regard to specific physiotherapy interventions, the results from this audit have shown that few participants received any form of preoperative physiotherapy. This is surprising given the results of the recent LIPPSMACK POP study which was partially undertaken at our centre (Boden et al., 2018). The LIPPSMACK POP study showed that a single one-off preoperative physiotherapy intervention aimed at education in regards to early post-operative respiratory and rehabilitation interventions halved the rate of post-operative complications and was highly cost effective (Boden et al., 2015; Boden et al., 2020). Nonetheless, preoperative physiotherapy appears not to be standard practice in NZ (Reeve et al., 2019) including at NSH where only 2% of the participants in this study received preoperative interventions. Reeve et al.'s 2019 survey of NZ surgical centres also demonstrated that the most common physiotherapy interventions implemented following abdominal surgery are deep breathing exercises and mobilisation (Reeve et al., 2019). Our study shows that the types of post-operative respiratory and rehabilitation interventions used by physiotherapists at NSH reflects current practice seen across most NZ surgical centres. The physiotherapy interventions undertaken during this study were predominantly focussed on educating the participant post-operatively about the importance of undertaking regular breathing exercises and mobilisation, as well as implementing these interventions early in the post-operative period where necessary. Mobilisation after surgery is thought to reduce PPCs and other complications although few studies have considered mobilisation in isolation and evidence is scant to guide clinicians in specific mobilisation interventions to improve outcomes. Our study showed that 63% of participants were deemed not to require physiotherapy input to assist with mobilisation post-operatively. The small number of participants that ambulated with physiotherapy could be a reflection of the higher percentage (59%) of participants that underwent laparoscopic surgery and are therefore not usually seen by a physiotherapist. One limitation of our study was

that interventions by other members of the health care team were not documented and this may have impacted upon the study findings; for example, achievement of mobilisation targets with staff other than physiotherapy may have occurred but was not documented.

The median post-operative LOS in our study (6 days) was comparable to other similar studies (Boden et al., 2018; Haines et al., 2013) and, as with other studies, the LOS was significantly greater for those participants who developed a PPC. (Boden et al., 2015; Smetana et al., 2006). Increased LOS is frequently used as an outcome measure in studies of this type but it is imperative to consider that LOS is impacted upon by many factors not all of which are amenable to physiotherapy interventions. In this study, complications that are amenable to physiotherapy were audited however many others complications that could increase LOS were omitted due to the amount of data being collected. Currently a number of physiotherapy studies are investigating the use of 'readiness to discharge from physiotherapy' as a more sensitive tool to determine the impact of physiotherapy on LOS and in any similar studies consideration of such a tool alongside LOS may be useful.

In this study, the MGS was chosen as the diagnostic tool for the primary outcome (PPC) as it was designed by physiotherapists to diagnose PPCs that are specifically amenable to physiotherapy interventions and has been used extensively in research studies by physiotherapists since this time (Agostini, 2011; Boden et al., 2018; Haines et al, 2013; Parry et al., 2014; Scholes et al., 2009;). This tool is not widely used by other health professionals and the data required to effectively use this tool relies heavily on documentation made by surgical teams and nursing staff. The reliance on other health professionals not involved in a study may have altered the availability and interpretation of results. Additionally, the reliability of any documentation by other health professionals during this study was unable to be accounted for; for example, if a change in respiratory status is mild and does not significantly alter the course of treatment (e.g., antibiotics or oxygen therapy are not required), it may not be documented at all. Even though the utilisation of tests such as sputum culture, chest x-rays, auscultation or blood tests reflect usual participant care, these are not normally carried out on a daily basis, yet are required by the MGS for daily PPC diagnosis. As such, there was a large amount of missing data where such tests were not conducted daily (these can be assumed 'missing not at

random'). Nonetheless, the REDCap software utilised for data analysis uses each daily data point to diagnose whether a PPC has occurred, thus if no data were recorded, then results are assumed to be negative. Potentially this could result in an underreporting of PPC rate for this study. For example, auscultation findings are commonly uncompleted by both doctors and/ or nurses and during this study this resulted in a large proportion of this data point being unrecorded. Whilst it is likely that this lack of recording reflects the clinical status of the participant i.e. that a well participant does not require a battery of clinical tests if clinical status remains well, the lack of rigour of some data points may explain our low PPC rate, although it is likely that this would have been exposed by other means such as referral by the medical team to physiotherapy for interventions associated with the onset of PPCs.

The audit style data collection sheet used during this study was predetermined as part of the wider CHESTY study. This meant that no additional data were collected particularly in regards to explanations for rationale of treatment interventions utilised, or the reasons for no physiotherapy input when this would normally be expected (for example pre-operatively). The physiotherapy interventions in the study were collected on a tick box hard copy sheet, which did not allow for more specific information that might be have been useful for audit purposes for example; the distance and frequency mobilised, by whom, and other health care professionals input into mobilisation interventions. Furthermore, during the current study, the experience level of the treating physiotherapist was not collected and this has been shown to impact upon patient outcomes in this population (Boden et al., 2018). Knowing the experience level of the attending physiotherapist may have been useful to determine the impact of this on some of the outcomes of this study.

Some further limitations of this small single centre audit highlight the need for a larger sample size over a greater time period to ensure data are an accurate reflection of patient and surgical demographics at our specific centre. Some of these limitations will be overcome by this study being nested within a much larger study which will allow for comparison of outcomes and interventions both within New Zealand and internationally. Our sample size of 100 participants and the time allocated to data collection was identified a priori and, as discussed, the limitations imposed by an unplanned nursing strike may have influenced the results of this study. Nonetheless, our results provide a starting point and highlights key areas that could be considered when conducting future audits to provide more useful

information. These include factors such as a need for more specific information in regards to interventions by physiotherapists, other team members and of the barriers to physiotherapy intervention.

## 5.2 Recommendations for Clinical Practice and Research

Conducting this study has highlighted to the author the importance of regular audits to objectively and accurately outline service delivery and outcomes associated with this. This study has given NSH the tools required to do so; however, it is evident when looking at some of the limitations of the study that additional data collection is required; such as obtaining more specific details (ambulation distance and intensity, level of staff member involved, barriers encountered to physiotherapy interventions) relating to interventions and the experience level of staff. This project has demonstrated an unusually low rate of PPCs in our centre compared to many other studies but a similar rate to that observed during the LIPPSMack-POP study also conducted at our centre; this provides some assurance that the current NSH physiotherapy service is appropriate and targets those most at risk and supports the current physiotherapy protocol at NSH of not routinely seeing patients with uncomplicated surgery.

Conversely, the study results showing a low rate of PPCs in our centre indicate that we could be seeing patients that do not require our input, utilising costly resources which might be better targeted elsewhere. Reviewing the results from the wider CHESTY trial may enable us to review our physiotherapy protocols further, consider our risk stratification and prioritise identifying at risk patients requiring physiotherapy input more accurately. Concerningly, this study identified that the protocols put into place for provision of pre-operative physiotherapy following the completion of the LIPPSMack-POP study and its findings are not being followed. The reasons for this should be investigated and a further audit undertaken to assess whether current practice is compliant with the protocol already in place.

The analysis of the wider CHESTY study with the data collected from the international centres, and with that from other New Zealand centres, will provide more information to address the aims of this study with a larger cohort. Due to the limitations of the small cohort, and the subsequent inability to determine specific risk factors for NSH patients, further research in a larger, more specific cohort at NSH

may be required. The author recommends that data collection is repeated at NSH with a larger sample size and a tailored data sheet, which includes details such as mobilisation distance, intensity, and barriers.



## Chapter Six: Conclusion

This project was designed to investigate the PPC incidence and length of stay, gather patient and surgical demographic data, audit physiotherapy service input and determine risk factors that contribute towards the development of PPCs following abdominal surgery at NSH. As this is a nested study within a wider study (CHESTY), where only the wider dataset will be analysed (i.e., no individual site data will be analysed); there was a need to undertake this investigation into NSH's data. Our study results demonstrate that we have a much lower PPC rate than that reported elsewhere. Our results also show that whilst specific physiotherapy interventions are similar to those found elsewhere in NZ, that there is limited physiotherapy input for surgical patients which does not reflect expected practice at NSH, or the usual physiotherapy practice provided throughout Australia and New Zealand. In part this may be due to the lower risk profile of participants during the period of the data collection for this study. The larger, international, multi-centre study will have a sample size of over 3000 participants, including multiple surgical centres and various surgical cohorts which will enable our centre to compare its attendances, interventions and outcomes with those of other centres. The extent of the data completed for the CHESTY study should reduce some of the limitations from the current study at NSH and, at a future point, NSH can compare its results with other New Zealand data collected for the wider study. This will enable the physiotherapy department at NSH to compare its PPC prevalence and physiotherapy/surgical policies and consider any further necessary changes to physiotherapy service provision.

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## Appendices

### Appendix A: The CHESTY Study

The CHEST infection prevalence following surgery study is a large international, multi-centre observational research study conducted through the University of Melbourne. This study was designed to determine the incidence of PPCs utilising standardised diagnostic criteria following major non-orthopaedic surgery for the first seven days post-operatively. The secondary aims where are as follows:

- Determine the incidence of Pneumonia, systemic inflammatory response syndrome (SIRS), sepsis, ICU LOS, unplanned ICU readmission rates, reintubation rates, hospital LOS, and in-hospital mortality.
- Audit physiotherapy service delivery to identify current practice
- Investigate associative relationships between causative factors and preventative physiotherapy for PPCs.
- To develop models to predict risk factors for PPCs within different surgical groups.

Thirty international centres were involved in collecting data in a sample size of over 6000 participants from 356 centres across Australia, New Zealand, UK, USA, Canada, Malaysia, and Singapore. Data collection started in April 2017 and is still ongoing at the time of writing. For feasibility purposes in this study the participating sites were able to pre-specify a particular surgical cohort (e.g., abdominal surgery) or location (e.g., ICU or ward) on which to focus data collection over a pre-specified time frame (e.g., 4 weeks) or to a priori sample size (e.g., 100). There are four sites within New Zealand taking part in the study, with an estimated 800 participants.

## Appendix B: Data Fields

Data will be collected from the anaesthetic record, operation notes and medical records

Data collected	Notes
Patient age	
Gender	
Weight	
Height	
Documentation of specified co-morbidities	Respiratory conditions (e.g. Asthma, COPD, ARDS, chronic respiratory diagnosis) Ischemic Heart Disease (e.g. Angina, Heart Attack) Congestive cardiac failure/disease Neurological disease including stroke/TIA/Parkinsons/any type of neuromuscular disease Diabetes (type 1 or 2) Upper GI disease (e.g. reflux, cystitis, ulcers) Cancer diagnosis within past 2 years
Day of surgery	
Type of surgery	
Reason for surgery	
Emergency or elective surgery	
Incision type and location	
Reason for surgery	
Duration of anaesthesia	Recorded in minutes
Intraoperative mechanical ventilation parameters and peak end expiratory pressure	
Average intra-operative FiO <sub>2</sub> delivery	
Total amount of intra-operative fluid delivered	Recorded in millilitres (ml)
Numbers of intra-operative blood transfusion units	
Post-operative location	ICU, surgical ward, other
Duration in days at each location	
Hours of post-operative invasive mechanical ventilation	
Hours and type of non-invasive ventilation use	
Days and types of oxygen therapy use	
Days of nasogastric tube insertion	
Epidural use in the first three post-operative days	

Unplanned ICU readmission	
Mechanical ventilation re-intubation rates	
Total hospital length of stay LOS including sub-acute rehabilitation if required.	
In-hospital mortality during the initial episode of care	

**The following data was collected from all patient's medical notes, laboratory or radiology reports**

**Post-operative day one is considered as midnight on the day of surgery to 2400 that day**

**If a data field was not measured routinely, this is recorded as missing**

Minimum systolic blood pressure	
Maximum oral or tympanic temperature	
Maximum heart rate	
Maximum respiratory rate	
Any documentation of shortness of breath at rest	
Any documentation of altered mentation	Confusion, delirium, drowsiness
Auscultation assessment	
Cough/sputum	Any indication of sputum documented, including darkest colour recorded
Chest X-ray report	Documenting collapse, consolidation, infiltrates

**The following data was only collected for those patients admitted to ICU/HDU**

Maximum FiO <sub>2</sub> of inspired gas	
Minimum PaO <sub>2</sub> as measured from an arterial blood gas assessment	
Minimum mean arterial blood pressure	
Vasopressor usage and dosage	
Minimum Platelet level (x10 <sup>3</sup> /μL)	
Maximum Bilirubin level (mg/dL or μmol/L)	
Maximum Creatinine level (mg/dL or μmol/L)	
Minimum urine output (mL/d)	
Maximum white cell count (WCC), or the minimum when the WCC is <4	
Minimum Glasgow Coma Scale	

Physiotherapy input will be recorded for any of the following therapies that have been provided as part of standard care:

- Pre-operative physiotherapy

- Post-operative respiratory physiotherapy interventions
- Respiratory exercises
- Use of incentive spirometers or positive expiratory pressure devices
- Non-invasive pressure breathing
- Manual hyperinflation
- Ventilator hyperinflation
- Use of a cough assist
- A section to record any other input
- Number of physiotherapy sessions, including day of the week/post-operative day
- Patient ambulated greater than one minute until ten minutes achieved
- Profession that provided early ambulation (i.e. physiotherapist, nursing staff, physiotherapy assistant, nursing assistant)

## Appendix C: Ethics Approval

**Health and Disability Ethics Committees**

Ministry of Health  
133 Molesworth Street  
PO Box 5013  
Wellington

0800 4 ETHICS  
hdec@hdec.org.nz

13 June 2017

Dr Julie Reeve

Dear Dr Reeve

Re:	<b>Ethics ref:</b>	<b>17/NTA/97</b>
	Study title:	CHESTY (CHEST infection prevalence after surgery); a multi-centre observational trial.

I am pleased to advise that this application has been approved by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

**Conditions of HDEC approval**

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

**After HDEC review**

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

Your **next progress report** is due by **12 June 2018**.

**Participant access to ACC**

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

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Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'B J Fergus', with a horizontal line underneath.

Dr Brian Fergus  
Chairperson  
Northern A Health and Disability Ethics Committee