Development of an international risk-stratified pressure injury prevention bundle for intensive care

Submitted by

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RN BN (Hons)

A thesis submitted in total fulfilment of the requirements of the degree of

Doctor of Philosophy

School of Nursing, Midwifery & Paramedicine (Brisbane)

Faculty of Health Sciences

Australian Catholic University

September 2022

Declaration

This thesis contains no material that has been extracted in whole or in part from a thesis that I have submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person's work has been used without due acknowledgment in the main text of the thesis.

All research procedures reported in the thesis received the approval of the relevant Ethics/Safety Committees (where required).

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THESIS PART ONE: PHASE ONE

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Lovegrove, J., Fulbrook, P., Miles, S., Steele, M., Liu, X., Zhang, L. & Cobos Vargas, A. (2022). Translation and piloting of the Chinese Mandarin version of an intensive care-specific pressure injury risk assessment tool (the COMHON Index). *International Journal of Nursing Sciences, 9*(2), 169-178. https://doi.org/10.1016/j.ijnss.2022.03.003

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THESIS PART FOUR: DISCUSSION AND CONCLUSION

Chapter Twelve

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Acknowledgements

I acknowledge the financial support of *The Prince Charles Hospital Foundation* through provision of a *PhD Scholarship* (reference PhD2019-01) for the duration of my PhD studies.

I gratefully acknowledge the support of the World Federation of Critical Care Nurses and its member associations and the participation of the expert critical care nurses in Phase Two of this program of research.

I acknowledge the participation of the hospital, intensive care unit and nurses and the contributions of the translators in Phase Three of this program of research. I also sincerely thank and acknowledge the contributions and support of Dr Xian-Liang Liu and Ms Lin Zhang in conducting the Phase Three studies.

Statement of Appreciation

Firstly, I would like to thank my supervisors. Their unwavering confidence in my ability to conduct this program of research has been deeply appreciated.

Specifically, my sincere thanks to Professor Paul Fulbrook (Principal Supervisor) and Dr Sandra Miles (Co-supervisor; Associate Supervisor) for their support, encouragement, and friendship, from the early days of my research experience to the completion of this thesis and beyond. To Professor Fulbrook for the opportunity to commence this program of research and for his ongoing guidance and expertise, and Dr Miles for her knowledge and guidance throughout this time.

My warm thanks to Dr Michael Steele (Assistant Supervisor; Co-supervisor), for his provision of statistical analysis expertise, guidance and support during the PhD journey. As well, my thanks to Mr Angel Cobos Vargas (Associate Supervisor) for his support and contribution to this research, along with his insights into intensive care and pressure injury risk assessment using the COMHON Index.

Loving thanks to my parents Simon and Caroline, and my brother Ben, for their continuous support and encouragement. To my dog Pepper, for her companionship and for sitting by me without fail.

And finally, my loving thanks to my husband Sam and my beloved daughters Bree and Quinn. To Sam, thank you from the bottom of my heart for your conviction in me and my ability to conduct and complete this program of research, along with your unfailing support, encouragement and patience. To my daughters, when it began, I never expected you would both arrive during this PhD journey, but I would not have had it any other way. You are the lights of my life.

Without all of you, this accomplishment would not have been possible.

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Abstract

Background

Intensive care patients are particularly vulnerable to hospital-acquired pressure injury, which is associated with significant patient harm. Pressure injury prevention begins with a risk assessment, often using a risk assessment scale; then, preventative interventions should be implemented relative to assessed risk. However, few scales are designed for intensive care and interventions are often not adequately implemented. The COMHON Index is one intensive care-specific pressure injury risk assessment scale which categorises patients as being at low, moderate or high risk, presenting an opportunity for interventions to be mandated relative to risk level in a 'minimum preventative intervention set'. This would ensure that, *at a minimum*, intensive care patients have a set of preventative interventions implemented relative to their pressure injury risk level, potentially overcoming inadequate intervention application while improving resource allocation.

Aim

The aim of this program of research was to develop a minimum set of pressure injury preventative interventions relative to pressure injury risk level, as determined by the COMHON Index, for international use within intensive care units.

Methods

A three-phase program of research was undertaken to address the overall aim.

Phase One: To identify which preventative interventions are effective in preventing pressure injury in adults admitted to acute and intensive care settings, a systematic review and meta-analysis of randomised controlled trials was undertaken across five databases. Included studies were grouped by intervention type. Studies were synthesised narratively, and random-effects meta-analysis was undertaken for homogenous interventions and data.

Phase Two: To develop international consensus about which preventative interventions should be applied relative to each COMHON Index pressure injury risk level in a minimum preventative intervention set, a modified Delphi study was conducted. Singular interventions which demonstrated effectiveness to prevent pressure injury in Phase One were considered by an expert panel (experienced intensive care nurses with expert pressure injury prevention knowledge) for inclusion in the intervention set. Consensus was developed across three rounds.

Phase Three: In preparation for future international testing of the minimum intervention set, the COMHON Index was formally translated into a very commonly used language (Chinese Mandarin)

using a four-step approach (forward-translation, back-translation, comparison of forward/back-translations, pilot testing). Pilot testing was undertaken in a Chinese intensive care unit with 20 nurses to assess instrument ease-of-use and understanding. A concurrent validity analysis was then undertaken using retrospective data comprising 80 paired COMHON Index and Braden scale patient assessments from the same intensive care unit.

Results

Phase One: Overall, 69 studies were included; 45 in an acute synthesis, and 26 in an intensive care synthesis (two in both). Intention-to-treat meta-analysis indicated that only one intervention had a significant effect to reduce pressure injury in acute (Australian medical sheepskin) and intensive care settings (prophylactic dressings: sacral and heel). However, several interventions (as listed in Phase Two results) individually demonstrated intervention effectiveness.

Phase Two: Twelve pressure injury preventative interventions were considered for inclusion by 67 panel members. Consensus indicated that all patients should receive: risk assessment within two hours of admission; eight-hourly reassessment of risk; and disposable incontinence pad use. Moderate- and high-risk patients should also receive: a reactive mattress support surface and a heel off-loading device. Additionally, high-risk patients should receive: oral nutritional supplements; preventative dressings (sacral, heel, trochanteric); an active mattress support surface; and a pressure-redistributing seating cushion. Repositioning is required ≥ four-hourly for low-risk, and ≥ two-hourly for moderate- and high-risk patients. Two interventions were discarded: medical grade sheepskin overlays and a urinary catheter care intervention.

Phase Three: Five iterations of the translation approach and two sets of original instrument amendments were required to achieve translation. Pilot testing demonstrated that the scale was easy-to-use and understand. Concurrent validity testing indicated that the sum scores of the COMHON Index and Braden scale were strongly correlated but not all subscales were correlated.

Conclusion

A minimum pressure injury preventative intervention set, which is a significant contribution to intensive care practice internationally, has been developed. Furthermore, this research has resulted in the COMHON Index being available in the three of the most commonly spoken languages worldwide. The instrument and matching preventative intervention set have promising global clinical applicability, and the potential to assist with overcoming poor preventative care. However, the minimum intervention set requires testing on an international scale.

Chapter One: Introduction and Background

1.1 Introduction

Hospital-acquired pressure injury (PI) is associated with negative consequences for the individual afflicted, including pain and decreased quality of life (Jackson *et al.*, 2017) and increased mortality (Labeau *et al.*, 2021; Song *et al.*, 2019). It continues to occur across hospital settings (Li, Lin *et al.*, 2020), with critically ill patients in intensive care units being particularly vulnerable (Coyer *et al.*, 2017; Nowicki *et al.*, 2018) due to factors associated with the seriousness of their condition and treatment intensity (Cox, 2017). While some PI are unavoidable, most are considered to be largely preventable with the use of appropriate preventative interventions (Black *et al.*, 2011; Edsberg *et al.*, 2014). When appropriate preventative measures are applied, it has been suggested that intensive care patients should be at no more risk of PI development than ward patients within hospital settings (Lahmann *et al.*, 2012). Given the association established between unavoidable PI and critical illness (Coyer *et al.*, 2017; Edsberg *et al.*, 2014) this may not be the case; however, it highlights the importance of intensive care PI prevention.

This introductory chapter first provides an overview of the theoretical background and literature surrounding PI and PI prevention overall. Following this, a more specific overview focused on hospital-acquired PI and PI prevention within intensive care is provided. A three-phase program of research comprising the examination of PI prevention within intensive care and the development of a risk-based intensive care-specific PI prevention care bundle is subsequently identified and situated against the theoretical background. Within this context, the formulation of an overarching research question, aim and objectives is presented herein. Future chapters present the individual phases of research undertaken to address the objectives developed to answer the overarching research question.

1.2 Background

1.2.1 Pressure injuries

1.2.1.1 Definition

Pressure injury is defined internationally as "localized damage to the skin and/or underlying tissues, as a result of pressure or pressure in combination with shear" (European Pressure Ulcer Advisory Panel [EPUAP] *et al.*, 2019, p. 16). Other synonymous terms for PI are used globally and include 'pressure ulcer' or 'pressure sore', 'bedsore' and 'decubitus ulcer' (EPUAP *et al.*, 2019; Gefen, Brienza *et al.*, 2022), while terms such as 'deformation injury' have also been suggested (Gefen, 2017). The term PI, however, has been used in Australia, New Zealand and parts of Asia since at least 2011 (Australian Commission on Safety & Quality in Health Care, 2011, Australian Wound Management Association, 2012). Given that PI can occur in several stages of injury, including ulcers, this term indicates that all PI present as injuries, but are not necessarily all ulcers (Edsberg *et al.*, 2016; Miles *et al.*, 2013). More recently, the term PI has been taken up in the United States of America (Edsberg, *et al.*, 2016; National Pressure Ulcer Advisory Panel [NPUAP], 2016), and is now used in the international clinical practice guideline for PI prevention and treatment (EPUAP *et al.*, 2019). As such, the term PI is used throughout this thesis.

1.2.1.2 Aetiology

By definition, PI occurs as a result of pressure (a perpendicular force), or pressure combined with shear (a parallel force) (EPUAP *et al.*, 2019). Also known as a 'mechanical load' (Coleman, Nixon *et al.*, 2014; EPUAP *et al.*, 2019; Gefen, Brienza *et al.*, 2022), such forces, when applied to an area of an individual's skin and subcutaneous tissue, have the potential to cause PI (Coleman, Nixon *et al.*, 2014; Gefen, 2018; Gefen, Brienza *et al.*, 2022; Mervis & Phillips, 2019; EPUAP *et al.*, 2019). Mechanical loading to the soft tissues may be a result of an individual's weight-bearing on a surface, such as the tissue-bearing weight at the sacrum when an individual is seated in a chair, or pressure applied to the tissue by the continuous use of an object or medical device (device- or medical device-related PI) (Gefen, 2018; Mervis & Phillips, 2019). While not specifically noted in the definition of PI, friction forces (caused by surfaces rubbing or sliding against each other) also have the potential to cause tissue deformation and contribute to PI (Gefen, 2017; Gefen, Brienza *et al.*, 2022), but other injuries caused by friction must be distinguished from PI (EPUAP *et al.*, 2019; Gefen, 2017).

These extrinsic forces cause tissue deformation, ischaemia, and subsequent necrosis, potentially culminating in PI (Gefen, 2018; Gefen, Brienza *et al.*, 2022; International Review, 2010; EPUAP *et al.*, 2019). Bony prominences, such as the sacrum or heels, are particularly vulnerable due to the pressure exerted on soft tissues compressed between the weight-bearing bony prominence and the external surface (International Review, 2010); thus, PI often occurs in these locations (EPUAP *et al.*, 2019). If PI

associated forces are removed from the tissue experiencing the insult, the damage may be reversed and PI may not develop (Gefen, 2018; International Review, 2010). Additionally, factors (outlined below in section 1.2.1.3, pp. 4, 6) such as microclimate and moisture, age and perfusion decrease the tolerance of tissues to these forces (EPUAP *et al.*, 2019; Gefen, Brienza *et al.*, 2022). If such factors are mitigated, PI may also be prevented. These are the principles behind PI prevention activities. However, tissue deformation may begin to occur within minutes of the ongoing application of these forces (Gefen, 2018; Gefen, Brienza *et al.*, 2022) and PI may develop within as little as an hour (Gefen, 2018); but it may take hours of sustained loading for deformations to be clinically visible (Gefen, Brienza *et al.*, 2022). Furthermore, the prolonged application of PI associated forces, known as 'sustained loading', may not only result in initial PI development, but may also lead to deterioration of the PI and necrosis of deeper tissues if sustained loading to the area is not relieved (Gefen, 2018; International Review, 2010; EPUAP *et al.*, 2019).

The deterioration of PI is represented by stages using a classification system (EPUAP *et al.*, 2019), although progression of a PI is not necessarily linear (Edsberg *et al.*, 2016). While there are other classification systems in use globally, the *International NPUAP/EPUAP Pressure Ulcer Classification System* (NPUAP *et al.*, 2014) is recognised internationally. It was described in the 2009 and 2014 versions of the international clinical practice guideline on PI prevention and treatment (NPUAP & EPUAP, 2009; NPUAP *et al.*, 2014), and classifies PI into six (6) stages (or categories):

- Stage I: non-blanchable erythema
- Stage II: partial thickness skin loss
- Stage III: full thickness skin loss
- Stage IV: full thickness tissue loss
- Unstageable PI: depth unknown
- Suspected Deep Tissue Injury: depth unknown.

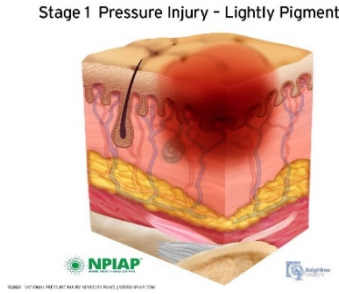
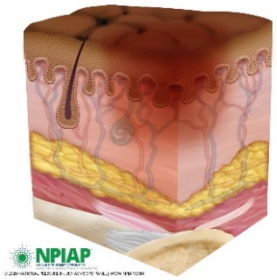
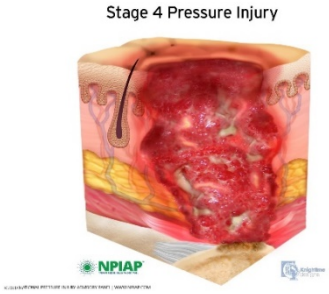
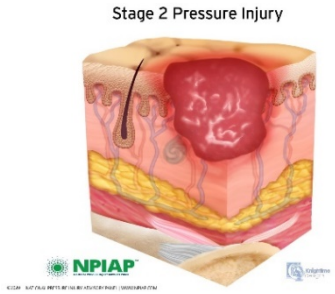
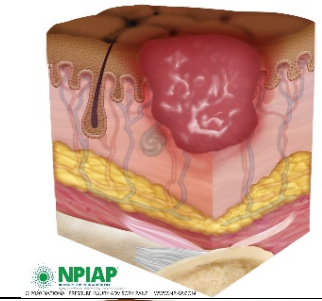
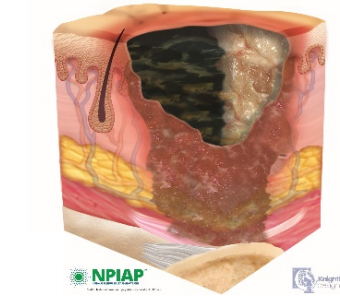
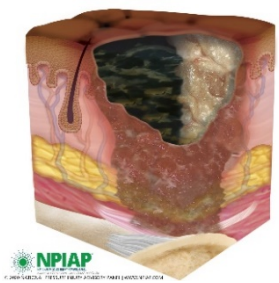
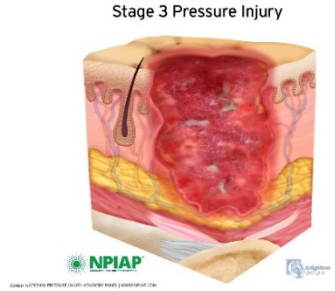
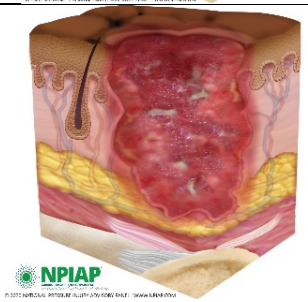
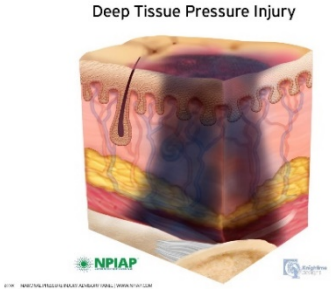
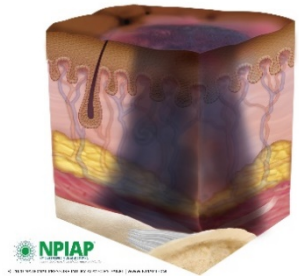
In 2016, NPUAP (now National Pressure *Injury* Advisory Panel [NPIAP]) updated their staging system (recommended for use in the United States of America), with key changes including adoption of the term PI rather than pressure ulcer and revised definitions of PI (including recognition that PI may be associated with a device, medical or otherwise) and associated stages (Edsberg *et al.*, 2016). Further changes include the use of Arabic numerals instead of Roman numerals to denote stages, and removal of the word 'suspected' from Deep Tissue Injury (Edsberg *et al.*, 2016). However, the International Guideline Development Group, which included representatives from EPUAP, Pan Pacific Pressure Injury Alliance and NPUAP, reviewed this updated staging and decided not to update the 2014 international clinical practice guideline (International Guideline Development Group, 2016). In the current 2019 guideline (EPUAP *et al.*, 2019), the 2009/2014 classification system (NPUAP & EPUAP, 2009; NPUAP *et al.*, 2014) is again detailed; however, the term PI (as opposed to pressure ulcer) is now

used, with the definition of PI updated to recognise device-related PI. Furthermore, mucous membrane PI (occurring on moist mucosal membranes which are often device related), is now distinguished from skin PI and cannot be staged (EPUAP *et al.*, 2019). National Pressure Injury Advisory Panel illustrations (NPIAP copyright, available from NPIAP website; NPIAP, 2020) of stages of PI in lightly and darkly pigmented skin are displayed in Table 1.1.

1.2.1.3 Pressure injury risk factors

While the forces discussed in section 1.2.1.2 (pp. 2-4) represent extrinsic factors associated with PI development, intrinsic risk factors also play a significant role in an individual's susceptibility to PI development (EPUAP *et al.*, 2019; Gefen, 2018; Santos *et al.*, 2018). As part of the phased (n = 5) development of a PI risk assessment instrument (the Pressure Ulcer Risk Primary or Secondary Evaluation Tool [PURPOSE-T]; Coleman, Nelson *et al.*, 2014; Coleman et al., 2016; Coleman et al., 2018) Coleman, Nixon *et al.* (2014) proposed a PI conceptual framework that recognises mechanical boundary conditions (mechanical loading forces, intensity and duration) and the susceptibility and tolerance of the individual as key determinants of PI development. PI risk factors may contribute to either or both mechanical boundary conditions (e.g. immobility) and the susceptibility and tolerance of the individual (e.g. perfusion and nutrition) (Coleman, Nixon *et al.*, 2014), and may be modifiable or non-modifiable (EPUAP *et al.*, 2019). Numerous potential PI risk factors have been identified; however, the results of studies identifying PI risk factors are often conflicting (Coleman *et al.*, 2013).

Table 1.1: National Pressure Injury Advisory Panel pressure injury staging illustrations

Stage	Lightly pigmented skin	Darkly pigmented skin	Stage	Lightly pigmented skin	Darkly pigmented skin
Stage I			Stage IV		
Stage II			Unstage-able (with slough or eschar)		
Stage III			(Suspect-ed) Deep Tissue Injury		

NPIAP = National Pressure Injury Advisory Panel
(NPIAP copyright, available from NPIAP website [https://npiap.com/page/PressureInjuryStages]; NPIAP, 2020)

Limited mobility is recognised as a primary risk factor of PI (Coleman *et al.*, 2013; Lahmann *et al.*, 2015). Usually, a person repositions themselves in response to sensory cues, such as discomfort or pain. If an individual is unable to respond to cues or unable to reposition themselves to relieve PI development-associated forces, then sustained loading to the affected area will continue (International Review, 2010). In addition to limited mobility, intrinsic factors associated with PI development include advanced age (Børsting *et al.*, 2018; Coleman *et al.*, 2013; Dreyfus *et al.*, 2018), diabetes (Børsting *et al.*, 2018; Coleman *et al.*, 2013), perfusion impairments (Coleman *et al.*, 2013), comorbidities and malnutrition (Coleman *et al.*, 2013; Dreyfus *et al.*, 2018), skin status, including pre-existing or prior PI (Coleman *et al.*, 2013; Dreyfus *et al.*, 2018), skin moisture including incontinence, and haematological factors (Coleman *et al.*, 2013). More recently, it has been found that microclimate (i.e. the temperature, humidity and airflow alongside the skin, such as between the skin and a support surface) is another indirect risk factor which may affect susceptibility of the skin and tissues to deformation and contribute to PI aetiology (Kottner *et al.*, 2018). Overall, it is not one risk factor alone which predisposes an individual to PI; rather, PI risk is complex and based on an interplay of multiple factors specific to an individual (Coleman *et al.*, 2013) and their current situation.

1.2.1.4 Impact of pressure injury

The presence of PI carries significant negative consequences for the afflicted individual (Burston *et al.*, 2022; Gorecki *et al.*, 2009; Khor *et al.*, 2014; Jackson *et al.*, 2017; Manzano, Pérez-Pérez *et al.*, 2014). Physically, pain associated with PI has been well documented (Ahn *et al.*, 2015; Gorecki *et al.*, 2011; Jackson *et al.*, 2017; Kim *et al.*, 2019; McGinnis *et al.*, 2014). Furthermore, management of PI associated pain has been reported to be poor (Jackson *et al.*, 2017). Such pain then leads to negative impacts on quality of life (Gorecki *et al.*, 2011; Jackson *et al.*, 2017), restricts activities of daily living, including sleep and mobility (Gorecki *et al.*, 2011; Jackson *et al.*, 2017), and affects psychosocial wellbeing (Gorecki *et al.*, 2011). Independent of pain, a qualitative study of factors which influence the impact of PI on quality of life in hospital and community patients (Gorecki *et al.*, 2012) found that participants suffered treatment burden, including prolonged hospital stays, time-consuming and costly PI management, discontent with treatment options and psychosocial implications. An earlier systematic review of the impact of PI on quality of life (Gorecki *et al.*, 2009) found PI carried negative physical, social, psychological and financial impacts, in addition to debilitating PI symptoms, impacts on family and friends, and treatment concerns. Similarly, a more recent meta-synthesis of qualitative studies reported that patients and carers experienced loss of autonomy and independence, social isolation, negative psychological effects and functional challenges as a result of living with PI, and significant life adjustments were required for management (Burston *et al.*, 2022). Of concern, PI and its complications have also been associated with increased mortality (Labeau *et al.*, 2021; Jaul & Calderon-Margalit, 2015; Khor *et al.*, 2014; Manzano, Pérez-Pérez *et al.*, 2014; Padula & Pronovost,

2018; Song *et al.*, 2019). Another recent systematic review and meta-analysis (Song *et al.*, 2018), which examined the relationship between PI and mortality in elderly patients, concluded that elderly patients with PI had a two times higher risk of mortality than those without.

The negative implications of PI are not limited to the individual, but also to health care facilities and systems through increased costs (Lim & Ang, 2017; Padula & Delarmente, 2019; Demarré *et al.*, 2015). Within hospitals, PI has been associated with increased length of stay (Dreyfus *et al.*, 2018; Lim & Ang, 2017; Theisen *et al.*, 2012), which not only burdens patients (Gorecki *et al.*, 2009; Gorecki *et al.*, 2012), but also the facilities, resulting in lost bed days (Nguyen *et al.*, 2015) and increased costs (Dreyfus *et al.*, 2018; Lim & Ang, 2017). Lim and Ang (2017) found that hospital-acquired PI resulted in a significantly longer hospital length of stay (30 days versus 6 days without hospital-acquired PI), with the longest mean length of stay associated with Stage II PI (mean 42 days, standard deviation [SD] 35 days), followed by Stage I (mean 26 days, SD 27 days) and Stage III and above PI (mean 23 days, SD 16 days). A longer length of stay of 3.7 days was reported in hospitals in the United States of America, with a mean length of stay of 13.3 days (SD 7.0 days) for patients with a hospital-acquired PI versus 9.3 days (SD 6.1 days) for those without (Dreyfus *et al.*, 2018). Dreyfus *et al.* (2018) also estimated that patients with a hospital-acquired PI had a higher total hospitalisation cost of US$8014 (approximately AU$11 144) than those patients without a hospital-acquired PI. Similarly, Lim and Ang (2017) reported that hospital acquired PI resulted in hospitalisation costs of S$35 936 (Singapore dollars, approximately AU$36 605), as opposed to S$6266 (approximately AU$6382) for patients without a hospital-acquired PI. Annual hospital-acquired PI treatment costs have been estimated internationally to be AU$938 billion in Australian public hospitals (Nguyen *et al.*, 2015), US$26.8 billion (approximately AU$37.2 billion) in the United States of America (Padula & Delarmente, 2019) and £531 million (approximately AU$963 million) in the United Kingdom (Guest *et al.*, 2017). Overall, a systematic review of the prevention and treatment costs of pressure ulcers (Demarré *et al.*, 2015) found that, across settings internationally, the cost of PI prevention ranged from €2.7 to €87.6 (approximately AU$4.0 to $133.6) per patient day. The cost of PI treatment was significantly higher, at up to €470.5 (approximately AU$717.6) per patient day; thus, highlighting the financial benefit of PI prevention as opposed to treatment (Demarré *et al.*, 2015).

1.2.1.5 Pressure injury avoidance

Where appropriate preventative measures are utilised to mitigate PI risk factors or reduce extrinsic forces, PIs are considered to be predominantly 'avoidable' (Alvarez *et al.*, 2016; Black *et al.*, 2011; Schmitt *et al.*, 2017). However, some PIs may be considered unavoidable (Alvarez *et al.*, 2016; Black *et al.*, 2011; Edsberg *et al.*, 2014; Schmitt *et al.*, 2017). In 2010, NPUAP held a consensus conference to examine the definition of avoidable and unavoidable PIs, and to establish consensus around situations in which PIs may be unavoidable (Black *et al.*, 2011). Avoidable PIs were classified as those occurring

when a health care provider does not perform appropriate PI preventative care. Conversely, unavoidable PIs were classified as those occurring even though a health care provider performed appropriate PI preventative care, due to complex clinical situations where the ability to relieve extrinsic forces (i.e. pressure) or improve tissue perfusion is restricted (Black *et al.*, 2011). There was unanimous consensus between participating experts that most PIs, but not all, were avoidable (Black *et al.*, 2011). However, PI avoidance should not be predetermined, and PI preventative measures should be implemented regardless of the presence of situations in which unavoidable PIs may occur (Black *et al.*, 2011). In 2014, a second NPUAP consensus conference was held, which reaffirmed consensus that unavoidable PIs do occur (Edsberg *et al.*, 2014). Internationally, the definitions of avoidable and unavoidable PIs, and the notion that most are preventable, have also been supported by other committees and organisations (Alvarez *et al.*, 2016; Schmitt *et al.*, 2017).

Several studies have reported on the occurrence of unavoidable PI. Palese *et al.* (2017) reported that 19.7% of hospital-acquired PIs that developed in 96 elderly patients admitted to Italian hospital medical units were unavoidable, based on a definition of those occurring in patients receiving best prevention practices who were hemodynamically unstable and/or with cachexia and/or terminal illness. In the United States of America, Pittman *et al.* (2016) developed and tested an instrument to assess PIs as avoidable or unavoidable in an acute care setting based on four components (evaluation of clinical condition, defined/implemented preventative interventions congruent with patient needs, monitoring/evaluation of intervention impacts, and subsequent revision of interventions), finding that, of 31 patients who developed a PI, 38.7% had an unavoidable PI. Using the same instrument and also in the United States, Pittman *et al.* (2019) deemed 40.6% of PIs to be unavoidable in 165 patients who developed a PI within intensive and progressive care units. In Italian nursing homes, Palese *et al.* (2020) found that the occurrence of unavoidable PI is much higher, indicating that, of 925 residents with a PI, 76.1% met the criteria of Black *et al.* (2011) for an unavoidable PI. However, these studies utilised different methods of measuring an unavoidable PI and are all limited in regard to method (retrospective analysis of previously collected data), and in some cases, small sample sizes (Palese *et al.*, 2017; Pittman *et al.*, 2016). Nonetheless, the results emphasize that many, if not the majority, of PIs are preventable.

1.2.1.6 Pressure injury prevention

The first step of PI prevention to undertake an assessment of an individual's PI risk (EPUAP *et al.*, 2019; Lovegrove, Miles & Fulbrook, 2018; Moore & Patton, 2019). Risk assessment should be structured and comprehensive to assess for and identify all individual PI risk factors and may be aided by the use of a risk assessment scale (or tool) (EPUAP *et al.*, 2019). Commonly used PI risk assessment scales include the Braden scale (Braden & Bergstrom, 1988; Braden & Maklebust, 2005), Norton scale (Norton *et al.*, 1962; Goldstone & Goldstone, 1982) and Waterlow score (Waterlow, 2005); of which, the Braden is

the most widely studied internationally (Garcia-Fernandez *et al.*, 2014). Further PI risk assessment instruments have been developed more recently, such as the PURPOSE-T which uses a colour coded system across three steps: (1) screening assessment of mobility and skin status to exclude those clearly not at risk, (2) full assessment of comprehensive risk factors, and (3) categorisation of risk based on responses to step two (Coleman *et al.*, 2016; Coleman *et al.*, 2018). However, the PURPOSE-T and commonly used risk assessment scales are largely not setting or intensive care specific (see section 1.2.2.3.1, pp. 19-20). Regardless of the scale used, if any, clinical judgement should always be employed when undertaking a PI risk assessment (EPUAP *et al.*, 2019), and some argue that clinical judgement alone may be sufficient for assessment of PI risk (Webster *et al.*, 2011). Others argue that it is not, and indicate that use of a risk assessment scale results in the increased application of PI preventative interventions (Garcia-Fernandez *et al.*, 2014). A recent systematic review found that there was insufficient evidence to support the use of clinical judgement alone as a method of risk assessment in clinical practice, contending that PI risk assessment using a structured risk assessment scale should be considered the 'gold standard', unless shown in future research to be inferior to another method (Lovegrove, Ven *et al.*, 2021). Notably, the authors found that some research indicates that a patient's risk status may differ between different methods of risk assessment, but the consequences of this on preventative intervention use remain unclear (Lovegrove, Ven *et al.*, 2021).

This is of particular importance, since risk assessment scales by themselves (and risk assessment overall) do not prevent PI (Fulbrook & Anderson, 2016). Rather, risk assessment should be a precursor to prompt the following steps of PI prevention; firstly, selection and then secondly, implementation, of PI preventative interventions based on the identified risk factors (Lovegrove, Miles & Fulbrook, 2018). Thus, while a Cochrane Review found that it was unclear whether risk assessment scales prevent PI (Moore & Patton, 2019), that is not really the issue to address. Instead, risk assessment scale effectiveness should be considered in terms of how the primary outcome of risk assessment (assessed risk status or level) guides subsequent preventative intervention use (Lovegrove, Ven *et al.*, 2021). The PI preventative interventions themselves, targeted by the risk assessment, act to reduce or mitigate the present PI risk factors (Lovegrove, Miles & Fulbrook, 2018).

The international guideline for PI prevention and treatment (EPUAP *et al.*, 2019) provides the most comprehensive best-practice guide to preventative interventions. The major PI preventative interventions include repositioning (Avsar *et al.*, 2020; EPUAP *et al.*, 2019; Gillespie *et al.*, 2020; Gillespie, Walker *et al.*, 2021), use of appropriate support surfaces (e.g. mattresses, chairs) (EPUAP *et al.*, 2019; McInnes *et al.*, 2015; Shi *et al.*, 2018; Shi, Dumville, Cullum, Rhodes, Leung & McInnes, 2021; Shi, Dumville, Cullum, Rhodes, Jammali-Blasi & McInnes, 2021; Shi *et al.*, 2021a; Shi *et al.*, 2021b), application of prophylactic dressings (Avsar *et al.*, 2021; EPUAP *et al.*, 2019; Moore & Webster, 2018), and nutritional interventions (EPUAP *et al.*, 2019; Langer & Fink, 2014). A recent meta-synthesis of

Cochrane PI prevention reviews (*n* = 8) and treatment reviews (*n* = 19) found that key PI prevention recommendations were made for nutrition, repositioning and support surface interventions (Walker *et al.*, 2020). However, it was also noted that evidence is lacking and mostly of low quality, with further high-quality evidence urgently required (Walker *et al.*, 2020). Nevertheless, PI prevention is of the utmost importance given the negative impacts of PI (Gorecki *et al.*, 2009; Khor *et al.*, 2014; Jackson *et al.*, 2017; Manzano, Pérez-Pérez *et al.*, 2014).

Overall, to emphasise, the PI prevention process (Figure 1.1) comprises three interlinked steps; risk assessment, the prescription of preventative interventions based on the assessed risk, and the implementation of the interventions to mitigate the identified risk (Lovegrove, Miles & Fulbrook, 2018). Further research linking risk assessment to preventative intervention prescription and implementation is needed (Lovegrove, Miles & Fulbrook, 2018), and this need forms part of the impetus for the program of research being presented in this thesis.

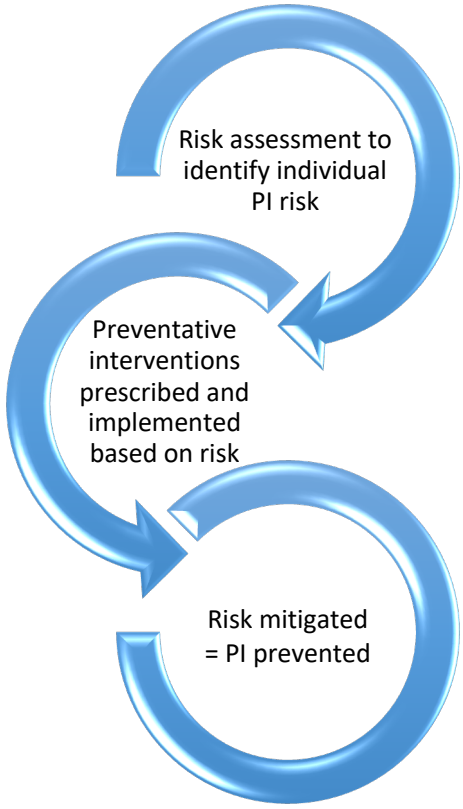


Figure 1.1: Pressure injury prevention process

1.2.1.7 International pressure injury prevalence and incidence

Internationally, PI incidence is generally decreasing but remains significant across various settings, despite the well-documented negative consequences of PI and recognition that these injuries are largely preventable. Within health care settings, PI may be 'present on admission' (the PI was acquired prior to admission to a facility and remains present, or was 'community-acquired' [Rodgers *et al.*,

2021]) or facility-acquired (the PI was acquired during admission, residency or stay within the facility, e.g. during hospitalisation, referred to as 'hospital-acquired' [Rodgers *et al.*, 2021]). In the United States of America, VanGilder *et al.* (2017) reported a 10-year PI prevalence (years 2006 to 2015) in volunteering acute care, long-term acute care, long-term and rehabilitation settings. The results of the study were that, with the exception of the long-term settings, the overall (i.e. present on admission and facility-acquired) prevalence of PI (greater than Stage I) declined over the 10-year period from 13.5% and 13.7% in 2006 and 2007 respectively, to 9.3% in 2015 (VanGilder *et al.*, 2017). By setting, the highest to lowest range of overall PI prevalence was 13.4% in 2007 to 8.8% in 2015 in acute care, 37.3% in 2011 to 28.8% in 2015 in long-term acute care, 12% in 2010 to 9.5% in 2012 in long-term care and 19.4% in 2009 to 11% in 2015 in rehabilitation (VanGilder *et al.*, 2017). In relation to facility-acquired PI, prevalence within settings ranged highest to lowest from 6.4% in 2006 and 2007 to 2.9% in 2015 in acute care, 9.8% in 2011 to 3.4% in 2012 in long-term acute care, 5.6% in 2006 and 2011 to 3.3% in 2007 in long-term care and 6.6% in 2008 to 2.6% in 2013 and 2014 in rehabilitation (VanGilder *et al.*, 2017).

In Australia, one state-wide (New South Wales) audit of public health inpatient facilities, aged care and community and outpatient services, found that, in 2018, overall PI prevalence was 7.9%, 8.0% and 9.4% respectively, which was an increase from 2017 results (New South Wales Government Clinical Excellence Commission, 2019). In regard to facility-acquired PI, results were comparable to 2017, at 4.0% in inpatient facilities, 5.6% in aged care and 1.2% in community and outpatient services (New South Wales Government Clinical Excellence Commission). Elsewhere in Australia, another 2018 state-wide (Queensland) audit of inpatient and residential aged care facilities found that facility-acquired PI prevalence in both these settings combined decreased annually from 14.0% in 2014 to 3.0% in 2018 (Queensland Health, 2019).

In Europe overall, a systematic review of PI prevalence found that, from 79 articles spanning the years 1982 to 2018, the median prevalence was 10.8% (SD 7%) with a range of 4.6% to 27.2% (Moore *et al.*, 2019). Settings included acute care, long-term care and community care, but facility-acquired PIs were not reported separately (Moore *et al.*, 2019). While in Finland, a cross-sectional national study found that overall PI prevalence in acute inpatient settings (n = 16) was 12.7% overall, and 10.0% when PIs acquired during hospital admission were included (Tervo-Heikkinen *et al.*, 2021). In Sweden, a nation-wide 10-year (2011 to 2020) study found that PI prevalence overall decreased significantly over the 10 years from 17.0% to 11.4%, while hospital-acquired prevalence decreased from 8.1% to 6.4% between 2018 and 2020 (Källman *et al.*, 2022). This was in line with improvements noted in PI preventative care over the study timeframe. However, care was still suboptimal, and the reported rates of PI remained clinically significant in later years.

Across Asian settings, reported PI prevalence and incidence varies (Feng *et al.*, 2018; Nakashima *et al.*,

2018; Sari *et al.*, 2019). In an Indonesian city in 2017, the prevalence of PI in 325 community-dwelling older adults was reported to be 10.8% (95% confidence interval [CI] 5.8%-15.8%) (Sari *et al.*, 2019). Also in 2017, across hospitals, long-term care, home-visit nursing services, group homes and geriatric facilities in a rural Japanese city, PI prevalence in 1126 adults aged 18 years and above was 9.2 per 1000 population (95% CI 8.1-10.2) (Nakashima *et al.*, 2018). In China, a 10-year retrospective prevalence study in a tertiary hospital found that 5838 out of 986 404 patients had a PI, resulting in a lower prevalence overall of 0.6%, while hospital-acquired PI prevalence was 0.1% (Zhao *et al.*, 2021). Finally, in the Middle East, a study of PI prevalence in a United Arab Emirates hospital compared PI prevalence in different years, finding an increase in overall PI prevalence from 6.4% in 2013 and 10.4% in 2018, but a decrease in hospital-acquired PIs from 2.0% in 2013 to 1.8% in 2018 (Tariq *et al.*, 2019). These studies indicate that the ongoing presence of PI remains clinically significant both internationally, and across care settings.

1.2.1.8 Hospital-acquired pressure injury

Within hospitals, PI occurrence is an ongoing challenge (Al Mutairi & Hendrie, 2018; Li, Lin *et al.*, 2020; Rodgers *et al.*, 2020; Tubaishat *et al.*, 2018) with PI considered to be an adverse event associated with hospital admission (Al-ghraiybah *et al.*, 2021; Australian Commission on Safety & Quality in Health Care, 2020; Tchouaket *et al.*, 2017). As PI occurrence is deemed predominantly preventable with the application of appropriate preventative measures, PI incidence/prevalence is an indication of the quality of care provided (Al-ghraiybah *et al.*, 2021; van Dishoeck *et al.*, 2016). Despite this, a systematic review of PI in acute care settings between the years 2000 and 2015 found that globally overall prevalence ranged from 4.9% to as high as 54.0% (Tubaishat *et al.*, 2018), but it was unclear whether all reported rates included both hospital-acquired and present on admission PI. Based on studies deemed to be of sufficient quality, with adequate reporting of PI including stage I (10 of 19 included studies), the reviewers estimated that global PI prevalence was likely to be between 6.0% and 18.5% (Tubaishat *et al.*, 2018). A more recent systematic review and meta-analysis of international PI incidence and prevalence in hospitalised adults between the years 2008 and 2018 reported that, overall, pooled PI prevalence and incidence was 12.8% (95% CI 11.8%-13.9%) and 5.4 per 10000 patient-days (95% CI 3.4-7.8), respectively (Li, Lin *et al.*, 2020). Of the overall PIs, 61.8% (95% CI 7.6%-9.3%) were hospital-acquired, and the pooled hospital-acquired PI rate was 8.4% (95% CI 7.6%-9.3%) (Li, Lin *et al.*, 2020).

Another systematic review of PI incidence and prevalence in public hospitals found that between the years 2000 and 2017 PI mean point prevalence and period prevalence was 14.8% (SD 8.2%, range 2.2%-40.0%) and 11.6% (SD 7.5%, range 1.4%-24.3%) respectively, while mean PI incidence was 6.3% (SD 4.4%, range 0.6%-17.9%) (Al Mutairi & Hendrie, 2018). One further systematic review of PI prevalence, in Australian and New Zealand hospitals, reported that overall PI prevalence was 12.9% (95% CI 9.5%-

16.8%) and hospital acquired PI prevalence was 7.9% (95% CI 5.7%-10.3%) spanning the years 1997 to 2018 (Rodgers *et al.*, 2020). However, while PIs may occur across acute hospital settings, it is critically ill individuals admitted to intensive care who are most susceptible (Coyer *et al.*, 2017; Nowicki *et al.*, 2018). Pressure injury incidence and prevalence is higher in critically ill patients admitted to intensive care settings (Chaboyer *et al.*, 2018) than in hospital settings overall (Al Mutairi & Hendrie, 2018; Li, Lin *et al.*, 2020; Tubaishat *et al.*, 2018). The ongoing occurrence of PI within intensive care indicates that further research to improve PI prevention practices within this setting is required. Within this context, the remainder of this chapter presents the theoretical background of PI within intensive care, and a three-phase program of intensive care PI prevention research.

1.2.2 Pressure injury in intensive care

1.2.2.1 Intensive care pressure injury prevalence and incidence

The higher occurrence of PI associated with intensive care admission was demonstrated by Coyer *et al.* (2017) who performed a secondary analysis of public healthcare facility annual point prevalence audit data from one Australian state (Queensland) between 2012 and 2014; and, found that PI point prevalence was 11.5% in intensive care patients versus 3.0% in ward patients These results revealed that intensive care patients were 3.8 times more likely to develop a PI than non-intensive care patients (Coyer *et al.*, 2017). Such results are consistent with those of older European studies that have reported higher rates of PI in intensive care (Bredesen *et al.*, 2015; Lahmann *et al.*, 2012). Similarly, another Australian study found that when compared to other hospitalised patients, hospital-acquired PI rates were ten-fold greater in intensive care patients (Nowicki *et al.*, 2018). Furthermore, a retrospective analysis of data from acute care hospitals in the United States between 2011 and 2016 reported that patients admitted to intensive care were significantly more likely to develop superficial and, even more so, severe PIs (Stage III, IV, Suspected Deep Tissue and Unstageable PI; Kayser *et al.*, 2019). More recent results are consistent with those of previous studies. An analysis of an observational, cross-sectional cohort study database covering 914 acute care facilities in the United States between 2018 and 2019 found that both overall PI and intensive care-acquired PI (14.3% and 5.9%, respectively) were higher than in other units (7.8% to 10.2% and 1.9% to 3.4%, respectively) (VanGilder *et al.*, 2021). Indeed, a secondary critical care analysis of the same dataset confirmed the intensive care PI rates (Cox *et al.*, 2022).

In intensive care alone, a systematic review and meta-analysis found that, between January 2002 and May 2017, the 95% CIs of PI cumulative incidence and prevalence were 10.0-25.9% and 16.9-23.8%, respectively on a global scale (Chaboyer *et al.*, 2018). However, the origins of the PIs were not reported (i.e. acquired in intensive care, elsewhere in the hospital, or present on admission). Since 2017, further research has been published which demonstrates that PI occurrence is a significant issue within

intensive care (Ali *et al.*, 2020; Akhand *et al.*, 2020; Alderden *et al.*, 2021; El-Marsi *et al.*, 2018; González-Méndez *et al.*, 2018; Jacq *et al.*, 2021; Yarad *et al.*, 2021). Another systematic review and meta-analysis of PI prevalence in Iranian intensive care units reported that the pooled prevalence of PI was 19.6% (95% CI 13.2-26.0%), but intensive care-acquired PI was not reported (Akhand *et al.*, 2020). In 2015, in a Spanish intensive care unit, a prospective cohort study (González-Méndez *et al.*, 2018) found a PI incidence of 8.1%, with a rate of 11.7 per 1000 days of stay (95% CI 7.9-16.8). In a Brazilian intensive care unit, Ali *et al.* (2020) found that the mean incidence of PI between the years 2010 and 2014 was 10.8% (SD 2.9%). The lowest reported incidence during the study time period was 1.6% (March 2014), while the highest was 26.3% (January 2012) (Ali *et al.*, 2020). In another Brazilian intensive care unit, but with a much smaller sample (*n* = 40), a prospective observational study in 2019 found a PI incidence of 20.0% (Rodrigues *et al.*, 2021). In a Lebanese medical-surgical intensive care unit, a retrospective chart review revealed that 33.7% of 145 patients admitted to the unit between December 2014 and June 2017 developed a hospital-acquired PI (El-Marsi *et al.*, 2018). In the United States of America, a retrospective cohort study found that 6.5% of 5101 patients admitted to a surgical intensive care unit and a cardiovascular surgical intensive care unit between 2014 and 2018 developed a hospital-acquired PI (Alderden *et al.*, 2021). In Australia and New Zealand, a prevalence study undertaken in 2016 reported that, across 47 intensive care units and 671 patients, PI point prevalence was 10.4%; although again, the origins of the PIs were unclear (Yarad *et al.*, 2021). In France, another prevalence study undertaken in 2017 across 86 participating intensive care units and 1228 patients found overall prevalence to be 18.7% (95% CI 16.6-21.0%), while intensive care-acquired PI prevalence was 12.5% (95% CI 10.6-14.3%) (Jacq *et al.*, 2021).

A much larger international point prevalence study was undertaken in 2018 in 1117 intensive care units with 13254 patients across 90 countries and 6 continents (Labeau *et al.*, 2021). Of concern, overall PI prevalence was 26.6% (95% CI 25.9-27.3%), and by continent, was highest in Latin, Central and South America (35.1%, 95% CI 32.2-38.1%), followed by Africa (34.2%, 95% CI 28.5-40.1%), Europe (28.9%, 95% CI 27.8-30.1%), Asia (23.7%, 95% CI 22.4-25%), North America (22.8%, 95% CI 20.8-25%) and Oceania (13.8%, 95% CI 10.8-17.5%) (Labeau *et al.*, 2021). Intensive care-acquired PI prevalence was 16.2% overall (95% CI 15.6-16.8%), 22.8% in Latin, Central and South America (95% CI 20.3-25.4%), 21.1% in Africa (95% CI 16.5-26.7%), 20% in Europe (95% CI 18.9-21%), 13.3% in North America (95% CI 11.7-15.1%), 11.2% in Asia (95% CI 10.3-12.2%) and 9.1% in Oceania (95% CI 6.7-12.3%) (Labeau *et al.*, 2021). Furthermore, of the overall reported PIs, the proportion that were intensive care-acquired was greater than 50.0% (range 58.1% [North America] to 69.0% [Europe]) in all but one continent (Asia, 47.3%) (Labeau *et al.*, 2021). A secondary analysis of the international point prevalence study which included intensive care units (*n* = 198) in Mainland China found that PI prevalence was lower in this location (overall 12.3%, intensive care-acquired 4.3%) (Lin *et al.*, 2022). Similarly, another secondary

analysis of the international study which included 16 intensive care units in Australia found that PI prevalence was 13.5% overall, and 9.7% for intensive care-acquired PI (Coyer *et al.*, 2022). Nonetheless, these rates are still clinically significant with PI occurrence presenting an ongoing global health care challenge.

1.2.2.2 Pressure injury risk factors in critically ill patients

The higher vulnerability of critically ill individuals to PI is attributable to PI risk factors associated with intensive care admission and critical illness (Cox, 2017), in addition to general extrinsic and intrinsic (e.g. age) PI risk factors (see section 1.2.1.3, pp. 4, 6). One literature review revealed a total of 43 PI risk factors, across 16 international studies, that were found to be significant predictors of PI (Cox, 2017). Of these, seven were significant across multiple studies; age, length of intensive care stay, diabetes, cardiovascular disease, hypotension, mechanical ventilation and use of vasopressors (Cox, 2017). A more recent systematic review examining the association of a disease severity score with PI (Acute Physiology and Chronic Health Assessment Evaluation score [APACHE II]; higher scores indicating greater disease severity and mortality risk; Knaus *et al.*, 1985) found that higher APACHE II scores were associated with higher PI incidence (Tang *et al.*, 2022). Meanwhile, a systematic review of PI risk factors in critically ill patients concluded that age, mobility and activity, perfusion and vasopressor infusion were important risk factors in this population (Alderden *et al.*, 2017). It was noted that further research is required to examine risk associated with nutritional status, skin status, and factors impacting perfusion, such as vasopressor use and decreased oxygen delivery to tissues (Alderden *et al.*, 2017). The authors found that the results of individual studies were often conflicting (Alderden *et al.*, 2017) and this is also evident in studies published since the finalisation of Alderden *et al.*'s (2017) systematic review searches in December 2016 (e.g. Alderden *et al.*, 2020; Cox *et al.*, 2018; Cox *et al.*, 2020; Cox *et al.*, 2022; de Almeida Medeiros *et al.*, 2018; El-Marsi *et al.*, 2018; González-Méndez *et al.*, 2018; Jacq *et al.*, 2021; Kim, Aribindi *et al.*, 2022; Labeau *et al.*, 2021; Lin *et al.*, 2022). These will now be discussed further.

A large international PI point prevalence study across 1117 intensive care units (90 countries and six continents) also examined risk factors associated with intensive care-acquired PI (Labeau *et al.*, 2021). A regression analysis found several factors independently associated with such injuries, including older age, male gender, underweight status, emergency surgery, higher Simplified Acute Physiology Score (SAPS) II (a disease severity and mortality probability score, in which higher scores suggest greater severity and increased probability of mortality; Barlow & Pilcher, 2019; Le Gall *et al.*, 1993), Braden scores < 19 indicating higher PI risk (Braden scale sum scores have been categorised as: ≤ 9 = very high risk, 10-12 = high risk, 13-14 moderate risk, 15-18 mild risk, 19-23 not at risk; Braden & Maklebust, 2005), prolonged intensive care stay over three days, chronic obstructive pulmonary disease, immunodeficiency, renal replacement, mechanical ventilation on intensive care admission and being

from a low to lower/middle income economy. In a secondary analysis of the international data focused on Mainland China (Lin *et al.*, 2022), univariate analysis revealed that intensive care-acquired PI occurred significantly more in those who were of older age, were admitted from a general ward, were on mechanical ventilation on intensive care admission or on the study day, had a primary respiratory diagnosis, increased comorbidities, chronic obstructive pulmonary disease, malignancy, heart failure, impaired mobility, malnutrition and who were immunocompromised, had therapeutic hypothermia treatment, a higher SAPS II score (greater disease severity), lower Braden score (higher PI risk), and increased length of intensive care stay prior to participation. The authors also reported a multivariate analysis, which demonstrated regional location, lack of cardiovascular disease, mechanical ventilation on participation, higher SAPS II score (greater disease severity), intensive care length of stay over nine days prior to participation and three or more comorbidities were all factors associated with PI (Lin *et al.*, 2022).

Univariate analysis in a French study of PI prevalence across 86 intensive care units showed longer intensive care length of stay, higher body weight, higher SAPS II score (greater disease severity) and higher plasma c-reactive protein concentration, lower plasma albumin concentration, invasive ventilation, high-dose steroids, need for artificial nutrition, and motor neurological disorder were all associated with intensive care-acquired PI (Jacq *et al.*, 2021). A prospective Chinese cross-sectional study in 23 intensive care units (19 hospitals), which included 421 patients, found that lower body mass index, chronic obstructive pulmonary disease, multiple organ dysfunction syndrome and a lower Braden score (higher PI risk) were associated with intensive care-acquired sacral PI (Hu, Zhao *et al.*, 2021). In a Spanish study by González-Méndez *et al.* (2018), across 335 patients admitted to intensive care for at least 24 hours, higher SAPS III score (greater disease severity as per SAPS III, the more recent disease severity and mortality probability score following SAPS II; Barlow & Pilcher, 2019; Moreno *et al.*, 2005), and complications occurring during the stay, emerged as independent factors associated with PI development. However, duration of immobility was found to be a protective factor, with risk of PI decreasing for each day the patient was immobile (González-Méndez *et al.*, 2018). The authors suggest this may be due to implementation of the local PI prevention protocol (González-Méndez *et al.*, 2018). Conversely, a small retrospective descriptive study of 57 patients admitted to a medical-surgical intensive care unit in the north-eastern United States between the years 2013 and 2016 found immobility to be a primary PI risk factor, along with septic shock, administration of vasopressors, continuous head-of-bed elevation, sedation and prolonged mechanical ventilation (Cox *et al.*, 2018). A larger retrospective cohort study undertaken in the United States, which included 23 806 adult intensive care patients, found that length of hospital stay, pre-existing diabetes, minimal arterial oxygen pressure, hypotension, gastrointestinal bleeding, cellulitis and minimum Braden score of ≤ 14 (moderate to very high PI risk; Braden & Maklebust, 2005) were all independent risk factors for PI in

this setting (Kim, Aribindi *et al.*, 2022).

A retrospective chart review of 145 individuals admitted to a Lebanese medical-surgical intensive care unit (El-Marsi *et al.,* 2018) identified length of intensive care stay, hypotension episodes and vasopressor administration as potential PI risk factors. In a Brazilian retrospective case control study of 180 patients admitted to a general intensive care unit in 2016, a set of six factors was found to be predictive of PI: friction, history of a previous PI, prolonged length of stay in intensive care, dehydration, increased skin temperature (1-2° Celcius) and comorbidity treatment (de Almeida Medeiros *et al.*, 2018). Also in Brazil, a retrospective chart review including 582 patients in 2017 and 2018 found that time-related factors (days of norepinephrine [a vasopressor and adrenergic stimulant; MIMS, 2022c] and mechanical ventilation use, and length of intensive care stay) were individual predictors of PI, along with impaired sensory perception as per Braden subscale ratings (Argenti *et al.*, 2022). Another retrospective study of data from 1460 patients admitted across five intensive care units in a United States hospital between 2001 and 2012, identified factors predictive of PI included age, Braden score on admission, cardiovascular disease and surgery, haemodialysis, hypotension, male gender, moderate to severe malnutrition, norepinephrine (vasopressor and adrenergic stimulant; MIMS, 2022c) administration, peripheral vascular disease, pneumonia or influenza and septic shock (Cox *et al.*, 2020). Of these, norepinephrine (vasopressor and adrenergic stimulant; MIMS, 2022c) was found to be the strongest predictor (Cox *et al.*, 2020). Furthermore, the authors noted that many of the identified predictors impact upon tissue oxygenation and perfusion, which is an important PI risk factor (Cox *et al.*, 2020). Alternatively, a much larger retrospective study of 5101 surgical intensive care patients in a United States hospital between the years 2014 and 2018 found the strongest predictor of PI to be skin irritation (i.e. rash or blanching, diffuse, non-localised erythema), as well as length of intensive care stay and lower Braden scores (higher PI risk, mean minimum Braden score 12 [equating to 'high risk' risk level; Braden & Maklebust, 2005]) (Alderden *et al.*, 2020).

Additionally, critically ill individuals with a pre-existing hospital-acquired PI are also at risk of developing a second hospital-acquired PI (Alderden *et al.*, 2021). A retrospective cohort study of mechanically ventilated adults, admitted to a North American surgical intensive care unit and cardiovascular intensive care unit with a hospital-acquired PI, examined risk factors associated with subsequent hospital-acquired PI development. Overall, 34% (*n* = 77) of 226 included patients developed a subsequent hospital-acquired PI, with the authors concluding that this cohort was at high risk for subsequent hospital-acquired PI development (Alderden *et al.*, 2021). Other risk factors found to be independently associated with subsequent hospital-acquired PI development were decreased haemoglobin, vasopressor infusion and longer intensive care length of stay (Alderden *et al.*, 2021).

Cox and Schallom (2021) proposed a conceptual schema to describe the relationship between PI risk factors, PI aetiology and prevention, and their impact on PI occurrence within intensive care. Following

a literature review, the authors classified PI risk factors as static intrinsic, dynamic intrinsic and dynamic extrinsic factors. Identified static intrinsic factors include age, baseline impaired mobility, smoking history, coronary and peripheral artery disease, diabetes and end-stage renal disease. Dynamic intrinsic risk factors include hypotension, hypoxia and respiratory failure, haemodynamic instability, protein-calorie malnutrition and anaemia, with note that these factors are similar in that they all impact tissue perfusion and oxygenation. Dynamic extrinsic factors include intensive care length of stay, operating theatre length of stay and treatment-related factors.

As noted by Cox and Schallom (2021), many of the above PI risk factors have the potential to impair tissue perfusion and oxygenation, an important PI risk factor overall (Cox *et al.*, 2020). Sedation, analgesia and muscle relaxant use may also impede an intensive care patient's ability to perceive or respond to stimuli such as tissue pressure and discomfort (Fulbrook & Anderson, 2016; González-Méndez *et al.*, 2018). In a retrospective record review across four Taiwanese intensive care units, Chang and Weng (2022) found that when intensive care patients were receiving both mechanical ventilation and either fentanyl (analgesic with sedative properties; MIMS Australia, 2022a) or midazolam (sedative and hypnotic; MIMS Australia, 2022b), the incidence of more severe PI (Stage II-IV; Suspected Deep Tissue and Unstageable) was greater. The authors (Chang & Weng, 2022) note that use of such sedative and analgesic agents may indeed impair the sensory responses of the patient. Similarly, another retrospective record review in a Japanese general intensive care unit found that deeper levels of sedation (as measured by the Richmond Agitation Sedation Scale; Sessler *et al.*, 2002), were associated with the occurrence of PI (Sasabe *et al.*, 2022). Elsewhere, another retrospective review in a United States medical intensive care unit found no statistically significant difference in the incidence of hospital-acquired PI in those receiving low-dose vasopressors versus those receiving high-dose vasopressors (Holt *et al.*, 2022). Nonetheless, hospital-acquired PI incidence was high in both cohorts (17% and 22.4%, respectively) and documented time to PI was significantly shorter in those receiving high-doses, with the authors emphasising the need for PI preventative measures in patients receiving vasopressor therapy.

Many factors associated with unavoidable PI are also associated with critical illness, such as haemodynamic instability, vasopressor use, systemic inflammatory response syndrome and multiorgan dysfunction syndrome (Cox, 2017; Edsberg *et al.*, 2014). Indeed, this was confirmed in a recent North American retrospective, matched case-control study (Solmos *et al.*, 2021). Comparison of 34 intensive care patients with sacrococcygeal PI (deemed unavoidable) to 34 patients without a PI at this location found that progressive multi-organ dysfunction or failure, increased use of supportive therapies, diagnosis of sepsis and mortality were associated with unavoidable sacrococcygeal hospital-acquired PI (Solmos *et al.*, 2021). Similarly, another North American case-control study of 165 intensive care patients with a hospital-acquired PI compared to 310 without PI, found that factors such as patient

acuity, organ failure, tissue perfusion, sepsis and prior PI history were associated with both avoidable and unavoidable PIs (Pittman *et al.*, 2021). Skin failure, which occurs as a result of hypoperfusion due to single or multi-organ failure and resulting in subsequent skin and underlying tissue death (Edsberg *et al.*, 2014), may also be associated with PI in this population (Dalgleish *et al.*, 2020; Nowicki *et al.*, 2018). The results of the study by Pittman *et al.* (2021) suggest that acute skin failure may be associated with both avoidable and unavoidable PI in intensive care. These studies demonstrate the vulnerability of critically ill patients to PI because of multiple factors and emphasise the importance of PI prevention within this population, which is the focus of the program of research presented in this thesis.

1.2.2.3 Pressure injury prevention in intensive care

1.2.2.3.1 Risk assessment

As noted previously (section 1.2.1.6, pp. 8-10), the first step of PI prevention is a PI risk assessment, which may be undertaken using a PI risk assessment scale in combination with clinical judgement (EPUAP *et al.*, 2019; Lovegrove, Miles & Fulbrook, 2018; Moore & Patton, 2019). Risk assessment scales commonly used in hospitals (i.e. Braden scale, Norton scale and Waterlow score) have also been used within intensive care (Adibelli & Korkmaz, 2019; Cox, 2020; García-Fernández *et al.*, 2013; Keller *et al.*, 2002), particularly the Braden scale. However, these scales were not specifically designed for intensive care use (Cox, 2020; Fulbrook & Anderson, 2016; Keller *et al.*, 2002). Other more recently developed scales intended for adults, such as the PURPOSE-T which has been tested in various settings including acute and community settings and nursing homes (Coleman *et al.*, 2018; Hutlin *et al.*, 2020), are also not specific to intensive care. Consequently, they do not consider all the PI risk factors associated with critical illness and intensive care admission (Cox, 2020; Cox *et al.*, 2020) and may thus underestimate PI risk. It has even been contended that risk factors vary across different intensive care subpopulations (e.g. surgical versus medical) (Deschepper *et al.*, 2022) with a recent systematic review and meta-analysis identifying, for example, a clinically significant higher incidence of PI in cardiac surgical patients (Fulbrook, Mbuzi & Miles, 2021). A systematic review and meta-analysis of studies published between 1962 and 2009 identified 16 risk assessment scales (ten adult/elderly; six paediatric) developed specifically for intensive care, along with studies exploring the use of five other non-intensive care-specific risk assessment scales in intensive care (Braden, Douglas, Norton, Song & Choi, Waterlow; García-Fernández *et al.*, 2013). Despite identifying these scales, due to limited validity, the authors recommended use of the Braden scale within the intensive care setting (García-Fernández *et al.*, 2013). However, a literature review of the predictive value of the Braden scale in intensive care suggested that its utility may be limited within intensive care use (Cox, 2012). As well, a more recent systematic review and meta-analysis of the diagnostic test accuracy of PI risk assessment scales in intensive care noted that the commonly used Braden scale was not ideal for intensive care, and

suggested that the Cubbin/Jackson scale (one of the few intensive care-specific risk assessment scales) was more suitable (Zhang, Zhuang *et al.*, 2021). This systematic review identified 16 risk assessment scales tested within intensive care, of which, eight were not intensive care-specific (Braden, Douglas, EMINA, Gosnell, Multi-pad pressure evaluator, Norton, Song & Choi, Waterlow; Zhang, Zhuang *et al.*, 2021). However, only studies which reported predictive validity in terms of sensitivity and specificity were included and the authors also called for further verification and improvement of the Cubbin/Jackson scale (Zhang, Zhuang *et al.*, 2021). To improve PI risk assessment within the intensive care setting, Cox (2012) recommended that either the Braden scale be modified or a specific scale be developed for intensive care. Further studies, presented below, have clearly indicated that the Braden, and other non-intensive care-specific instruments, are not sufficient for PI risk assessment in this setting.

An interrater reliability and validity study found that, while the Braden scale demonstrated the best interrater reliability and agreement compared to the Waterlow score and subjective assessments using a visual analogue scale, none of the risk assessment methods were precise enough for use within intensive care (Kottner & Dassen, 2010). A Spanish prospective observational study reported that the Braden Scale demonstrated moderate to good interrater reliability within intensive care, but predictive validity and precision were inadequate (Lima-Serrano *et al.*, 2018). A meta-analysis (Wei *et al.*, 2020) found that the Braden scale offered 'moderate' predictive validity, while a large Brazilian cohort study (Ranzani *et al.*, 2016) found the Braden scale to be valid for use within intensive care. However, both suggested that the Braden scale be modified for intensive care to better identify PI risk in critically ill patients (Ranzani *et al.*, 2016; Wei *et al.*, 2020), or a new scale be developed (Wei *et al.*, 2020).

A secondary data analysis found the Braden scale to be lacking in terms of predictive validity in intensive care and suggested this may be due to high cut off scores for recognising PI risk, insufficiencies in nurses' subjective assessments and, notably, specific characteristics of the intensive care setting (Han *et al.*, 2018). Similarly, a retrospective study using four years of data to examine the predictive validity of the Braden scale concluded that said validity was inadequate, accuracy was poor and that the Braden scale did not adequately represent the characteristics of those admitted to intensive care (Hyun *et al.*, 2013). Indeed, it has been noted that most critically ill individuals within intensive care are at higher PI risk according to the Braden scale, but that this may indicate that the Braden is unable to detect varying levels of PI risk within such a highly vulnerable, specialist population (Richardson & Barrow, 2015a). Thus, these results may be symptomatic of the lack of specification of these risk assessment scales to the intensive care setting.

1.2.2.3.1.1 Intensive care-specific risk assessment scales

In the past, there were few available intensive care-specific PI risk assessment scales (Cox, 2020; Keller *et al.*, 2002). A systematic review and meta-analysis identified ten adult intensive care-specific risk

assessment scales in evidence published prior to 2010; however, many were unvalidated (García-Fernández *et al.*, 2013). Meanwhile, a literature review also published in 2013 (Tayyib *et al.*, 2013) covering the years 2000 to 2012 identified 11 articles that reported the use of PI risk assessment scales in intensive care, but only three scales used throughout the articles were intensive care-specific, and all were identified in the systematic review of García-Fernández *et al.* (2013). A more recent systematic review identified eight, but this review was limited to only those studies reporting predictive validity (Zhang, Zhuang *et al.*, 2021). Additionally, a review by Keller *et al.* (2002) identified the Birty Pressure Area Risk Assessment Scale (Birtwistle, 1994), but testing of this scale was limited to nurse questionnaires (Keller *et al.*, 2002). Reference has also been made by others to the Cornell Ulcer Risk Score as an intensive care-specific risk assessment scale (Torra I Bou *et al.*, 2006) and its use within such a setting has been reported (Eachempati *et al.*, 2001); although, any mention of the scale in the evidence is scant and its construct does not appear to have been reported.

The ten intensive care specific PI risk assessment scales identified by García-Fernández *et al.* (2013) include the Cubbin/Jackson (Cubbin & Jackson, 1991) and Jackson/Cubbin (a revised version of the original 1991 instrument; Jackson, 1999), the Norton Modified Scale by Bienstein and the 4-factors model (both described by Feuchtinger *et al.*, 2007), a potential pressure area scoring system (instrument not finalised or tested; Batson, Adam, Hall & Quirke, 1993), the Decubitus Ulcer Potential Analyzer (tested by Jiricka *et al.*, 1995), the Sunderland pressure sore risk calculator (another modification of the Cubbin/Jackson; Lowery, 1995), the EVARUCI (Escala de Valoración Actual del Riesgo de desarrollar Ulceras por presión en Cuidados Intensivos [Current Risk Assessment Scale for Pressure Injury in Intensive Care] (González-Ruiz *et al.*, 2001), a nursing skin assessment to identify risk as proposed by Compton *et al.* (2008) and the Suriadi and Sanada (S.S.) scale (Sanada *et al.*, 2008). Only three (Cubbin/Jackson; Jackson/Cubbin; Norton Modified Scale by Bienstein) were considered validated with more than one supporting study; but all three were only tested in small samples. Thus, it was concluded that all scales required further testing, and the Braden scale was subsequently recommended for use within intensive care (García-Fernández *et al.*, 2013).

Of these risk assessment scales, the Cubbin/Jackson and Jackson/Cubbin have been studied further. One retrospective study found that the Jackson/Cubbin had greater predictive validity than the Braden scale in a trauma-surgery intensive care population (Higgins, Casey *et al.*, 2020). Conversely, similar to the conclusions of García-Fernández *et al.* (2013), others have suggested that the Cubbin/Jackson and Jackson/Cubbin scales are not superior to the Braden scale (Adibelli & Korkmaz, 2019; García-Fernández *et al.*, 2014). One meta-analysis of the predictive capacity of PI risk assessment scales (and clinical judgement) concluded that there was no advantage to using the Cubbin/Jackson and Jackson/Cubbin scales (which are often confused by clinicians) over the Braden scale within intensive care (García-Fernández *et al.*, 2014). Similarly, a comparison of the reliability and predictive validity of

the Jackson/Cubbin and Braden scales found them to be valid and reliable in intensive care; although, the authors note that predictive validity was higher for the Jackson/Cubbin (Adibelli & Korkmaz, 2019). More recently, an observational project undertaken in five intensive care units over six months compared a Braden scale assessment with a Cubbin/Jackson assessment in 4137 patients (Delawder *et al.*, 2021). The construct of the two instruments was found to be similar, with the instruments comparable in terms of predictive validity (Delawder *et al.*, 2021). However, the authors concluded that both scales were suboptimal due to poor specificity and positive predictive values, and thus suggest future research be focused on the development of an intensive care appropriate scale (Delawder *et al.*, 2021).

Evidently, the availability of a reliable and valid intensive care-specific risk assessment scale has been limited. More recently, since the review of García-Fernández *et al.* (2013), this practice gap has been recognised and several new intensive care-specific PI risk assessment scales have been developed and tested (Cobos Vargas *et al.*, 2013; Ninbanphot *et al.*, 2020; Richardson & Barrow, 2015a; Wåhlin *et al.*, 2020). Further supporting research suggesting sufficient reliability and validity has also been reported for one previously identified scale, the EVARUCI (González-Ruiz *et al.*, 2001). The more recent systematic review (Zhang, Zhuang *et al.*, 2021) that only included risk assessment scales which had reports of predictive validity identified only two of these (COMHON [Level of COnsciousness, Mobility, Haemodynamics, Oxygenation, Nutrition] Index; RAPS-ICU [Risk Assessment Pressure Ulcer Scale – Intensive Care Unit]), along with the EVARUCI and other older scales (Cubbin/Jackson, 4-factors model, Norton Modified Scale, S.S. scale, Sunderland pressure sore risk calculator) identified by García-Fernández *et al.* (2013). Table 1.2 presents a summary of all recent intensive care-specific risk assessment scales and supporting evidence.

Table 1.2: Recent (post year 2009) intensive care-specific risk assessment scales

Instrument	Content	Scoring	Testing (initial or secondary) Secondary testing author, year	Testing Design Country Setting	Sample criteria Patient sample size Assessors	Results
CALCULATE (Critical Care Pressure Ulcer Assessment Tool made Easy) (Richardson & Barrow, 2015a; Richardson & Barrow, 2015b)	8-item: too unstable to turn, impaired circulation, dialysis, mechanical ventilation, immobility, long surgery/cardiac arrest, low protein, faecal incontinence Preliminary version: 7-item scale amended to 8-item with addition of immobility based on nursing staff feedback	≥4 scale factors or too unstable to turn factor present = very high PI risk, ≤3 scale factors present = high PI risk	Initial testing	Part 1: Literature review & development; Part 2: Audit & survey United Kingdom 4 ICUs; hospital not specified	Not reported Not reported Not applicable	Audit of tool completion: 75% completed within 12 hours of admission, 100% assessed 2-daily, 25% reassessed every 12 hours, 58% reassessed every 24 hours, 17% reassessed every 2 days. Nurse rating of ease of use (5-point scale, 1 = difficult, 5 = easy): ratings range 3 – 5, 65% rated 5 Psychometric properties not reported
			Secondary testing Theeranut *et al.* (2020)	Prospective descriptive comparison of 4 PI RASs (Braden, Braden [ALB], COMHON Index, CALCULATE) Thailand Internal medicine & surgical ICUs; tertiary care hospital	Thai patients ≥18 years, LOS ≥ 24 hours, APACHE II score < 35, no PI POA, without DNR order *n* = 288 2 trained nurse assessors, IRR of assessors analysed using kappa statistic prior to data collection (kappa = 1.0)	**7-item CALCULATE**: AUC 0.71 (95% CI 0.61-0.80), YI optimal cut-off ≥ 3, with sensitivity 68.75%, specificity 68.75%, PPV 21.57%, NPV 94.62%, LRP 2.2, LRN 0.45, YI 0.38 **8-item CALCULATE**: AUC 0.70 (95% CI 0.60-0.70) **Braden (ALB)**: AUC 0.69 (95% CI 0.61-0.78), YI optimal cut-off ≤ 13, with sensitivity 65.62%, specificity 73.04%, PPV 23.33%, NPV 94.44%, LRP 2.43, LRN 0.47, YI 0.38 **Braden**: AUC 0.65 (95% CI 0.56-0.74), YI optimal cut-off ≤ 12, with sensitivity 50%, specificity 80.15%, PPV 23.85%, NPV 92.85, LRP 2.52, LRN 0.62, YI 0.30 **COMHON**: AUC 0.61 (95% CI 0.52-0.70), YI optimal cut-off ≥ 14, with sensitivity 37.5%, specificity 83.98%, PPV 22.64%, NPV 91.49%, LRP 2.34, LRN 0.74, YI 0.21
			Secondary testing Souza *et al.* (2022)	Prospective cohort study comparison of Braden and CALCULATE Brazil 2 medical-surgical ICUs, 1 tertiary hospital	Patients ≥18 years, no PI on admission *n* = 51 Braden completed by ICU bedside nurses in standard care, CALCULATE completed by same researcher for each patient	**CALCULATE:** Day 1 AUC 0.91 (95% CI 0.82-0.99), Day 3 AUC 0.92 (95% CI 0.85-1.00); with YI cut off point ≥ 3 – sensitivity 89.7%, specificity 81.8%, PPV 86.7%, NPV 85.7% **Braden:** Day 1 AUC 0.71 (95% CI 0.56-0.86), Day 3 AUC 0.70 (95% CI 0.53-0.87); with YI cut off point ≤ 15 – sensitivity 72.4%, specificity 72.7%, PPV 71%, NPV 65%
CAVE (Cardiovascular-low Albumin-Ventilator-Edema) **score** (Ninbanphot	4-item: cardiovascular disease (score yes = 2.5, no = 0), serum albumin < 3.3mg/dl (score yes = 2, no = 0), mechanical ventilation (score yes = 1.5, no = 0), edema (score yes = 1, no = 0)	Potential sum score: 0-6.5 Suggested cut-off score: ≥2.5 at high PI	Initial testing	Prospective instrument development & validation Thailand Internal medicine	Thai patients ≥18 years, LOS ≥ 24 hours, APACHE II score < 35, no PI POA, without DNR order Validation study *n* = 270 2 trained nurse	YI & ROC curve: optimal cut-off score 2.5 Predictive validity overall: AUC 0.67 (states 'poor'), sensitivity 58.3%, specificity 67.1%, PPV 14.7%, NPV 94.3%, LRP 1.77, LRN 0.62 Predictive validity for cut-off ≥ 2.5: sensitivity 87.5%, specificity 61.3%, AUC 0.74, PPV 22%, NPV 97.5%, YI 0.49, LRP 2.26, LRN 0.20

et al., 2020)		risk		(development & validation) & surgical ICUs (development only); tertiary care hospital	assessors, IRR of assessors analysed using kappa statistic prior to data collection (kappa = 1.0)	
COMHON (Conscious level, mobility, haemodynamics, oxygenation, nutrition) **Index** (Cobos Vargas *et al.*, 2013) *(Reported in Spanish)*	5-item: level of consciousness (score 1-4), mobility (score 1-4), haemodynamic (score 1-4), oxygenation (score 1-4), nutrition (score 1-4) Preliminary version: 3 items removed (humidity, background, length of stay) as reliability correlation coefficient between items poor (*r* = 0.30)	Potential sum score: 5-20 Cut-off scores: 5-9 at low PI risk, 10-13 at moderate PI risk, 14-20 at high PI risk (cut-off scores confirmed via personal communication with lead author)	Initial testing	Prospective, cross-sectional instrument development & reliability & validity study Spain ICUs; 2 hospitals	LOS > 24 hours, not a hospital/unit transfer, no PI POA *n* = 496 (hospital 1 *n* = 250, hospital 2 *n* = 246 3 assessors' 1 hospital; 2 assessors' other hospital	Construct validity: Pearson's correlation coefficient $r > 0.30$ and $p < 0.05$ for 5 retained items (items with $r < 0.30$ discarded) Cut-off scores selected based on sensitivity/specificity balance Low risk scores 5-8 (ranges): sensitivity 97.1-100%, specificity 37-60.2%, PPV 20-27.7%, NPV 99.2-100% Revised low risk scores 5-9 (ranges): sensitivity 97.1-100%, specificity 37-73.2%, PPV 20-36.3%, NPV 99.4-100% Moderate risk scores 9-13 (ranges): sensitivity 47.1-97.1%, specificity 73.2-88%, PPV 36.3-38.1%, NPV 91.4-99.4% Revised moderate risk scores 10-13 (ranges): sensitivity 47.1-88.2%, specificity 79.2-88%, PPV 38.1-40%, NPV 91.4-97-7% High risk scores 14-20 (ranges): sensitivity 2.9-23.5%, specificity 90.7-98.2%, PPV 20-28.6%, NPV 86.5-88.3% Internal consistency reliability: states 'good', Cronbach's alpha coefficient 0.723 & 0.796 in each hospital Concurrent validity: **COMHON and Braden** *k* = 0.738 (95% CI 00.6571-0.8184) - *k* = 0.812 (95% CI 0.7410-0.8836); **COMHON and Norton** *k* = 0.721 (95% CI 0.6504-0.7925) & *k* = 0.733 (95% CI 0.6631-0.8034) IRR in each hospital: **COMHON** *k* = 0.8860 (95% CI 0.8281-0.9437) & *k* = 0.930 (95% CI 0.8839-0.9770); **Braden** *k* = 0.738 (95% CI 0.6571-0,8184) & *k* = 0.812 (95% CI 0.7410-0.8836); **Norton**: *k* = 0.721 (95% CI 0.6504-0.7925) & *k* = 0.733 (95% CI 0.6631-0.8034). COMHON IRR in each hospital for each scale item: consciousness *k* = 0.813 & 0.892, mobility *k* = 0.821 & 0.883, haemodynamics *k* = 0.979 & 1.000, oxygenation *k* = 0.923 & 0.979, nutrition *k* = 0.910 & 0.965 Predictive validity comparison: **COMHON** (cut-off score 9) sensitivity 97.1%, specificity 73.2%, PPV 36.3%, NPV 99.4%; **Braden** (cut-off score 16) sensitivity 82.4%, specificity 81.5%, PPV 41.2%, NPV 96.7%; **Norton** (cut-off score 14) sensitivity 100%, specificity 41.2%, PPV 21.1%, NPV 100%
			Secondary testing Fulbrook & Anderson (2016)	Prospective IRR comparison of 4 RASs Australia ICU; tertiary hospital	Convenience sample, no criteria reported *n* = 26 5 assessors	IRR & agreement for sum scores: **COMHON** ICC 0.90 (95% CI 0.83-0.95), SEM 1.32, MDC 3.65; **Braden** ICC 0.66 (95% CI 0.50-0.80), SEM 1.83, MDC 5.07; **Norton** ICC 0.77 (95% CI 0.65-0.88), SEM 1.34, MDC 3.73); **Waterlow** ICC 0.47 (95% CI 0.22-0.69) SEM 3.83, MDC 10.61 IRR & agreement also reported for subscale items Concurrent validity for sum scores: Correlations observed between **COMHON, Braden, Norton** (*r* > 0.50). Weakest correlations between **Waterlow and other RASs** (*r* 0.10-0.30).

						Concurrent validity for subscale items: Correlations between some subscale items of **COMHON, Braden, Norton** (mobility, neurological $r > 0.50$). Correlation between **Braden & COMHON** nutrition subscale $r = -0.46$. Weakest between **Waterlow and other RASs** (mobility, neurological, nutrition $r < 0.30$).
			Secondary testing Leal-Felipe *et al.* (2018)	Retrospective cohort study, comparison of 2 RASs Spain ICU; tertiary university hospital	No criteria reported; excluded where RASs assessments missing *n* = 2777 ICU staff (retrospective chart review)	Optimal cut-off points for PI development as per ROC: **COMHON =** 12; **EVARUCI** = 11.5 Predicative validity with 3-day moving average: **COMHON** 0.445, SD 0.075, $p = 0.008$; **EVARUCI** 0.438, SD 0.059, $p = 0.004$
			Secondary testing Theeranut *et al.* (2020)	Prospective descriptive comparison of 4 PI RASs (Braden, Braden [ALB], COMHON Index, CALCULATE) Thailand Internal medicine & surgical ICUs; tertiary care hospital	Thai patients ≥18 years, LOS ≥ 24 hours, APACHE II score < 35, no PI POA, without DNR order *n* = 288 2 trained nurse assessors, IRR of assessors analysed using kappa statistic prior to data collection (kappa = 1.0)	**COMHON**: AUC 0.61 (95% CI 0.52-0.70), YI optimal cut-off ≥ 14, with sensitivity 37.5%, specificity 83.98%, PPV 22.64%, NPV 91.49%, LRP 2.34, LRN 0.74, YI 0.21 **Braden (ALB)**: AUC 0.69 (95% CI 0.61-0.78), YI optimal cut-off ≤ 13, with sensitivity 65.62%, specificity 73.04%, PPV 23.33%, NPV 94.44%, LRP 2.43, LRN 0.47, YI 0.38 **Braden**: AUC 0.65 (95% CI 0.56-0.74), YI optimal cut-off ≤ 12, with sensitivity 50%, specificity 80.15%, PPV 23.85%, NPV 92.85, LRP 2.52, LRN 0.62, YI 0.30 **7-item CALCULATE**: AUC 0.71 (95% CI 0.61-0.80), YI optimal cut-off ≥ 3, with sensitivity 68.75%, specificity 68.75%, PPV 21.57%, NPV 94.62%, LRP 2.2, LRN 0.45, YI 0.38 **8-item CALCULATE**: AUC 0.70 (95% CI 0.60-0.70)
			Secondary testing Arroyo-López *et al.*, 2022	Retrospective cohort study Spain Adult ICU with cardiac, neurocritical surgery & multipurpose beds	Inpatients without PI on admission, LOS > 24 hours, with complete medical records *n* = 1335 Bedside nurses assess daily PI risk using COMHON Index in electronic system, overall score and moving average score calculated automatically	Logistic regression indicated moving average score a significant predictor for PI (OR 1.39, 95% CI 1.20-1.62, $p < 0.001$) Optimal cut off point ≥ 11 with YI, AUCC = 0.87 (95% CI 0.85-0.89; $p < 0.001$), sensitivity 94.94% (95% CI 87.5-98.6), specificity 76.91% (CI 74.5-79.2), LRP 4.11 (95% CI 3.7-4.6), LRN 0.066 (95% CI 0.03-0.2), PPV 20.5 (95% CI 18.8-22.5), NPV 99.6 (95% CI 98.9-99.8)
EFGU (Efteli Güneş) **Pressure Ulcer Risk Assessment Scale** (Efteli & Güneş, 2020)	7-item: skin status in areas exposed to pressure (score 0-2), incontinence (score 0-3), age (score 0-1), ability to make small movement/ position shifts in areas exposed to pressure (score 0-3), discomfort/pain sensation in areas exposed to pressure (score 0-2), diastolic blood pressure (score 0-1),	Potential sum score: 0-14 Suggested cut-off score: > 6 at high PI risk	Initial testing	Prospective instrument development & validation Turkey 5 ICUs (neurology, internal medicine, neurosurgery, orthopaedics,	> 18 years, without PI, bedbound, without inotropes/ vasopressors, expected LOS > 6 days *n* = 207 overall Interrater agreement	Construct validity: Pearson's correlation coefficient $r > 0.25$ and $p < 0.05$ for 7 retained items (items with $r < 0.30$ discarded) Interrater agreement: ICC 0.99 Reliability: Cronbach alpha coefficient 0.81, item-total correlation coefficient range 0.27-0.79 Predictive validity for cut-off > 6: sensitivity 97%, specificity 17%, PPV 69%, NPV 99%; diagnostic index 163.3, YI 0.80

	skin tolerance test (score 0-2) Preliminary version: 8th item removed (diabetes, score 0-1) as reliability correlation coefficient between items poor (*r* = 0.18)			trauma); university hospital	assessed prior to overall study with 2 trained nurses assessing *n* = 30 patients; but unclear who completed assessments for overall validation study	
EVARUCI (Current Risk Assessment Scale for Pressure Injury in Intensive Care) (González-Ruiz *et al.*, 2001)	5-item plus LOS: consciousness (score 1-4), haemodynamics (score 1-4), respiratory status (score 1-4), mobility (score 1-4), other (score 1 for each of the following present; temperature > 38°C, oxygen saturation < 90%, systolic blood pressure < 100mmHg, skin condition, prone position), plus 0.5 points for each week of ICU LOS up to 2 points (as reported by Lospitao-Gómez *et al.* (2017) & Souza *et al.* (2018))	Potential sum score: 4-23 Suggested cut-off score ≥ 10 (as reported by Lospitao-Gómez *et al.* (2017) & Souza *et al.* (2018))	Not tested with initial development			
			Secondary testing González-Ruíz *et al.* (2004) *Reported in Spanish)*	Reliability study, t*ranslation not available* Spain *Translation not available*	*Translation not available* *Translation not available* *Translation not available*	IRR: ICC 0.9762 *Translation not available for full results*
			Secondary testing González-Ruíz *et al.* (2008) *(Reported in Spanish)*	Prospective, descriptive validity study Spain *Translation not available*	*Translation not available* *n* = 97 *Translation not available*	Predictive validity of mean, initial & final EVARUCI assessment: sensitivity (100%, 100%, 90.91%), specificity (68.63%, 49.02%, 92.16%), PPV (40.74%, 29.73%, 71.43%) NPV (100%, 100%, 97.2%), AUC 0.938, 0.909, 0.952 *Translation not available for full results*
			Secondary testing Leal-Felipe *et al.* (2018)	Retrospective cohort study, comparison of 2 RASs Spain ICU; tertiary university hospital	No criteria reported; excluded where RASs assessments missing *n* = 2777 ICU staff (retrospective chart review)	Optimal cut-off points for PI development as per ROC: **EVARUCI** = 11.5; **COMHON =** 12 Predictive validity with 3-day moving average: **EVARUCI** 0.438, SD 0.059, *p* = 0.004; **COMHON** 0.445, SD 0.075, *p* = 0.008
			Secondary testing Lospitao-Gómez *et al.* (2017)	Prospective, descriptive validity study of 2 RASs Spain Adult ICU; university hospital	None *n* = 2534 ICU staff nurses	Predictive validity: EVARUCI with cut-off score 10, sensitivity 80.43% (95% CI 79.15–81.72), specificity 64.41 (95% CI 63.68–65.14), PPV 33.71%, NPV of 93.60%, AUC-ROC 0.756 (95% CI 0.749-0.764) Norton-MI with cut-off score 14, sensitivity 94.05% (95% CI 93.28–94.82), specificity 40.47% (95% CI 39.72–41.22), PPV 26.22%, NPV 96.80%, AUC-ROC 0.774 (95% CI 0.766-0.781) Predictive validity value for all other scores also reported

			Secondary testing Souza *et al.* (2018)	Transcultural adaption (to Brazilian Portuguese) & reliability study Brazil 2 general & 1 neurological ICU; university hospital	≥18 years, no PI POA, without brain death Internal consistency *n* = 207 overall, IRR *n* = 30 Unclear for internal consistency ? ICU staff, 3 nurse assessors for IRR	Overall internal consistency: Cronbach's alpha 0.782, states 'acceptable' Subscale internal consistency Cronbach's alpha values: consciousness 0.668; hemodynamic status 0.751; respiratory status 0.686; mobility 0.768; and other 0.801, states consciousness & respiratory status 'questionable' IRR: ICC 0.980 Mean rating time: rater 1, 4.5 minutes; rater 2, 3.6 minutes; rater 3, 4.4 minutes
			Secondary testing Roca-Biosca *et al.* (2015a) *(Reported in Spanish)*	Observational, longitudinal IRR study of 2 RASs Spain ICU; university hospital	*n* = 72 Not reported 2 assessors from research team (pool of 6 ICU nurses), 4 daily assessments	IRR: **EVARUCI** ICC 0.99 (95% CI 0.989-0.994); **EMINA** 0.92 (95% CI 0.90-0.93) Kappa values for subscale items also reported
			Secondary testing Roca-Biosca *et al.* (2015b) *(Reported in Spanish)*	Prospective validity study of 2 RASs Spain ICU; reference hospital	≥18 years, no PI *n* = 189 *Translation not available*	Predictive validity for mean of assessments: **EVARUCI** with cut-off score > 11 sensitivity 92.45 (95% CI 84.40-100), specificity 42.96 (95% CI 34.24-51.68); **EMINA** with cut-off score > 10 sensitivity 94.34 (95% CI 87.17-100), specificity 33.33 (95% CI 25.01-41.66) *Translation not available for full results*
RAPS-ICU (Risk Assessment Pressure Ulcer Scale – ICU) (Wåhlin *et al.*, 2020)	6-item: failure in vital organs (score 1-3), mobility (score 1-4), moisture due to e.g. sweat, urine, faeces (score 1-4), sensory perception (score 1-4), special treatment in form of ventilator, dialysis and/or inotropes (score 1-4), level of consciousness (score 1-4) Preliminary version: 3 items removed as no significant association with PI (S-albumin, score 1-4; body temperature, score score 1-2; BMI, score 2-4)	Potential sum score: 6-23 Suggested cut-off score: ≤ 18 at risk (further suggest ≤ 15 high PI risk, ≤ 12 very high PI risk)	Initial testing	Prospective instrument development & validation Sweden 5 ICUs (3 general, 2 neuro, 1 burns); 2 county hospitals & 1 university hospital	≥18 years *n* = 300 overall IRR of preliminary 9-item instrument with different sets of 2 nurse assessors on *n* = 50 patients; nurse in charge conducted assessments for overall study	Construct validity: 3-items removed from preliminary version as not predictive of PI (authors don't refer to construct validity specifically) IRR only on preliminary 9-item: sum score ICC 0.96 (95% CI 0.93-0.98), $p < 0.001$ Predictive validity: Higher scores significantly associated with lower odds of PI (OR = 0.83, 95% CI = 0.77–0.90, p < 0.001). YI: optimal cut-off score 17.5 Predictive validity for cut-off ≤17: sensitivity 80%, specificity 49% Predictive validity for cut-off ≤18: sensitivity 88%, specificity 37%

Acute Physiology and Chronic Health Evaluation = APACHE, AUC = area under the receiver operating characteristic curve, BMI = body mass index, confidence interval = CI, do not resuscitate = DNR, ICC = intraclass correlations, ICU = intensive care unit, IRR = inter-rater reliability, LOS = length of stay, LR = likelihood ratio, LRN = likelihood ratio negative, LRP = likelihood ratio positive, MDC = minimally detectable change, NPV = negative predictive value, OR = odds ratio, PI = pressure injury, POA = present on admission, PPV = positive predictive value, RAS = risk assessment scale, ROC = receiver operating characteristic, SD = standard deviation, SEM = standard errors of measurement, YI = Youden index

Of the six intensive-care-specific risk assessment scales presented in Table 1.2, half (CAVE score, Ninbanphot *et al.*, 2020; EFGU scale, Efteli & Güneş, 2020; RAPS-ICU, Wåhlin *et al.*, 2020) have only been tested by one study. Thus, similarly to many of those reviewed by Garcia-Fernandez *et al.* (2013), they cannot be considered as validated. Of these, one was tested in terms of interrater reliability and construct and predictive validity (Wåhlin *et al.*, 2020), while the second (EFGU) was tested for reliability (internal consistency and interrater reliability) and construct and predictive validity (Efteli & Güneş, 2020). Both demonstrated high rates of interrater reliability (intraclass correlation coefficient [ICC] 0.99, Efteli & Güneş, 2020; ICC 0.96, Wåhlin *et al.*, 2020), but interrater reliability testing was undertaken with smaller sample portions of the overall studies. The third study tested predictive validity alone (Ninbanphot *et al.*, 2020).

The use of predictive validity is a common theme across the testing of risk assessment scales (e.g. Adibelli & Korkmaz, 2019; Efteli & Güneş, 2020; García-Fernández *et al.*, 2014; Han *et al.*, 2018; Hyun *et al.*, 2013; Ninbanphot *et al.*, 2020; Ranzani *et al.*, 2016; Sanada *et al.*, 2008; Wei *et al.*, 2020; Zhang, Zhuang *et al.*, 2021). However, as noted in PI prevention (section 1.2.1.6, pp. 8-10), PI risk assessment scales should underpin the use of preventative interventions, which in turn should theoretically prevent PI (Lovegrove, Miles & Fulbrook, 2018); thus, any notion of 'predicting' PI is confounded. Indeed, while two studies concluded their respective scales had 'excellent discrimination power', 'high sensitivity and specificity' (Efteli & Güneş, 2020) and 'good sensitivity and acceptable specificity' (Wåhlin *et al.*, 2020), both note that some of their predictive validity values may have been impacted by successful prevention practices. Subsequently, studies of predictive validity alone should be interpreted within this context, and other psychometric properties considered. Another property which may not be relevant is the use of internal consistency, which examines the extent to which subscales of a scale are homogenous and measure the same/overall construct (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c McClure, 2020). Pressure injury risk as a construct is multidimensional and thus subscales are not necessarily required to be interrelated, yet are all important (Kottner & Streiner, 2010; Streiner & Kottner, 2014). The psychometric properties of the fourth scale (CALCULATE, Richardson & Barrow, 2015a; Richardson & Barrow, 2015b) were not tested or reported by its developers. Two secondary studies did examine the predictive validity of the CALCULATE in comparison to the Braden, Braden (ALB) and the COMHON Index (Theeranut *et al.*, 2020), and the Braden scale alone (Souza *et al.*, 2022). But again, the comparison was limited to the confines of predictive validity.

The remaining two scales (COMHON Index, Cobos Vargas *et al.*, 2013; EVARUCI, González-Ruíz *et al.*, 2004) were more widely tested in terms of psychometric properties and multiple studies. The EVARUCI was initially developed in Spain (González-Ruiz *et al.*, 2001; Lospitao-Gómez *et al.*, 2017; Souza *et al.*, 2018). While discounted by García-Fernández *et al.* (2013) as unvalidated, the scale has since

undergone further testing. In Spain, the EVARUCI scale has demonstrated high rates of interrater reliability alone (ICC 0.98; González-Ruíz *et al.* 2004), and in comparison to a non-intensive care-specific instrument, the EMINA scale (EVARUCI ICC 0.99, EMINA ICC 0.92; Roca-Biosca *et al.*, 2015a). Furthermore, it has been formally translated into Brazilian Portuguese and tested within a Brazilian intensive care setting, yielding a high rate of interrater reliability (ICC 0.98) and 'acceptable' overall internal consistency (Cronbach's alpha 0.78); although, the authors interpreted the internal consistency of two subscales (consciousness; respiratory status) as 'questionable' (Cronbach's alpha 0.67 and 0.69, respectively) (Souza *et al.*, 2018). However, further studies were again limited to predictive validity (González-Ruíz *et al.* 2008; Leal-Felipe *et al.*, 2018; Lospitao-Gómez *et al.*, 2017; Roca-Biosca *et al.*, 2015b), and other types of validity have not been reported (i.e. concurrent, construct). As well, the ability of clinicians to translate the findings of Spanish reports into practice internationally is limited by access and translation difficulties.

The COMHON Index, also developed in Spain, has been the most thoroughly examined in terms of psychometric properties, in addition to predictive validity and internal consistency. The Spanish report also details interrater reliability, content validity, construct validity and concurrent validity (Cobos Vargas *et al.*, 2013). Cobos Vargas *et al.* (2013) note content validity of the COMHON is supported by other scales and previous studies, a point not acknowledged for other scales. Internal consistency was 'good' (Cronbach's alpha 0.72 and 0.80 in two hospitals), as was interrater reliability (κ = 0.89-0.93) which was superior to that of the Braden and Norton scales; although interrater reliability was measured using kappa statistics, while ICC is preferable (Fulbrook & Anderson, 2016; Kottner & Dassen, 2010). The COMHON Index is also the only scale which has been correlated to other commonly used scales (i.e. Braden, Norton, Waterlow). In initial testing, the scale was strongly correlated with the Braden and Norton instruments (Cobos Vargas *et al.*, 2013). Furthermore, the scale has been translated to English, and has been tested in an Australian intensive care setting for interrater reliability with ICC, and concurrent validity with the Braden scale, Norton scale and Waterlow score (Fulbrook & Anderson, 2016). While this second (independent) study was small, it was adequately powered with the use of five (5) nurse assessors for each patient (Fulbrook & Anderson, 2016). The COMHON was found to be superior to the three comparison scales, with an ICC of 0.90 (Braden ICC 0.66; Norton ICC 0.77; Waterlow ICC 0.47). It was also found to have strong correlations to the Braden and Norton scales (i.e. concurrent validity), but not the Waterlow score. Moreover, the authors concluded that the COMHON Index is more sensitive to small changes in patient condition, which would subsequently be reflected in PI risk status. This is particularly relevant, given that it has been acknowledged that the Braden scale may not be able to detect such changes in this specialty population (Richardson & Barrow, 2015a).

Elsewhere, it has been found that other scales (CALCULATE; Braden [ALB]) are superior to the

COMHON Index (Theeranut *et al.*, 2020); while conversely, another study found that the COMHON Index outperformed the EVARUCI in terms of predictive efficacy on a three-day moving average (Leal-Felipe *et al.*, 2018). Similarly, a third study found that using the COMHON Index with a three day-moving average was efficacious in predicting PI (Arroyo-López *et al.*, 2022). However, these studies were both based on predictive validity. Furthermore, the authors of one study (Theeranut *et al.*, 2020) assigned their own cut-off scores rather than those suggested by instrument developers, while another also reported the predictive validity of a different cut off score for identifying at risk patients using a moving average (Arroyo-López *et al.*, 2022). Overall, of these recently developed and tested PI risk assessment scales, the COMHON Index has been the most thoroughly tested, and has demonstrated reliability and validity in Spanish (Cobos Vargas *et al.*, 2013) and Australian (Fulbrook & Anderson, 2016) intensive care settings. It is also important to again emphasise that it is not PI risk assessment alone which prevents PI, but the use of preventative interventions. Consequently, these scales need to be considered in terms of their impact on guiding the use of PI preventative interventions. Therefore, the program of research presented here links PI risk assessment using the COMHON Index to the selection of PI preventative interventions based on risk.

1.2.2.3.2 Pressure injury preventative interventions

PI risk assessment is followed by and guides the prescription and implementation of PI preventative interventions (Lovegrove, Miles & Fulbrook, 2018). As described in section 1.2.1.6 (pp. 8-10), available PI preventative interventions are wide ranging, and most comprehensively described by the international PI prevention and treatment guideline (EPUAP *et al.*, 2019). It is notable though, that the supporting evidence for individual PI preventative interventions varies in strength (EPUAP *et al.*, 2019). The international guideline recognises critically ill individuals as a population with specific PI-related needs and acknowledges that such individuals are particularly vulnerable to PI (EPUAP *et al.*, 2019). Thus, it is noted that, along with general preventative measures, there is a need for intensified or additional preventative interventions for the critically ill (EPUAP *et al.*, 2019). Particular mention is also made of the relevance of medical-device related PI prevention and use of prophylactic dressings in this population (EPUAP *et al.*, 2019, p. 29). However, in the main, evidence for each intervention type and recommendation is synthesised across settings, rather than specifically for each individual setting (e.g. separate evidence syntheses for aged care and critical care). Only two PI preventative intervention recommendations are made specifically for critically individuals (EPUAP *et al.*, 2019, p. 134):

- 5.17: Reposition unstable critically ill individuals who can be repositioned using slow, gradual turns to allow time for stabilization of hemodynamic and oxygenation status
- 5.18: Initiate frequent small shifts in body position for unstable critically ill individuals who are too unstable to maintain a regular repositioning schedule, and to supplement regular repositioning.

Many systematic reviews also synthesise evidence across various settings (e.g. Cochrane reviews, Gillespie *et al.*, 2020, Langer & Fink, 2014; McInnes *et al.*, 2015, Moore & Webster, 2018, Shi, Dumville, Cullum, Rhodes, Leung & McInnes, 2021; Shi, Dumville, Cullum, Rhodes, Jammali-Blasi & McInnes, 2021; other systematic reviews, Avsar *et al.*, 2020, Kim, Kim *et al.*, 2022; Shi *et al.*, 2018). While such reviews are still relevant, intensive care populations are inherently different to others; thus, intensive care-specific syntheses and studies are required (Llaurado-Serra & Labeau, 2021; Tayyib & Coyer, 2016). Two systematic reviews have examined the use of preventative interventions within intensive care alone (Alshahrani *et al.*, 2021; Tayyib & Coyer, 2016). The earlier review included 25 studies and meta-analysis revealed supporting evidence for the use of prophylactic dressings (sacral and heel) within intensive care (Tayyib & Coyer, 2016). For sacral prophylactic dressings, this is congruent with the results of a more recent systematic review, which found that dressing use decreased risk of sacral PI by 83% in intensive care (Fulbrook, Mbuzi & Miles, 2019). However, Tayyib and Coyer (2016) noted that evidence of the effectiveness of nutritional, skin care, positioning/repositioning, support surface and educational interventions was limited. The more recent systematic review identified only 14 studies for inclusion, which were categorised into four intervention types; PI prevention bundles, repositioning and support surface use, device-related PI prevention and access to expert nurses (Alshahrani *et al.*, 2021). While most individual studies reported a decrease in PI incidence, the results were limited to a narrative synthesis (Alshahrani *et al.*, 2021). It is of note that the searches of Alshahrani *et al.* (2021) yielded fewer included studies than the former review, suggesting the search strategy may not have been sufficiently comprehensive. As well, these systematic reviews were limited in that they both included lower levels of evidence, one did not report time limiters and its protocol was registered retrospectively (Alshahrani *et al.*, 2021) while the other was limited to the years 2000 to 2015 (Tayyib & Coyer, 2016).

Similarly, lacking and low-quality evidence for PI prevention has been noted in research across settings (Walker *et al.*, 2020). Regardless, critically ill individuals should be provided with PI preventative interventions (EPUAP *et al.*, 2019). Recently, studies have indicated that PI preventative measures may be well implemented (Jacq *et al.*, 2021; Yarad *et al.*, 2021). Jacq *et al.* (2021) found that 91.5% of patients surveyed (*n* = 1228) in 86 French intensive care units had an 'antiulcer' mattress in place, the majority of which were active support surfaces. Yarad *et al.* (2021) found that all surveyed Australian and New Zealand intensive care units used PI preventative mattresses, with all patients (*n* = 671) having one *in situ*; although, both studies only observed mattress use. However, the identification of barriers to PI prevention within intensive care in other studies, such as time demands, heavy workload and patient acuity, suggests that PI prevention may not always be well implemented (Coyer *et al.*, 2019; Mirshekari *et al.*, 2017; Tayyib *et al.*, 2016).

While the effectiveness of many individual PI preventative interventions has not been well established

within intensive care (Alshahrani *et al.*, 2021; Tayyib & Coyer, 2016), the effectiveness of bundled interventions has more support (Lin *et al.*, 2020). Care bundles, or programs, involve the simultaneous use of a set of evidence-based interventions, targeted at improving patient care or outcomes (Resar *et al.*, 2012), such as PI prevention. A systematic review of multicomponent PI prevention programs within intensive care identified an evidence-base of 20 studies (21 papers) for such programs (Lin *et al.*, 2020). While the majority of studies were quality improvement projects, and high-quality further research is required, the results indicate that the use of such programs, or bundles, is effective to reduce PI within intensive care (Lin *et al.*, 2020). Furthermore, several of the included studies found that use of the tested program resulted in a significant increase in compliance with PI prevention (Lin *et al.*, 2020).

However, while most of the reported bundles included in the review by Lin *et al.* (2020) included PI risk assessment, use of a specific PI risk assessment scale was not stated. As well, the outcome of the risk assessment did not underpin the use of preventative interventions, meaning that the risk assessment itself was largely redundant. Bundled interventions and actions were generally applied either to all patients regardless of risk, or to patients 'at risk' overall. While this non-selective approach, on the whole, may prevent PI, it is not individualised and may result in inappropriate resource allocation (over- or under-use of interventions) (Lovegrove *et al.*, 2018; Lovegrove, Ven *et al.*, 2021). This carries significant implications for patient safety or, alternatively, resource costs. As such, while there is an indication of the potential benefit of care bundle use, further research is warranted, particularly in terms of risk-based care bundling.

1.3 The knowledge and practice gap

Against this background, it was evident that while several intensive-care specific PI risk assessment scales are available, they are underused. For example, a national survey of PI prevention practices in Australian intensive care units found that across 70 intensive care units, the most used scales were the Braden and Waterlow, and no intensive care-specific scales were utilised (Levido *et al.*, 2021). As well, such scales have not been considered and tested in terms of subsequent intervention use, particularly risk-based intervention use. Thus, the researcher was interested in the future use of an intensive care-specific PI risk assessment scale combined with the matching of PI preventative interventions to the assessed risk level. This is the topic of the program of research presented in this thesis.

As emphasised previously, the first step of PI prevention is a risk assessment, followed by the prescription and implementation of PI preventative interventions to mitigate the identified risk (Lovegrove, Miles & Fulbrook, 2018). A PI risk assessment may be aided by the use of a risk assessment scale, in combination with clinical judgement (EPUAP *et al.*, 2019; Lovegrove, Miles & Fulbrook, 2018; Moore & Patton, 2019). However, previously, there have been few available tested and validated PI risk assessment scales specific to intensive care (Cox, 2020; García-Fernández *et al.*, 2013; Keller *et al.*,

2002). Consequently, non-specific scales do not take into account intensive-care specific risk factors (Cox, 2020; Cox *et al.*, 2020). More recently, several intensive care-specific PI risk assessment scales have emerged and/or been further tested to a varying degree (Cobos Vargas *et al.*, 2013; González-Ruiz *et al.*, 2001; Ninbanphot *et al.*, 2020; Richardson & Barrow, 2015a; Wåhlin *et al.*, 2020). A review of the available intensive care-specific PI risk assessment scales (section 1.2.2.3.1.1, pp. 20-30) indicated that the COMHON Index has been the most thoroughly tested in terms of psychometric properties, demonstrating reliability and validity in Spanish (Cobos Vargas *et al.*, 2013) and Australian (Fulbrook & Anderson, 2016) intensive care settings. It was therefore selected for this program of research.

The COMHON Index (original version, Appendix A) is used to assess five subscales related to PI risk within intensive care, which provide the acronym for this scale (Cobos Vargas *et al.*, 2013; Fulbrook & Anderson, 2016):

- level of COnsciousness as measured by the Richmond Agitation Sedation Scale (Sessler *et al.*, 2002)
- Mobility (e.g. independent, limited, unable to reposition)
- Haemodynamic support (e.g. vasoactive medication use, intravenous fluid use, mechanical support)
- Oxygenation (e.g. invasive and non-invasive oxygenation, spontaneous breathing)
- Nutrition (e.g. oral, parenteral, enteral)

The instrument provides subscale definitions and explanations to aid scoring. Each of the subscales is scored from one to four, from which subscales are summed into a sum score of between five to 20 (Cobos Vargas *et al.*, 2013; Fulbrook & Anderson, 2016). Individual level of risk is then categorised based on the final sum score (Cobos Vargas *et al.*, 2013; Fulbrook & Anderson, 2016):

- Low risk – score 5 to 9
- Moderate risk – score 10 to 13
- High risk – score 14 to 20.

Once level of risk has been identified, the selection and implementation of PI preventative interventions should follow (Lovegrove, Miles & Fulbrook, 2018). While previous research has indicated that the evidence supporting the effectiveness of individual PI preventative interventions within intensive care is limited (Alshahrani *et al.*, 2021; Tayyib & Coyer, 2016), the evidence-base does indicate that bundled interventions for PI prevention are effective in reducing PI occurrence within intensive care (Lin *et al.*, 2020). As noted however, previously tested bundled interventions and actions were generally either applied to all patients, regardless or risk, or to patients 'at risk' overall. Alternatively, a risk-based approach to bundling may be more individualised and assist appropriate resource allocation. The COMHON Index categorises patients as low, medium or high PI

risk (Cobos Vargas *et al.*, 2013), presenting an opportunity for interventions to be applied relative to PI risk level. This approach was suggested for hospital ward populations following a descriptive, exploratory study in an Australian hospital (Lovegrove, Fulbrook & Miles, 2018). The study revealed that nurses tended to prescribe more PI preventative interventions as risk level increased, but that overall preventative intervention prescription was inadequate to appropriately mitigate patient risk. The authors suggested that bundling a *minimum* set of interventions relative to level of risk may improve preventative intervention use and address varying levels of risk.

Indeed, such a bundle (or minimum intervention set) would ensure that, *at a minimum*, critically ill individuals admitted to intensive care would have a set of PI preventative interventions selected and implemented based on their individual level of PI risk, as assessed by the COMHON Index. This may also positively contribute to overcoming the inadequate application of interventions resulting from known barriers to PI preventative care (Adibelli & Korkmaz, 2022; Awoke *et al.*, 2022; Coyer *et al.*, 2019; Johansen *et al.*, 2022; Mirshekari *et al.*, 2017; Tayyib *et al.*, 2016), while additional interventions may be provided as required. For example, if intensive care nurses have inadequate PI prevention knowledge (Araújo *et al.*, 2022; Azhar *et al.*, 2022; Hu, Sae-Sia & Kitrungrote, 2021a; Khojastehfar *et al.*, 2020; Tayyib *et al.*, 2016), it then follows that PI preventative interventions may not be appropriately prescribed and implemented based on individual risk. Even where nurses do have PI prevention knowledge, such knowledge is not necessarily translated into practice and implemented (Ghazanfari *et al.*, 2022; Saleh *et al.*, 2019). For example, a qualitative study which interviewed nine intensive care nurses in Turkey found that not only did the PI risk assessment of nurses lack structure, comprehensiveness and replicability as they deviated from use of scales, but also that PI preventative practices were not congruent with evidence-based recommendations and intervention implementation was suboptimal (Adibelli & Korkmaz, 2022).

If a standard set of risk-stratified interventions were in place to guide practice, such situations and threats to patient safety would be diminished, while more experienced or knowledgeable nurses would be able to individualise the interventions as required. From a resourcing perspective, following an approach that applies all interventions to all patients, or patients 'at risk' overall, may be costly and resource intensive. A before and after study in a Turkish intensive care unit found that implementation of a PI prevention bundle not only decreased PI incidence, although not significantly, but also significantly decreased nursing workload costs (Yilmazer & Tuzer, 2022b). However, the bundle was not risk-stratified, which may have further improved PI incidence while also resulting in greater cost decreases and resourcing improvements. Padula and colleagues (2019) examined the cost-effectiveness of repeated risk assessment at all levels of PI risk, repeated risk assessments at higher levels of risk only, and standard care. The authors found that repeated PI risk assessment of all patients was most cost-effective, while both all-patient and risk-stratified risk assessment approaches were

superior to standard care. However, risk-stratification was used to 'cut-off' those at lower levels of PI risk from the assessments, rather than decreasing the intensity of interventions (or assessment). Furthermore, despite labelling it 'risk-stratified prevention', this appears to only be for the frequency of PI risk assessment and has not taken into account implementation of preventative interventions. While the study certainly supports PI risk assessment for all, a risk-stratified bundle of interventions warrants further investigation.

To reiterate, setting-specific risk-stratification of PI preventative interventions within intensive care may carry several benefits. Firstly, underpinning a bundle of interventions with use of an intensive care PI risk assessment scale ensures appropriate PI risk assessment and subsequent outcomes for the population of interest. Importantly, PI risk assessment is used to underpin the implementation of PI preventative interventions based on risk (i.e. risk-stratification), ensuring all critically ill individuals admitted to an intensive care unit have a set of PI preventative interventions applied relative to their assessed level of risk *at a bare minimum*. This may assist to overcome barriers to PI prevention (e.g. nurses knowledge) thus protecting patients from potentially avoidable harm. In other words, such a bundle should ensure interventions are not under-utilised resulting in patient harm, while also preventing over-use of resources which may be costly and wasteful. Interventions may also then be adapted based on individual requirements. Overall, it is this linking of PI risk assessment with an intervention bundle for intensive care that is the focus of this program of research.

1.4 Research problem

Prior to a minimum intervention set being developed, preventative interventions which are effective in preventing PI would first need to be identified for inclusion. As noted, there has previously been little high-level evidence demonstrating the effectiveness of individual PI preventative interventions within intensive care and previous systematic reviews have been limited with the inclusion of lower levels of evidence and time restrictions (Alshahrani *et al.*, 2021; Tayyib & Coyer, 2016). Thus, there is a need to examine high-level evidence (randomised controlled trials) about the testing of interventions within the wider acute hospital setting for potential inclusion in a minimum intervention set.

Once such a minimum intervention set has been developed, it would require testing. A limitation of previous research has been that bundles have been tested in single settings or countries. Consequently, their results are not internationally generalisable, and it would be of benefit to test bundles on an international scale. The COMHON Index was developed in Spanish, and has since been translated into English, enabling the potential development of a minimum intervention set within these languages and across countries speaking these languages. While English and Spanish are the first and fourth most spoken languages respectively in terms of native and non-native speakers, Chinese Mandarin is the second most spoken language in this respect and is the largest language when counting only native speakers (Eberhard *et al.*, 2022). The COMHON Index is not yet available in Chinese

Mandarin, which is an issue requiring address.

Therefore, the research problem identified is the need to develop a specific bundle of interventions for use in intensive care settings, that is linked to risk levels determined by an intensive care-specific risk assessment. To break this into steps, there is a need to:

1. Determine which PI preventative interventions have demonstrated effectiveness in acute hospital and intensive care settings in randomised controlled trials.
2. Establish which interventions should be implemented for each COMHON Index level of risk in intensive care patients (thus establishing a minimum set of preventative interventions for application relative to risk level).
3. In preparation for international testing of the developed minimum intervention set for application relative to risk level, translate the COMHON Index into Chinese Mandarin and test the translated instrument.

Within this context, the following overall research question, aim and objectives were developed.

1.5 Research question

What interventions should be applied relative to the level of PI risk for critically ill patients, as determined by an intensive care-specific PI risk assessment scale (the COMHON Index), and as part of a minimum set of PI preventative interventions for international use within intensive care units?

1.5.1 Research Aims and Objectives

To address the research question, the overall aim of this program of research is to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care units.

This encompasses the following objectives:

1. To identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.
2. To develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index.
3. To translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale.

1.6 Program of research

To address this overarching research question and aim, and its associated objectives, a three-phase program of research was developed and completed. Each phase was designed to address one of the

overarching research objectives. Then, individually, each phase is underpinned by its own, more specific research objectives.

1. **Phase One:** To address the first objective and identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings, a systematic review and meta-analysis was undertaken.
2. **Phase Two:** To address the second objective, a modified Delphi study was conducted to identify which PI preventative interventions identified in Phase One should be applied relative to each COMHON Index level of PI risk in a minimum PI preventative intervention set, as determined by international consensus.
3. **Phase Three:** To address the third objective, the COMHON Index was translated into Chinese Mandarin using a formal process, and a concurrent validity study was undertaken to test the translated version in a Chinese intensive care setting against the widely used Braden scale.

1.7 Conclusion

Chapter One has presented an overview of PI and PI prevention across settings, and more specifically, within critically ill individuals and intensive care. These individuals are particularly vulnerable to PI development due to risk factors associated with their critical illness and the life-sustaining treatments required within intensive care. Given the negative implications of PI, prevention within this setting is fundamental to clinical care quality and patient safety. Pressure injury prevention is underpinned by a risk assessment, which in turn guides the selection and implementation of preventative interventions. While there was an evidence-base supporting the effectiveness of PI prevention bundles in intensive care, most bundles were not previously targeted at individual level of PI risk. Thus, the impetus to develop a minimum PI preventative intervention set for application relative to intensive care patients identified level of PI risk arose. Furthermore, once developed, the minimum PI preventative intervention set would require testing within intensive care units internationally. The selected PI risk assessment scale, the COMHON Index, has not previously been available in one of the most commonly spoken languages in the world, Chinese Mandarin. Thus, the need for a formal translation into Chinese Mandarin was also identified. An overarching research question, and associated aim and objectives were developed within this context.

To address this overarching research question and aim, and its associated objectives, the following chapters present a three-phase program of research.

These chapters are presented across ***four parts*** within this thesis:

1. **Part One (Phase One):** To address the first objective, *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings*, a systematic review and meta-analysis was undertaken. The methodology and extended methods for this phase are detailed in Chapter Two, and the corresponding published papers (Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022) are set forth in Chapters Three and Four. Searches were later updated for the contemporaneity of this thesis, the results of which are presented in Chapter Five.
2. **Part Two (Phase Two)**: Phase Two entailed a modified Delphi study, conducted to identify which PI preventative interventions identified in Phase One should be applied relative to each COMHON Index level of PI risk. Phase Two addressed the objective *to develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index*. The Phase Two methodology and extended methods are described in Chapter Six, an overview of intervention identification selection is detailed in Chapter Seven, and the published paper (Lovegrove *et al.*, 2020) is presented in Chapter Eight.

3. **Part Three (Phase Three):** The third phase, a translation and concurrent validity study, was undertaken to address the objective *to translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale*. The Phase Three methodology and extended methods are detailed in Chapter Nine. The translation of the COMHON Index from English into Chinese Mandarin is presented as a published paper (Lovegrove, Fulbrook, Miles, Steele & Liu *et al.*, 2022) in Chapter Ten, and the concurrent validity study results are provided in Chapter Eleven.
4. **Part Four (Discussion and Conclusions):** Chapter Twelve presents a synthesised discussion of the results from the overall program of research, relates these results to the wider evidence-base, highlights the strengths and limitations of the program of research, and concludes with recommendations for future practice.

As the methodology for each phase is presented at the beginning of each respective thesis part, there is some duplication where the research design of the phase is situated within that of the overall program of research. Similarly, there is some duplication between the phase-specific methodology chapters, and the reporting of the phase in a published study report. However, this has been minimised as much as possible in respect to the methods. Full lists of publications, conference presentations and higher degree research seminars stemming from this program of research are detailed in the Research Portfolio Appendices (A, B). The next chapter will begin the introduction of Phase One.

PART ONE: PHASE ONE

Chapter Two: Phase One: Methodology

2.1 Introduction

The research problem was established in Chapter One, within the context of the theoretical background. Based on the established research problem, a research question, aim and objectives were developed, which were subsequently addressed by a three-phase program of research.

1. **Phase One: Systematic review and meta-analysis**
2. Phase Two: Modified Delphi study
3. Phase Three: Translation and concurrent validity study.

This chapter presents the methodology and rationale of **Phase One**. Additionally, extended methods are also presented to support the full methods described in the corresponding publications.

To set the scene for this chapter, the overall research question, aim and objectives are re-presented, and the research design of Phase One is situated against the overall design of the program of research. Further detail on each following phases is provided in future chapters.

2.2 Overall research question

What interventions should be applied relative to critically ill patients' PI level of risk, as determined by an intensive care-specific risk assessment scale (the COMHON Index), as part of a minimum set of PI preventative interventions for international use within intensive care units?

2.2.1 Overall research aim and objectives

The overall aim of this program of research is to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care units.

This encompasses the following objectives:

1. To identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.
2. To develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index.
3. To translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale.

2.3 Research design

In order to address the overall research question and aim, an interlinked three-phase program of quantitative research was designed with each phase addressing one of the research objectives. Prior to establishing international consensus about a minimum PI prevention set, PI preventative interventions which are effective in preventing PI in adults admitted to acute hospital and intensive care settings needed to be identified, to form the basis of the minimum intervention set. Once developed, the minimum PI preventative intervention set would require testing on an international scale, but the COMHON Index is not yet available in one of the most commonly spoken languages globally, Chinese Mandarin. To this end, the three-phase program of research was developed.

In the context of **Phase One** and to address the first research objective, a systematic review and meta-analysis of randomised controlled trials was undertaken to identify and synthesise high level evidence demonstrating the effect of PI preventative interventions in adult acute hospital and intensive care inpatients. While the minimum PI preventative intervention set is intended for use within an intensive care setting, there is little supporting evidence for individual PI preventative interventions within intensive care alone, as established in Chapter One (pp. 30-35). Thus, to identify all relevant PI preventative interventions in Phase One for potential inclusion within the minimum PI preventative intervention set, the systematic review and meta-analysis was broadened to include acute hospital

settings.

Systematic reviews of randomised controlled trials are classified as the highest form of research evidence for effectiveness (Level 1.a, The Joanna Briggs Institute, 2014; Level I, National Health & Medical Research Council [NHMRC], 2000). The results of Phase One were used to inform the development of the intervention set in Phase Two. Further details of the systematic review and meta-analysis undertaken in Phase One, including rationale and methodology, are now provided in this chapter (pp. 42-63). The published study reports for Phase One (Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022) are presented in Chapters Three and Four. Further detail on Phases Two and Three is provided in future chapters.

2.4 Phase One methodology

2.4.1 Rationale

Phase One was undertaken to address objective one:

- to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings

and to inform Phase Two. To do so, it was necessary to identify, appraise and synthesise research evidence which tested the effectiveness of PI preventative interventions for adults in acute hospital settings. This was undertaken by systematic review, where a structured approach is taken to identify and appraise studies relevant to the research question (Clarke, 2007; Lasserson *et al.*, 2022; LoBiondo-Wood & Haber, 2018a; Nelson, 2014a; Tufanaru *et al.*, 2020). The systematic review findings are then summarised and, where possible, the results of identified studies are statistically combined using meta-analysis (Clarke, 2007; Lasserson *et al.*, 2022; LoBiondo-Wood & Haber, 2018a; Nelson, 2014a; Tufanaru *et al.*, 2020).

To ensure rigour and minimise bias, there are standards relating to the development of a strict, transparent and reproducible review protocol to guide the systematic process (Shamseer *et al.*, 2015) and the subsequent reporting of the review (Liberati *et al.*, 2009; Moher *et al.*, 2009). Furthermore, to ensure the robust conduct of reviews, several groups have developed systematic review standards and guidance resources (Nelson, 2014a), including The Cochrane Collaboration (Higgins, Thomas *et al.*, 2022), The Joanna Briggs Institute (Aromataris & Munn, 2020) and the Centre for Reviews and Dissemination (Centre for Reviews and Dissemination, 2009).

While randomised controlled trials are undertaken to test the effectiveness of interventions (Hariton & Locascio, 2018; Sullivan-Bolyai & Bova, 2018a), any demonstrated effect of a randomised controlled trial is limited to the individual study (Clarke, 2007). A systematic review of randomised controlled trials, however, provides a synthesis of overall trial evidence and examines intervention effectiveness

across studies (Clarke, 2007) to inform evidence-based practice and future research (Clarke, 2007; Nelson, 2014a; Shamseer *et al.*, 2015). Such a review may be referred to as a systematic review of effectiveness (Tufanaru *et al.*, 2020) or a systematic review of interventions (Higgins, Thomas *et al.*, 2022). Systematic reviews of randomised controlled trials have been used to explore the effectiveness of interventions to address a range of issues, such as the use of aromatherapy for pre-operative anxiety in adults (Guo *et al.*, 2020), increasing physical activity in individuals with intellectual disability (Hassan *et al.*, 2019) and increasing the success of first attempts in paediatric peripheral intravenous catheterisation (Parker *et al.*, 2017). Thus, a systematic review of randomised controlled trials was conducted for Phase One.

2.4.2 Protocol

To minimise bias, the development of a protocol *a priori* ensures that decisions are based on rigorous methodology, as opposed to being based on the results of the review as it progresses (Lasserson *et al.*, 2022; Shamseer *et al.*, 2015). The protocol planning and development stage maps out the research question, aims and objectives; the search strategy; the study selection and appraisal methods; the data extraction, synthesis and analysis methods; use of systematic review software; and intended dissemination plans (Centre for Reviews and Dissemination, 2009; Nelson, 2014a; Shamseer *et al.*, 2015; Tufanaru *et al.*, 2020). Many aspects of the systematic review are based on the key systematic review components of Population, Intervention, Comparator and Outcome (PICO) (Centre for Reviews and Dissemination, 2009; Shamseer *et al.*, 2015; Thomas *et al.*, 2022; Tufanaru *et al.*, 2020). The use of PICO focuses the review, including its guiding research question (Centre for Reviews and Dissemination, 2009; Shamseer *et al.*, 2015; Thomas *et al.*, 2022; Tufanaru *et al.*, 2020).

As noted by Shamseer *et al.* (2015), for the most part, the rigour and trustworthiness of a systematic review is due to the *a priori* development of a protocol. Systematic review protocols serve to prevent review duplication and promote transparency and reproducibility (Lasserson *et al.*, 2022; Shamseer *et al.*, 2015). Additionally, protocols allow others to assess the validity of the methodology, and to compare the protocol and outcomes to assess for the introduction of bias or variations from the protocol (Lasserson *et al.*, 2022; Shamseer *et al.*, 2015). To enable this, once prepared, a systematic review protocol should be published on a protocol register (Lasserson *et al.*, 2022; Shamseer *et al.*, 2015). Given the importance of a protocol to ensure rigour and validity (Lasserson *et al.*, 2022; Shamseer *et al.*, 2015), the Phase One: Systematic review and meta-analysis was planned *a priori*, with a protocol developed and published on a systematic review protocol register (Lovegrove *et al.*, 2019; Registration number CRD42019129556), referenced in the published reports (Chapter Three, p. 66; Chapter Four, p. 97), and is available at https://www.crd.york.ac.uk/PROSPERO/.

2.4.3 Search strategy

To identify as many potentially relevant studies as possible, a search strategy should be comprehensive (Lefebvre *et al.*, 2022; Shamseer *et al.*, 2015; Tufanaru *et al.*, 2020), yet also as relevant and precise as possible (Lefebvre *et al.*, 2022). The strategy should be clearly and explicitly defined, and include search terms and subject headings, the databases or information systems to be searched, and limiters or filters to be applied to the intended searches (Centre for Reviews and Dissemination, 2009; Tufanaru *et al.*, 2020). Often, the PICO mnemonic is used to structure and focus a search (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022). The elements of PICO may be used to assist the identification of search terms (Centre for Reviews and Dissemination, 2009). As many alternative or synonymous terms and database specific subject headings relevant to an identified term should also be included (Centre for Reviews and Dissemination, 2009). The PICO mnemonic may also be expanded to include Study design (PICOS) (Centre for Reviews and Dissemination, 2009) or Timing and Study design (PICOTS) (Nelson, 2014b). The comprehensiveness of these aspects of a search strategy are vital to the completeness of a review (Shamseer *et al.*, 2015). To further facilitate this, it is recommended that when developing a systematic review search strategy, a specialised research librarian should be consulted (Lefebvre *et al.*, 2022; Tufanaru *et al.*, 2020; Vassar *et al.*, 2017). Vassar *et al.* (2017) suggest that collaboration with a librarian or information specialist may increase the quality of a systematic review. Based on these recommendations and to ensure the comprehensiveness and completeness of the review, a search strategy was developed in collaboration with a specialised health service librarian for Phase One. The search terms, presented in section 2.5.2 (p. 62), were identified based on PICOS.

2.4.4 Eligibility criteria

As with the search strategy, the eligibility criteria that will determine which studies are included in the review must be clearly defined and focused (Centre for Reviews and Dissemination, 2009; Peterson *et al.*, 2014; Tufanaru *et al.*, 2020). Eligibility criteria must be applicable to the review and practical to apply (Centre for Reviews and Dissemination, 2009). This is of importance, as these criteria will be used in the study selection process (Peterson *et al.*, 2014: Tufanaru *et al.*, 2020). Two aspects of eligibility criteria should be considered; criteria relating to study characteristics, and criteria relating to publication characteristics (Tufanaru *et al.*, 2020). Publication characteristics refers to publication specific elements, such as language, year and type of publication (e.g. peer-reviewed paper) (Shamseer *et al.*, 2015; Tufanaru *et al.*, 2020). Such publication characteristics may also be used as limiters in the search strategy (Shamseer *et al.*, 2015). Study characteristics refers to the systematic review PICO elements, and its research questions and objectives (McKenzie, Brennan, Ryan, Thomson, Johnston & Thomas, 2022; Shamseer *et al.*, 2015; Thomas *et al.*, 2022; Tufanaru *et al.*, 2020). The use of PICO to refine the eligibility criteria (Centre for Reviews and Dissemination, 2009; McKenzie, Brennan, Ryan, Thomson, Johnston & Thomas, 2022; Peterson *et al.*, 2014; Shamseer *et al.*, 2015; Tufanaru *et al.*,

2020) ensures the criteria are relevant (Peterson *et al.*, 2014; Tufanaru *et al.*, 2020) and not too broad or narrow (Centre for Reviews and Dissemination, 2009; Peterson *et al.*, 2014).

Eligibility criteria define inclusion or exclusion criteria, though it may not be necessary to define all aspects of both (Tufanaru *et al.*, 2020). Where inclusion criteria are explicitly defined, it is implicit that the opposite of the inclusion criteria would be excluded, and vice versa (Tufanaru *et al.*, 2020). For example, in Phase One, the population (P) of interest was adult inpatients within acute hospital settings, and thus this was specified in the inclusion criteria. It was, therefore, not necessary to explicitly state that paediatric populations or settings outside of hospitals were excluded. The inclusion and exclusion criteria for Phase One were developed and refined using PICO and are outlined in the published study reports (Chapter Three, p. 66; Chapter Four, p. 97).

2.4.5 Study selection

Study selection is the process used to select studies from the results yielded by searching databases or information systems using the search strategy (Centre for Reviews and Dissemination, 2009). Although few papers may be included in the final results, the search strategy may result in a large volume of records; thus, initially, the title and abstract of each record is screened against the eligibility criteria (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022; McDonagh & Peterson, 2014; Shamseer *et al.*, 2015). Where it is possible to determine from an abstract whether the study meets the eligibility criteria, the paper will be retained or excluded accordingly, with full records retrieved for those abstracts assessed as potentially eligible (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022; McDonagh & Peterson, 2014; Porritt *et al.*, 2014). Full records should then be assessed against the eligibility criteria for inclusion or exclusion (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022). For transparency and reporting purposes, the screening process should be documented, including the number of records screened, retrieved, excluded and included, and reasons why (Centre for Reviews and Dissemination, 2009; Liberati *et al.*, 2009; McDonagh & Peterson, 2014; Moher *et al.*, 2009).

Screening is undertaken by more than one reviewer, as this decreases the chance of error and bias (Centre for Reviews and Dissemination, 2009; Edwards *et al.*, 2002; Lefebvre *et al.*, 2022; McDonagh & Peterson, 2014; Porritt *et al.*, 2014; Tufanaru *et al.*, 2020). Using at least two reviewers is recommended (Edwards *et al.*, 2002; Lefebvre *et al.*, 2022). Edwards *et al.* (2002) found that, on average, single reviewers missed 8% of papers which were of relevance, while pairs of reviewers did not miss any and increased the number of relevant papers included by an average of 9%. Screening being undertaken by multiple reviewers should occur independently (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022; McDonagh & Peterson, 2014; Shamseer *et al.*, 2015; Tufanaru *et al.*, 2020), which in turn increases reliability and reproducibility (Centre for Reviews and Dissemination, 2009). Disagreements between reviewers may occur and be solved through reviewer

discussion (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022) or with an additional reviewer included for arbitration (Centre for Reviews and Dissemination, 2009; Lefebvre *et al.*, 2022; Shamseer *et al.*, 2015; Tufanaru *et al.*, 2020). Based on these recommendations and to minimise the risk of bias and errors, a study selection process with multiple reviewers using a systematic review software package, Covidence™, was developed for Phase One.

2.4.6 Study appraisal (risk of bias assessment)

Appraisal is undertaken to examine the risk of bias, or methodological quality, of a study (Centre for Reviews and Dissemination, 2009; Higgins, Savović, *et al.*, 2022; Tufanaru *et al.*, 2020). This may include identification of problems with the design, conduct or analysis of a study, which may impact the validity of the effects or outcomes (Centre for Reviews and Dissemination, 2009; Higgins, Savović, *et al.*, 2022; Tufanaru *et al.*, 2020). As with study selection, it is recommended that appraisal is undertaken by two reviewers independently, and any disagreements are resolved via consensus or by the decision of a third, arbitrating reviewer (Boutron *et al.*, 2022; Tufanaru *et al.*, 2020). Appraisal may be undertaken using a checklist (Centre for Reviews and Dissemination, 2009; Higgins *et al.*, 2011; Tufanaru *et al.*, 2020) or a numerical scale (Centre for Reviews and Dissemination, 2009; Higgins *et al.*, 2011). Level of quality may be defined by percentages of checklist items met (e.g. Lovegrove, Miles & Fulbrook, 2018; Reilly *et al.*, 2016; Tayyib & Coyer, 2016), or the overall score of a numerical scale; although the latter is not recommended (Centre for Reviews and Dissemination, 2009; Chou, 2014; Higgins *et al.*, 2011). This is due to a lack of established reliability and validity (Centre for Reviews and Dissemination, 2009; Chou, 2014). Checklists, however, are considered to be reliable and are often specific to study design (Centre for Reviews and Dissemination, 2009).

Within the context of randomised controlled trials, appraisal considers the randomisation method, allocation concealment, blinding, similarities between intervention groups, participant attrition, adequacy of reporting and appropriateness of analysis (Centre for Reviews and Dissemination, 2009; Chou, 2014). These aspects may be referred to as selection bias, performance bias, detection bias, attrition bias and reporting bias (Chou, 2014; Higgins *et al.*, 2011; Tufanaru *et al.*, 2020). Such aspects relate to the internal validity, or quality, of the study (Chou, 2014; Porritt *et al.*, 2014). External validity takes into account the generalisability (Porritt *et al.*, 2014) or applicability (Chou, 2014) of the outcomes to other populations not participating in the study. External validity may be assessed by exploring the characteristics of the study population and setting (Porritt *et al.*, 2014).

The Joanna Briggs Critical Appraisal Tools are examples of standardised checklists which are used to assess methodological quality and presence of bias (The Joanna Briggs Institute, 2020; Tufanaru *et al.*, 2020), with a specific tool available for different study designs (The Joanna Briggs Institute, 2020; Tufanaru *et al.*, 2020). The tools are readily available online (The Joanna Briggs Institute, 2020) or may be used through the Joanna Briggs Institute systematic review software (The Joanna Briggs Institute,

2017). Tayyib and Coyer (2016) used these checklist tools (The Joanna Briggs Institute, 2020) to assess studies testing the effectiveness of singular interventions on preventing hospital-acquired PI in intensive care, excluding those that met less than 50% of checklist criteria. Reilly *et al.* (2016), who examined the effectiveness of management programs for chronic kidney disease in Indigenous people, also utilised the checklist tools (The Joanna Briggs Institute, 2020). The authors (Reilly *et al.*, 2016) defined good quality studies as those meeting greater than 80% of checklist criteria, moderate quality as those meeting 50% to 80% of the criteria, and poor quality studies as those meeting less than 50%; poor quality studies were excluded. Lovegrove, Miles and Fulbrook (2018) also assessed and excluded studies in this manner when conducting a systematic review to explore connections between PI risk assessment and preventative intervention prescription and implementation. Thus, use of these appraisal tools was considered for this study.

The Cochrane Collaboration also provides a tool for appraisal; however, they differentiate between quality and risk of bias, focusing on the latter (Higgins *et al.*, 2011; Boutron *et al.*, 2022). The distinction arose from concerns that a study may be performed to a high standard, or quality, but may still have a risk of bias (Higgins *et al.*, 2011). Some markers of quality may not impact bias associated with a study and assessment of quality may focus on the quality of reporting, as opposed to the reported methodology (Higgins *et al.*, 2011). Thus, the Cochrane Collaboration's tool (the Cochrane risk-of-bias tool [RoB]) was first developed in 2008 as a 'tool for assessing risk of bias' (Higgins *et al.*, 2011), and was slightly modified in 2011 (Boutron *et al.*, 2022). The tool was not considered a checklist, but rather a 'domain-based evaluation' (Higgins *et al.*, 2011). The domains assessed included selection bias (randomisation and allocation concealment), performance bias (participants and researcher blinding), detection bias (outcome assessment blinding), attrition bias (incomplete data and participant attrition), reporting bias (selective reporting) and other biases not elsewhere covered (Higgins *et al.*, 2011). The reviewers then judge the bias of a study as 'low risk', 'high risk' or 'unclear risk', and report on and consider biases in the systematic review (Higgins *et al.*, 2011). The use of the tool for assessing risk of bias is demonstrated widely in both Cochrane systematic reviews (e.g. McInnes *et al.*, 2015; Moore & Patton, 2019), and other studies (e.g. Guo *et al.*, 2017; Hassan *et al.*, 2018; Parker *et al.*, 2017). In 2016, version 2 of the Cochrane risk of bias tool (RoB 2.0) was released (Higgins *al.*, 2016) and has since been updated in 2019 (Higgins, Savović, Page & Sterne, 2019).

The RoB 2.0 tool provides templates to assess risk of bias in randomised parallel group trials, cluster-randomised trials and randomised cross-over trials (Higgins, Savović, Page & Sterne, 2019). For individual randomised parallel group trials, five bias domains are assessed; bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result (Higgins, Savović, Page & Sterne, 2019). Each domain is comprised of 'signalling questions', the

response of which are processed by an algorithm which proposes a judgement of 'low risk of bias', 'some concerns' or 'high risk of bias' (Higgins, Savović, Page & Sterne, 2019). Reviewers are then required to verify the judgement, or if necessary, change the judgement (Higgins, Savović, Page & Sterne, 2019).

Systematic reviews may exclude studies based on an appraisal (Chou, 2014; Tufanaru *et al.*, 2020). However, Chou (2014) argues that a comprehensive review includes all studies, while considering the impact of the quality or risk of bias of each study. Chou (2014) also notes that excluding studies based on appraisal outcomes may not be appropriate since identified flaws may vary across studies. Applying percentage definitions to checklist appraisals may also not be appropriate, given that the importance of each checklist criterion may not be taken into account (Higgins *et al.*, 2011). Based on this, all studies were included regardless of risk of bias in Phase One. Furthermore, given the focus on risk of bias and the availability of the Cochrane tool within systematic review software used for Phase One (Covidence™), the tool for assessing risk of bias from the Cochrane Collaboration was used. While version 2 of the tool had been released, it was not yet available for use in Covidence™ when Phase One was being undertaken. Thus, the revised 2011 version of the tool was used.

2.4.7 Data extraction

Once studies have been selected for inclusion, it is necessary to comprehensively and accurately extract relevant data (Tufanaru *et al.*, 2020). To ensure accuracy and rigour, and in continuation from study selection and appraisal, data extraction is often undertaken by at least two reviewers, and disagreements are solved through discussion or arbitration by a third reviewer (Blazina *et al.*, 2014; Centre for Reviews and Dissemination, 2009; Li, Higgins & Deeks, 2022; Tufanaru *et al.*, 2020). To address the purpose of the review, data should be extracted based on the review focus and eligibility criteria (Tufanaru *et al.*, 2020); thus, most data are based on the PICO criteria of the review (Centre for Reviews and Dissemination, 2009; Li, Higgins & Deeks, 2022; Tufanaru *et al.*, 2020). Other data may include publication characteristics and data analysis methods (Centre for Reviews and Dissemination, 2009; Li, Higgins & Deeks, 2022; Tufanaru *et al.*, 2020). Data may also be collected not only from the study report or paper, but from other sources, such as a published protocols or protocol registers (Centre for Reviews and Dissemination, 2009; Li, Higgins & Deeks, 2022), especially if there is any information to clarify, given the word limit of journal publications.

The type of data extracted may vary, including free text, numerical data or dichotomous outcomes (Centre for Reviews and Dissemination, 2009). Data may also need to be categorised, or coded, for analysis (Centre for Reviews and Dissemination, 2009). While this may occur during data extraction, categorisation may occur following extraction and prior to analysis, to ensure that all the required data is extracted and no data are lost during this process (Centre for Reviews and Dissemination, 2009). Data should be extracted using a standardised data extraction form, which has been developed specific

to the review, to ensure consistency across studies (Centre for Reviews and Dissemination, 2009; Li, Higgins & Deeks, 2022). Data extraction forms may be electronic or paper-based (Li, Higgins & Deeks, 2022); however, electronic forms may be favourable given that data extraction and entry for analysis can be combined into one task (Centre for Reviews and Dissemination, 2009). Moreover, using electronic forms through systematic review software may facilitate data management, coordination between reviewers (Li, Higgins & Deeks, 2022), data coding and data analyses (Centre for Reviews and Dissemination, 2009). Given this, standardised electronic data extraction forms based on PICO were utilised. Data extraction was undertaken within the same systematic review software (Covidence™) used for study selection and appraisal (sections 2.4.5 and 2.4.6, pp. 46-49), enabling the seamless management of the included studies and data.

2.4.8 Data synthesis and analysis

The following considerations were made in regard to this part of the systematic review process for Phase One. Systematic review synthesis refers to the combination and reporting of the extracted data of the included studies (Centre for Reviews and Dissemination, 2009; Fu, 2014; McKenzie, Brennan, Ryan, Thomson & Johnston, 2022; Tufanaru *et al.*, 2020). Synthesis may be undertaken narratively, or statistically, such as in meta-analysis (Tufanaru *et al.*, 2020). Unlike other pre-determined components of a systematic review, aspects of synthesis may not be determined until the nature of the study data is revealed (Centre for Reviews and Dissemination, 2009); however, where possible, the approach to synthesis should be determined *a priori* (Lasserson *et al.*, 2022), and as such, a pre-determined approach was detailed in the protocol for Phase One.

In the case of systematic reviews of randomised controlled trials, often meta-analysis is possible given the reported quantitative outcomes of the trials (Centre for Reviews and Dissemination, 2009). However, the included studies and reported quantitative outcomes must be homogenous in nature for statistical combination (Centre for Reviews and Dissemination, 2009). Heterogeneous studies and outcomes are unable to be compared statistically, and thus narrative synthesis is primarily undertaken in these cases (Centre for Reviews and Dissemination, 2009). Narrative synthesis and meta-analysis are not used exclusively (Centre for Reviews and Dissemination, 2009). Systematic reviews using narrative synthesis may still include some statistical analysis (Centre for Reviews and Dissemination, 2009). In reviews using meta-analysis, narrative synthesis should be incorporated to provide an initial summary of the included studies in a descriptive manner (Centre for Reviews and Dissemination, 2009) and to supplement the analysis (Tufanaru *et al.*, 2020). In these cases, narrative synthesis should also be used to summarise the process, the data not explored in the statistical analysis and the results (Tufanaru *et al.*, 2020). Summary tables may be included to present both narrative data, such as study characteristics, PICO and risk of bias (Centre for Reviews and Dissemination, 2009), while statistical data may also be presented in summary tables, along with figures and forest plots (McKenzie, Brennan,

Ryan, Thomson & Johnston, 2022; Deeks *et al.*, 2022).

2.4.8.1 Narrative synthesis

Overall, narrative synthesis is considered a 'textual' approach (Centre for Reviews and Dissemination, 2009; Popay *et al.*, 2006), and although narrative synthesis is undertaken where studies are heterogeneous and statistical analyses are not possible, the characteristics of included studies and the relationships between studies are still considered and analysed (Centre for Reviews and Dissemination, 2009). Furthermore, a narrative assessment of the level of evidence should be provided (Centre for Reviews and Dissemination, 2009). In addition to an initial narrative descriptive summary, Popay *et al.* (2006, p. 11) recommend that narrative synthesis incorporates the following elements; a theory of how, why and for whom the intervention is effective, a synthesis of included study findings, an exploration of the relationships in and between included studies, and an assessment of the robustness of the synthesis. Narrative synthesis, however, is more subjective than a statistical analysis approach (Centre for Reviews and Dissemination, 2009). Such a narrative approach was undertaken in Phase One where studies were heterogeneous, although meta-analyses were also undertaken where appropriate.

2.4.8.2 Meta-analysis

A meta-analysis involves the statistical synthesis of quantitative results, undertaken for studies (two or more) which are sufficiently homogenous methodologically, including risk of bias, and clinically, in relation to their PICO elements (Tufanaru *et al.*, 2020). Combining selected studies in meta-analysis expands the estimated effect outside of a single study and into multiple studies, resulting in improved precision, a demonstration of effect across more populations and the ability to examine conflicts between studies (Deeks *et al.*, 2022). While there may be some minor differences between studies, studies which are, for example, all randomised controlled trials testing the effectiveness of the same intervention against standard care, in the same population, may be comparable (Centre for Reviews and Dissemination, 2009). Therefore, where possible, meta-analysis was undertaken for Phase One.

Homogeneity is initially established by the reviewers through a thorough understanding of the review focus and research question and the included study characteristics and findings (Tufanaru *et al.*, 2020). Thus, the selection of studies to combine and analyse does introduce a level of subjectivity (Centre for Reviews and Dissemination, 2009). Following the initial judgement of homogeneity, for example, selecting studies which examined the effectiveness of a sacral PI preventative dressing in adult acute care patients, statistical exploration of heterogeneity may be undertaken during meta-analysis (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Tufanaru *et al.*, 2015). Risk of bias and potential exclusion of studies should also be taken into account when considering meta-analysis; the inclusion of studies which are at high risk of bias may result in misleading and inaccurate outcomes,

due to a compounding effect of the errors present in the high risk studies (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022).

Pair-wise comparisons are undertaken in meta-analysis, meaning intervention groups are compared to control groups or other intervention groups, such as the comparison of an intervention group and a control group in a randomised controlled trial (Deeks *et al.*, 2022). Special consideration should be given to studies with variations in design and methods of randomisation, like those used in cluster and cross-over randomised controlled trials (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Higgins, Eldridge & Li, 2022). These variations should be acknowledged, and specific methods of analysis applied to avoid errors and inaccurate results (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Higgins, Eldridge & Li, 2022).

Two commonly used models of meta-analysis are the fixed-effect model and the random-effects model (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). Both are based on the same two-step process (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). Firstly, a summary statistic which describes the intervention effect is calculated for each included study (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). The individual study effects are then combined to result in an overall summary effect estimate, which is often calculated as a weighted average (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). Essentially this means that individual studies are given a weighting which reflects the amount of information provided in each study (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). Larger studies contribute a greater amount, while conversely, smaller studies will contribute a smaller amount to the overall weighted average of the intervention effect (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). The summary measurements used, both for individual studies and for the overall effect estimate, are dependent upon the type of study data, such as odds or risk ratios for dichotomous data, the mean difference for continuous data, or hazard ratios for time-to-event data (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Fu, 2014). Confidence intervals, which represent the uncertainty around an effect (Centre for Reviews and Dissemination, 2009; Partlett & Riley, 2017), are also calculated and displayed with these measurements (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; IntHout *et al.*, 2016; Veroniki *et al.*, 2019).

However, the two models vary in that the fixed-effect model is used where the review results will not be generalisable outside of the included studies, while the random-effects model is considered generalisable (Tufanaru *et al.*, 2020). The fixed-effect model is more appropriate where the number of included studies is small, as opposed to the random-effects model which requires the number of included studies to be large enough to justify generalisability (Tufanaru *et al.*, 2015). Furthermore, a fixed-effect model is only appropriate where it is assumed that the included studies are estimating the same one effect and that the quantity of this effect will be the same across studies (Deeks *et al.*, 2022;

Fu, 2014; Tufanaru *et al.*, 2015). Whereas, the random-effects model assumes that included studies are estimating different effects, that there may be differences between studies outside of the intervention, and that the effect sizes are distributed across studies (Deeks *et al.*, 2022; Fu, 2014; Tufanaru *et al.*, 2015). Based on these considerations, a random-effects model was selected for use in Phase One. In the random-effects model, variations between studies may be estimated using tau-squared statistical tests (Deeks *et al.*, 2022), and heterogeneity may be calculated using statistical tests such as chi-square and I^2 statistics (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Tufanaru *et al.*, 2015), which is then incorporated in the meta-analysis (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Tufanaru *et al.*, 2015).

In meta-analysis, as previously noted above, the overall effect estimate is often reported as a weighted average summary measurement with a CI (IntHout *et al.*, 2016; Veroniki *et al.*, 2019). However, it is argued that expressing uncertainty with a CI is insufficient in representing the heterogeneity between study settings and populations which may be present when using a random-effects model (Riley *et al.*, 2011; Veroniki *et al.*, 2019). The use of CIs where heterogeneity is present may result in an overly narrow CI, resulting in an underestimation of uncertainty (Riley *et al.*, 2011; Veroniki *et al.*, 2019). Furthermore, it may incorrectly indicate a common effect across settings (Riley *et al.*, 2011). It is suggested that prediction intervals should also be calculated and reported in random-effects meta-analysis (Deeks *et al.*, 2022; IntHout *et al.*, 2016; Riley *et al.*, 2011; Veroniki *et al.*, 2019), with some authors advocating the routine use of prediction intervals (Graham & Moran, 2012; IntHout *et al.*, 2016).

Confidence intervals represent the uncertainty of the meta-analysis effect estimate based on the included studies settings and populations (Deeks *et al.*, 2022; Partlett & Riley, 2017); while prediction intervals consider the effect of an intervention when applied in a population or setting which differs from those included in the meta-analysis (Deeks *et al.*, 2022; Higgins *et al.*, 2009; Partlett & Riley, 2017; Riley *et al.*, 2015; Veroniki *et al.*, 2019). Thus, potential heterogeneity between settings and populations included and not included in the analysis is acknowledged (Riley *et al.*, 2011; Veroniki *et al.*, 2019). Using prediction intervals in this manner results in a more generalisable outcome, meaning that it predicts the potential effect of the intervention in differing populations and settings, such as those that may be used across future studies (Deeks *et al.*, 2022; Higgins *et al.*, 2009; Riley *et al.*, 2011; Veroniki *et al.*, 2019) or clinical settings (IntHout *et al.*, 2016; Partlett & Riley, 2017). Thus, for Phase One, in addition to CIs, it would seem appropriate to calculate prediction intervals when using a random-effects model. However, it may not be appropriate to calculate prediction intervals if study sizes are unbalanced (Partlett & Riley, 2017) or there are too few studies (Deeks *et al.*, 2022; IntHout *et al.*, 2016; Higgins *et al.*, 2009). It has been suggested that at least five studies are required for prediction intervals to be calculated and studies must be balanced with sufficient heterogeneity

(Partlett & Riley, 2017), but even so, a minimal number of studies may result in an exceedingly wide prediction interval which cannot be interpreted (Riley *et al.*, 2011).

2.4.8.3 Subgroup and sensitivity analyses

Subgroup and sensitivity analyses may also be undertaken (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Fu, 2014; Tufanaru *et al.*, 2015). Subgroup analysis refers to separating participant data into groups based on study or participant characteristics for analysis (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). This may be undertaken to make comparisons between subgroups, to explore heterogeneity, or answer research questions pertaining to the relevant subgroup (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). However, it is recommended that subgroup analysis be undertaken with caution as statistical findings may be misleading when comparing groups (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). Where subgroup analysis is to be undertaken, it should be justified (Tufanaru *et al.*, 2015), be considered observational, and any differences found in comparisons between subgroups should be supported by evidence and be clinically relevant (Deeks *et al.*, 2022). Subgroup analysis may also be undertaken for a subset (such as a subset of studies within one country or setting) (Deeks *et al.*, 2022). Sensitivity analysis is undertaken to test the robustness of the results, which are based on the overall process of the systematic review (Deeks *et al.*, 2022; Tufanaru *et al.*, 2015). The process of the systematic review entails a series of decisions, such as determining eligibility criteria (Deeks *et al.*, 2022). Sensitivity analysis involves re-running the primary analysis with alternate criteria or decisions, to assess whether the criteria or decision impacted the results (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Fu, 2014; Tufanaru *et al.*, 2015), and thus the robustness of the results (Tufanaru *et al.*, 2015). Where differences are identified, the interpretation of results should be cautious (Centre for Reviews and Dissemination, 2009; Tufanaru *et al.*, 2015). Such decisions or issues often arise during the review process, and thus may not be predetermined (Centre for Reviews and Dissemination, 2009) as is the case for the systematic review for Phase One.

2.4.8.4 Publication bias

Publication bias arises from the increased likelihood of the publication of studies which have found an intervention effect, as opposed to those studies that did not demonstrate an effect (Centre for Reviews and Dissemination, 2009; Fu, 2014; Page *et al.*, 2022; Tufanaru *et al.*, 2015). While publication bias can be minimised through comprehensive searches of unpublished studies in addition to those published, it should be considered when interpreting results (Centre for Reviews and Dissemination, 2009; Fu, 2014; Page *et al.*, 2022; Tufanaru *et al.*, 2015). Publication bias may be assessed using visual examination of funnel plots, or statistical tests (Centre for Reviews and Dissemination, 2009; Fu, 2014; Page *et al.*, 2022; Tufanaru *et al.*, 2015). Funnel plots should present study intervention effect

estimates plotted against the standard error of the estimated effect (Centre for Reviews and Dissemination, 2009; Page *et al.*, 2022). Theoretically, a symmetrical plot shaped like an inverted funnel is considered to indicate absence of bias (Centre for Reviews and Dissemination, 2009; Page *et al.*, 2022). Conversely, an asymmetrical plot is considered to indicate publication bias (Centre for Reviews and Dissemination, 2009; Fu, 2014; Page *et al.*, 2022; Tufanaru *et al.*, 2015); the more asymmetrical and mis-shaped, the more likely the presence of publication bias (Centre for Reviews and Dissemination, 2009; Page *et al.*, 2022) although visual inspection is not always reliable (Terrin *et al.*, 2005). The gap in the plot, which results in asymmetry and lack of inverted funnel shape, represents the studies which found no intervention effect, and remained unpublished (Centre for Reviews and Dissemination, 2009; Page *et al.*, 2022).

While asymmetry has been associated with publication bias, it may be a more accurate representation of small study effects, meaning the intervention effects in smaller studies differ to those in larger studies, resulting in an asymmetrical plot (Page *et al.*, 2022). The symmetry and shape of a funnel plot (Centre for Reviews and Dissemination, 2009) may also be impacted by other factors, such as selection bias and poor methodological quality (Page *et al.*, 2022; Tufanaru *et al.*, 2015). Statistical tests may also be used to test for publication bias, with recommendations as to which tests to undertake based on the type of study data (Centre for Reviews and Dissemination, 2009; Fu, 2014; Tufanaru *et al.*, 2015). However, there are also limitations when using statistical tests, and both funnel plots and statistical tests are deemed inappropriate for assessing publication bias where there is statistical heterogeneity, low power, and where there are not enough studies (Centre for Reviews and Dissemination, 2009). It is recommended that at least 10 studies are required for the generation of funnel plots (Page *et al.*, 2022).

2.4.8.5 Phase One considerations

Within the context of the systematic review for Phase One, it was anticipated that the searches would yield randomised controlled trials examining the effectiveness of a variety of PI preventative interventions within acute and intensive care settings. As such, studies were first separated by setting (acute ward and intensive care) and were synthesised and reported separately, with the intensive care-specific studies and data considered a subset. Furthermore, within settings, analysis was planned to compare studies which tested the effect of the same intervention. Where studies examining the same intervention were not sufficiently homogenous for meta-analysis, narrative synthesis was undertaken (Centre for Reviews and Dissemination, 2009; Tufanaru *et al.*, 2020). Where studies examining the same intervention were homogenous in regards to PICO, they were comparable by meta-analysis (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Tufanaru *et al.*, 2020). Despite sufficient homogeneity for comparison via meta-analysis, there were differences between the studies outside of the intervention, such as variations in populations and standard care. Thus, a random-

effects model was utilised for meta-analysis (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Tufanaru *et al.*, 2015). This was further supported by the need for the results to be generalisable to inform the Modified Delphi study in Phase Two (Tufanaru *et al.*, 2015). Given the use of a random-effects model, statistical heterogeneity between compared studies was measured using I^2 statistics (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022; Tufanaru *et al.*, 2015).

Intention-to-treat analysis, which refers to analysing participants in the study group they were randomised to regardless of attrition, is recommended for randomised controlled trials (Abraha *et al.*, 2017; Elkins & Mosely, 2015; Gewandter *et al.*, 2014; Higgins, Savović, *et al.*, 2022; McCoy, 2017; Ranganathan *et al.*, 2016). However, many studies undertake 'as treated' (Elkins & Moseley, 2015) or 'per protocol' (McCoy, 2017; Ranganathan *et al.*, 2016) analysis, which may result in bias (Elkins & Moseley, 2015). Similarly, modified versions of intention-to-treat analysis may also introduce bias (Abraha *et al.*, 2017; Gewandter *et al.*, 2014). While Dossing *et al.* (2016) suggest that modified intention-to-treat analysis does not introduce bias, meta-analysis may be unachievable if intention-to-treat analyses are modified in various ways across studies (Gewandter *et al.*, 2014). Therefore, where possible, both intention-to-treat and per protocol data were extracted from included studies for separate meta-analyses. As intention-to-treat analysis is recommended (Abraha *et al.*, 2017; Elkins & Mosely, 2015; Gewandter *et al.*, 2014; Higgins, Savović, *et al.*, 2022; McCoy, 2017; Ranganathan *et al.*, 2016), this was considered the primary meta-analysis. Secondarily, per protocol meta-analysis was undertaken for comparison. Using this approach gave an indication of the interventions effectiveness (i.e. implementation within a real world clinical setting in which intervention non-adherence may occur) versus its efficacy (i.e. when the intervention is implemented in the exact manner intended) (Elkins & Moseley, 2015).

Randomised controlled trials which examined whether an intervention prevented an adverse outcome or not, represented by incidence, were included in this study. Such data are dichotomous (Deeks *et al.*, 2022). Thus, individual study effects were summarised using risk ratios with CIs (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). While odds ratios may be used instead of risk ratios, risk ratios are considered easier to interpret (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). Risk ratios indicate the probability of an event occurring in those receiving the intervention in comparison to those not receiving it (Centre for Reviews and Dissemination, 2009; Deeks *et al.*, 2022). For example, a risk ratio of 0.30 (30%) indicates that the intervention decreases the risk of the event by 30%. Risk ratios may also be re-expressed as relative risk reduction (Centre for Reviews and Dissemination, 2009). Where the risk ratio was 0.30 (30%), the relative risk reduction would be 0.70 (70%) (the opposite numerical figure to the risk ratio), indicating a 70% reduction in the event occurring (Centre for Reviews and Dissemination, 2009). Using weighted averages, the summary effect estimate of each intervention was calculated as a risk ratio with CIs (Centre for Reviews and Dissemination,

2009; Deeks *et al.*, 2022). Furthermore, the calculation of prediction intervals was planned for each intervention effect estimate where there were at least five studies (Partlett & Riley, 2017). While there were limitations to assessing publication bias with both funnel plots and statistical tests and recommended statistical tests were not available in the systematic review software used for analysis (Review Manager™; RevMan Version 5.3); the software did facilitate the generation of funnel plots. Therefore, where appropriate, visual inspection of funnel plots was planned for Phase One with the results interpreted with caution and reported as such for transparency. Funnel plot use was not appropriate where there were less than 10 studies (Deeks *et al.*, 2022).

2.4.9 Reporting

Similar to protocol recommendations (Shamseer *et al.*, 2015), the subsequent reporting of the review is also subject to recommendations (Liberati *et al.*, 2009; Moher *et al.*, 2009; Page, McKenzie *et al.*, 2021). The recommendations facilitate continued transparency from point of protocol development (Shamseer *et al.*, 2015) to the reporting of results (Liberati *et al.*, 2009; Page, McKenzie *et al.*, 2021). The recommendations, known as the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, comprise a 27-item checklist and four-phase flow diagram to guide systematic review reporting (Liberati *et al.*, 2009). The checklist includes recommendations on reporting the review title, abstract, introduction, methods, results, discussion, and funding (Liberati *et al.*, 2009). Furthermore, the four-phase flow diagram presents the number of records yielded from the search, and the number of records moving through the screening and selection process, along with reasons studies were excluded throughout (Liberati *et al.*, 2009). More recently, the 2009 PRISMA statement was updated to PRISMA 2020 to reflect advancements in methodology and terminology, as well as updated checklists and flow diagrams to facilitate implementation (Page, McKenzie *et al.*, 2021). To ensure high quality reporting and continued transparency, the reporting of the results of the systematic review in Phase One was guided by the PRISMA statement current at the time of reporting (Liberati *et al.*, 2009).

2.4.10 Certainty of evidence

While quality appraisal examines and reports risk of bias (section 2.4.6, pp. 47-49), and data synthesis combines and reports extracted data of included studies either narratively or statistically with meta-analysis and estimated effects (section 2.4.8, pp. 50-57), these systematic review components do not provide an estimate of *certainty of evidence*. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach is a structured system for assessing and rating the certainty (or quality) of evidence in a synthesis body (Schünemann *et al.*, 2013). It is widely used for this purpose and for assessing the strength of recommendations by international organisations developing clinical practice guidelines, such as the NHMRC, the World Health Organisation and the National Institute for Health and Care Excellence (NHMRC, 2019). It is also used

to assess the certainty of evidence in systematic reviews and other evidence syntheses, with its use included in the Cochrane Handbook (Schünemann *et al.*, 2022). For systematic reviews, certainty/quality of evidence refers to the extent of confidence in the correctness of an estimate of effect (Schünemann *et al.*, 2013; Schünemann *et al.*, 2022). Certainty of evidence is generally applied to single pooled effect estimates from meta-analyses, although the GRADE approach may also be applied to narrative syntheses (Murad et al., 2017).

The GRADE approach rates the quality of evidence into four grades (Schünemann *et al.*, 2013):

- High – Very confident that the true effect lies close to that of the estimate of effect
- Moderate – Moderately confident in the effect estimate; true effect is likely close to the estimate of effect, but there is a possibility that it is substantially different.
- Low – Confidence in the effect estimate is limited; true effect may be substantially different from the estimate of effect.
- Very low – Little confidence in the effect estimate; true effect is likely to be substantially different from the estimate of effect.

Rating is made firstly on the basis of study design, and then factors are considered which may reduce or, in the case of observational studies, increase the quality of the evidence (Schünemann *et al.*, 2013). In terms of study design, randomised trials are initially rated as high quality, while observational studies are rated as low quality. Five factors are then considered which may *reduce* the quality of evidence; study limitations (risk of bias, see section 2.4.6, pp. 47-49), inconsistency of results (unexplained heterogeneity of results and effects across studies), indirectness of evidence (directness/relevance to the intervention, populations and outcomes of interest), imprecision (uncertainty of results due to fewer participant/events and subsequently wide confidence intervals) and publication bias (selective publication of studies, see section 2.4.8.4, pp. 54-55). Quality of evidence for observational studies may be *increased* based on three factors; large magnitude of effect (as defined by risk ratios and width of confidence intervals), dose-response gradient (medications and cause-effect relationships) and effect of plausible residual confounding (confounding reduces or increases effect where no effect observed in observational studies) (Schünemann *et al.*, 2013).

The results of GRADE assessments should be summarised in 'evidence tables', for which there are two approaches (Schünemann *et al.*, 2013). 'GRADE Evidence Profiles' comprise a list of outcomes, data about the body of evidence (number of studies, design), assumed and corresponding risk data, judgements for each assessment factor, statistical data including the relative effect and absolute effect, overall quality of evidence rating and the importance of each outcome and rating. These detailed evidence tables are intended for review authors, for preparation of 'Summary of findings'

tables, and for those questioning the assessments. Summary of findings tables are more brief, providing concise information in an accessible format, are intended for a wider audience including review and guideline end users, and are also used in Cochrane reviews (Schünemann *et al.*, 2022). A Summary of findings table comprises the same information as a GRADE Evidence Profile, without the judgement details of individual assessment factors. For both table formats, different comparisons (e.g. a sacral PI prophylactic dressing versus standard care, and a comparison of two different sacral PI prophylactic dressings) require separate tables (Schünemann *et al.*, 2013).

In the context of Phase One of this program of research, reporting was guided by the 2009 PRISMA statement current at the time of reporting (Liberati *et al.*, 2009), which did not require reporting of certainty of evidence. Thus, certainty of evidence was not included in the protocol (Lovegrove *et al.*, 2019) and reporting of Phase One and the subsequent publications (Chapters Three and Four; Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022). However, the updated PRISMA statement (Page, McKenzie *et al.*, 2021) does call for certainty assessment. Furthermore, as noted, certainty of evidence assessment is widely used internationally for guideline development, and while systematic reviews should not make recommendations for practice (Schünemann *et al.*, 2013), they may still assess quality of evidence and such recommendations are made by the Cochrane Handbook (Schünemann *et al.*, 2022). Therefore, for the purposes of this thesis, certainty of evidence assessment was undertaken using GRADE for different intervention types included in the Phase One acute and intensive care syntheses. As Phase One conducted intention-to-treat meta-analysis where appropriate for each intervention type within the acute and intensive care syntheses (see section 2.4.8.5, pp. 55-57), GRADE ratings were applied separately to each intention-to-treat meta-analysis (or comparison) demonstrating an effect for both syntheses. Individual study effects were summarised using risk ratios with CIs in the intention-to-treat meta-analyses (section 2.4.8.5, pp. 55-57), thus these estimates of effect were used for GRADE rating, which is appropriate for dichotomous outcomes (i.e. PI occurence) (Schünemann *et al.*, 2013).

GRADE assessments were undertaken by two reviewers independently, and disagreements were resolved through discussion (Schünemann *et al.*, 2022). The results were presented in Summary of findings tables in line with the GRADE (Schünemann *et al.*, 2013) and Cochrane Handbooks (Schünemann *et al.*, 2022), with the tables developed in GRADEpro™. GRADEpro™ is an online platform for synthesising and rating evidence using GRADE methodology, in which data may be imported from RevMan™ (see section 2.4.8.5, pp. 55-57), and components of the Summary of findings tables may be automatically calculated based on the information entered (e.g. overall GRADE ratings based on entered study design and factor judgements; absolute risk based on study data and effect estimates entered). Where risk of bias assessments have been undertaken for evidence using the Cochrane Risk of Bias tool, the results are directly relevant to the study limitations

factor of the GRADE assessment. As this was the case in Phase One (see section 2.4.6, pp. 47-49), the risk of bias assessments (using the 2011 version of the Cochrane tool; see section 2.4.6, pp. 47-49) were considered for the relevant component of the GRADE assessments (low risk of bias = GRADE no serious limitations, do not downgrade; unclear risk of bias = GRADE no serious limitations, do not downgrade OR serious limitations, downgrade one level; high risk of bias = serious limitations, downgrade one level OR very serious limitations, downgrade two levels (Schünemann *et al.*, 2011). I^2 statistical measures of heterogeneity were used to guide judgements of inconsistency (Schünemann *et al.*, 2013; see section 2.4.8.2, p. 53; section 2.4.8.5, p. 56). Imprecision was considered in terms of the Optimal Information Size (OIS; if total number of participants included in the synthesis was less than the number of participants required as per a conventional sample size calculation for a single powered trial, rate as having limitations) and the width of the CIs excludes no effect (if OIS was met and risk ratio excluded 1.0, do not rate with limitations) (Schünemann *et al.*, 2013). Publication bias was unable to be assessed using funnel plots in both the acute and intensive care syntheses due there being less than 10 studies in each meta-analysis (see section 2.4.8.5, p. 57; Chapter Three, p. 89; Chapter Four, p. 110). Thus, publication bias was assessed as 'undetected' from the options of 'undetected' and 'strongly suspected' in GRADEpro™.

2.5 Methods

While the overarching research question and aim are intensive care focused, there is little supporting evidence for individual PI preventative interventions within intensive care alone, as established in Chapter One (pp. 30-35). Thus, to identify all relevant PI preventative interventions for potential inclusion within the minimum PI preventative intervention set, the systematic review and meta-analysis was broadened to include acute hospital settings. However, also as previously noted, (p. 31), critically ill patients and intensive care settings are inherently different to patients admitted to acute ward settings. Therefore, studies selected for inclusion were separated by setting (acute ward and intensive care) for synthesis. Setting-specific data were extracted were possible in studies with mixed acute and intensive care settings. As such, the syntheses were reported separately. The acute care setting synthesis was published in the *International Journal of Nursing Studies* (Lovegrove *et al.*, 2021), and the published report is presented in Chapter Three. The intensive care specific synthesis was published in *Australian Critical Care* (Lovegrove, Fulbrook, Miles & Steele, 2022), and the published report is presented in Chapter Four. The methods of these works are provided within the published reports. However, given that the works were based upon the same search strategy and study selection process, there is some duplication of the method descriptions. Furthermore, while the specific research question for each synthesis is provided within the published reports (Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022), the aim and objectives are stated below. A more comprehensive overview of the search terms and database-specific used is also provided.

2.5.1 Aim and objectives

The overall aim was to identify and assess which interventions (single or bundled) are effective to prevent PI in adult inpatients admitted to acute hospital and intensive care settings.

The objectives were to:

- Identify randomised controlled trials which assessed the effectiveness of interventions (single or bundled) to prevent PI in adult inpatients admitted to *acute hospital settings*.
- Identify randomised controlled trials which assessed the effectiveness of interventions (single or bundled) to prevent PI in adult inpatients admitted to *intensive care settings*.
- Assess the effectiveness of interventions (single or bundled) to prevent PI in adult inpatients admitted to *acute hospital settings* in studies from which intention-to-treat data were extracted.
- Assess the effectiveness of interventions (single or bundled) to prevent PI in adult inpatients admitted to *acute hospital settings* in studies from which per protocol data were extracted.
- Assess the effectiveness of interventions (single or bundled) to prevent PI in a subset of adult patients admitted to *intensive care settings* in studies from which intention-to-treat data were extracted.
- Assess the effectiveness of interventions (single or bundled) to prevent PI in a subset of adult inpatients admitted to *intensive care settings* in studies from which per protocol data were extracted.

2.5.2 Search terms and subject headings

Search terms and subject headings were not included for the Comparison (C) component of PICO. This is because “randomized controlled trial” OR “controlled clinical trial” for control group were included in the ‘P’ component. Furthermore, comparisons may be made with interventions included in the ‘I’ component, a variation of standard care or no intervention. The PICO components displayed in the Table 2.1 columns were combined with ‘AND’. Subject headings were available and used in EBSCO CINHAL Complete, EBSCO Medline Complete and Ovid Embase.

Table 2.1: Systematic review key words and subject headings

	Population (P)	**Intervention (I)**	**Outcome (O)**
Search terms	(“pressure ulcer*” OR “pressure sore*” OR “pressure injur*” OR “bed sore*” OR “bed ulcer*” OR “heel ulcer*” OR “heel sore*” OR “deep tissue injur*” OR “deep tissue ulcer*” OR “deep tissue sore*” OR “decubitis ulcer*” OR “decubitus sore*” OR “decubitis injur*”) AND (hospital* OR “hospital-acquired” OR “acute care” OR “primary care” OR “tertiary care” OR “secondary care” OR iatrogenic OR “health facility*” OR inpatient* OR hospitali?ation) AND (random* OR RCT OR “randomized controlled trial*” OR “controlled clinical trial*” OR “random allocation” OR “double blind method” OR “single blind method”) OR ((singl* OR doubl* OR treb* OR tripl*) N (blind* OR mask*))	(intervention* OR prevent* OR strateg* OR plan* OR bundle* OR device* OR implement* OR manage* OR “pressure relie*” OR “pressure redistribute*” OR “support surface*”)	(incidence OR outcome)
Subject Headings			
EBSCO CINAHL Complete	((MH "Pressure Ulcer+") OR (MH "Deep Tissue Injury") OR (MH "Heel Ulcer")) AND ((MH "Hospitals+") OR (MH “Inpatients”) OR (“Hospitalization+”) OR (MH "Acute Care") OR (MH "Primary Health Care") OR (MH “Tertiary Health Care”) OR (“Secondary Health Care”) OR (MH "Iatrogenic Disease") OR (MH "Health Facilities+")) AND ((MH “Random Assignment) OR (MH “Randomized Controlled Trials+”) OR (MH “Clinical Trials”))	((MH "Nursing Interventions") OR (MH “Pressure Ulcer Care (Saba CCC)+”) OR (MH "Pressure Ulcer Prevention (Iowa NIC)") OR (MH "Preventive Health Care+") OR (MH "Nursing Care Plans, Computerized") OR (MH "Nursing Care Plans+") OR (MH "Patient Care Plans+") OR (MH "Nursing Orders") OR (MH “Nursing Protocols”))	((MH "Incidence") OR (MH "Treatment Outcomes+") OR (MH "Nursing Outcomes") OR (MH “Outcomes Research”) OR (“Outcomes (Health Care)+”) OR (“IOWA Nursing Outcomes Classification+”) OR (MH “Outcome Assessment”))
EBSCO MEDLINE Complete	((MH "Pressure Ulcer”)) AND ((MH “Hospitals+”) OR (MH “Tertiary Care Centers”) OR (MH “Secondary Care Centers”) OR (MH "Health Facilities+") OR (MH "Iatrogenic Disease+") OR (MH “Hospitalization+”) OR (MH "Primary Health Care+") OR (“Tertiary Healthcare”) OR (“Secondary Care”)) AND ((MH “Random Allocation”) OR (MH “Randomized Controlled Trial+”) OR (MH “Clinical Trial+”) OR (MH “Controlled Clinical Trial”))	((MH “Standardized Nursing Terminology”) OR (MH “Patient Care Bundles”) OR (MH "Primary Prevention+") OR (MH "Tertiary Prevention”) OR (MH "Health Plan Implementation") OR (MH “Patient Care Management”) OR (MH "Nursing Care+") OR (MH "Patient Care Planning+") OR (MH "Primary Care Nursing”))	((MH "Incidence") OR (MH "Treatment Outcome+") OR (MH “Outcome Assessment (Health Care)”))
Ovid Embase	exp decubitus/ AND exp hospital patient/ or exp hospital/ or exp hospitalization/ or exp primary medical care/ or exp tertiary health care/ or exp secondary health care/ or exp iatrogenic disease/ or exp health care facility/ or exp hospital patient/ AND exp intervention study/ or exp controlled study/	exp nursing intervention/ or exp prevention/ or exp nursing care plan/ or exp care bundle/ or exp devices/	exp incidence/ or exp clinical outcome/ or exp outcome assessment/ or exp treatment outcome/
Key			
+ or exp = subject heading exploded, * = truncation to find all variations of the key word, ? = find one character variations in spelling, N = proximity operator to find words near each other (a specified number of words apart) Please note: Operators were changed according to the relevant operators of each database			

2.6 Conclusion

This chapter has introduced Phase One and has presented the research design and methodology of this phase.

Phase One was justified as appropriate for addressing the relevant objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings*.

The next two chapters present the published reports of Phase One, a systematic review and meta-analysis of randomised controlled trials.

Chapter Three: Phase One: A systematic review and meta-analysis (acute hospital settings)

3.1 Introduction

In Phase One, a systematic review and meta-analysis was undertaken to address the overall research objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.*

As noted previously (pp. 30-34), while the overarching research question and aim are intensive care focused, there is little supporting evidence for individual PI preventative interventions within intensive care alone. Thus, to identify all relevant PI preventative interventions for potential inclusion within the minimum PI preventative intervention set, the systematic review and meta-analysis was broadened to include acute hospital settings (pp. 35, 55, 60). Included studies were then separated by setting (acute ward and intensive care) for synthesis (pp. 55, 60). This chapter presents the acute hospital setting-specific synthesis, while the following chapter (Chapter Four) presents the intensive care-specific synthesis.

A systematic review protocol was registered and published *a priori* with PROSPERO: International prospective register of systematic reviews (Lovegrove *et al.*, 2019; Registration number CRD42019129556), and is available at https://www.crd.york.ac.uk/PROSPERO/.

The acute hospital setting synthesis was published in the *International Journal of Nursing Studies* (Lovegrove *et al.*, 2021). This Q1 journal (Scimago, 2022c) was selected as it is a highly regarded international nursing journal which is furthering the discussion and provision of evidence surrounding PI prevention across settings. For the year of publication (2021), it has an Impact Factor (Clarivate™, 2022b) of 6.612 and a Scimago Journal Ranking (2022c) of 4/154 Nursing – Miscellaneous. On seeking permission to present the published paper within this thesis in PDF form, the journal editorial office (see Research Portfolio Appendix C) referred to the Elsevier Permissions webpage (Elsevier, 2021b), which notes that articles can be included in full or in part in a thesis for non-commercial purposes. Theses which contain embedded published journal articles can also be posted publicly by the awarding institution with DOI links (Elsevier, 2021a). Thus, the PDF of the published paper is now presented herein (pp. 65-92).

3.2 Certainty of evidence

Certainty of evidence was assessed using the GRADE approach for intervention types which demonstrated effectiveness in intention-to-treat meta-analysis (see section 2.4.10, pp. 57-60). For the acute hospital setting synthesis presented in this chapter, the only intervention meeting these criteria was Australian medical sheepskin overlay when compared to standard care. The certainty of evidence for this intervention was judged to be very low (Table 3.1) due to risk of bias, inconsistency and indirectness. The result is congruent with the limitations of the included studies noted in the published report (Lovegrove *et al.*, 2021; pp. 87, 89 of this chapter), and its conclusion that further contemporary research is required to confirm the intervention's effectiveness.

Table 3.1: Summary of findings: Australian medical sheepskin overlay

Summary of findings:

Australian medical sheepskin overlay compared to standard care for adults admitted to acute hospital settings

Patient or population: Adult inpatients
Setting: Acute hospital settings
Intervention: Australian medical sheepskin overlay
Comparison: Standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with standard care	**Risk with Australian medical sheepskin ITT**				
Pressure injury	195 per 1,000	**82 per 1,000** (43 to 152)	**RR 0.42** (0.22 to 0.78)	836 (2 RCTs)	⊕◯◯◯ Very low[a,b,c,d, e]	Publication bias unable to be assessed

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. 1 of 2 studies had a risk of bias criterion judgment of high risk
b. Heterogeneity substantial (I^2 64%)
c. 1 study included general patients, 1 study limited to over 60s only and orthopaedic only
d. Optimal Information Size met
e. Large effect (RR < 0.5); no change to rating as not observational

3.3 Conclusion

This chapter has presented the acute hospital setting-specific synthesis of the systematic review and meta-analysis undertaken in Phase One. The synthesis has identified randomised controlled trials which assessed the effectiveness of interventions (single or bundled) to prevent PI in adult inpatients admitted to acute hospital settings and assessed the effectiveness of the reported interventions. This chapter, in part, addressed the research objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.* To further address this research objective, the next chapter presents the intensive care-specific synthesis from the systematic review and meta-analysis.

Chapter Four: Phase One: A systematic review and meta-analysis (intensive care settings)

4.1 Introduction

In Phase One, a systematic review and meta-analysis was undertaken to address the overall research objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.* As detailed in the preceding chapters (pp. 35, 55, 60) studies selected for inclusion were separated by setting (acute ward and intensive care) for synthesis. The previous chapter presents the acute hospital setting-specific synthesis, while this chapter presents the intensive care-specific synthesis.

The intensive care-specific synthesis has been published in *Australian Critical Care* (Lovegrove, Fulbrook, Miles & Steele, 2022). *Australian Critical Care* was selected as it disseminates evidence specific to critical care and is progressing the dialogue surrounding PI prevention in this setting. It is a Q1 journal (Scimago, 2022a) with a 2021 Impact Factor of 3.265 (Clarivate™, 2022a) and a Scimago Journal Rankings (2022a) of 2/20 Nursing – Critical care nursing and 3/27 Nursing – Emergency nursing. As with the acute hospital setting synthesis (p. 64), on seeking permission to present the published paper within this thesis in PDF form, the Editor-In-Chief (see Research Portfolio Appendix D) referred to the Elsevier Permissions webpage (Elsevier, 2021b), which specifies that articles may be included in a thesis/dissertation for non-commercial purposes, and that written permission from Elsevier is not necessary. The publisher Article Sharing policy (Elsevier, 2021a) also notes that theses which have published articles embedded in the submission can be posted by the awarding institution with DOI links to the publication. Thus, the published paper is presented in this chapter in PDF form (pp.96-113).

4.2 Certainty of evidence

Certainty of evidence was assessed using the GRADE approach for intervention types which demonstrated effectiveness in intention-to-treat meta-analysis (see section 2.4.10, pp. 57-60). For the intensive care setting synthesis presented in this chapter, the interventions meeting these criteria were prophylactic sacral dressings (plus standard care) compared to standard care alone and prophylactic heel dressings (plus standard care) compared to standard care alone. The certainty of evidence for sacral prophylactic dressings was judged to be low (Table 4.1) due to risk of bias and indirectness.

Table 4.1: Summary of findings: Prophylactic sacral dressings

Summary of findings:

Prophylactic sacral dressings compared to standard care for adults admitted to intensive care settings

Patient or population: Adult inpatients
Setting: Intensive care settings
Intervention: Prophylactic sacral dressings
Comparison: Standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with standard care	**Risk with prophylactic sacral dressings**				
Pressure injury	70 per 1,000	**15 per 1,000** (8 to 30)	**RR 0.22** (0.11 to 0.43)	1352 (4 RCTs)	⊕⊕◯◯ Low[a,b,c,d,e]	Publication bias unable to be assessed

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. 2 of 4 studies had a risk of bias criterion judgment of high risk
b. No heterogeneity (I^2 0%)
c. 1 study included limited to high/very high risk patients and patients expected for > 3 days, 1 study limited to very high risk patients, 1 study limited to mild risk patients
d. Optimal Information Size met
e. Large effect (RR < 0.5); no change to rating as not observational

The certainty of evidence for heel prophylactic dressings was also judged to be low (Table 4.2) due to risk of bias and indirectness. While the effect size was large in both (risk ratio < 0.5), and sensitivity analyses suggested the meta-analysis results for sacral dressings were robust (pp. 109 of this chapter), the judgement of low certainty of evidence emphasises the limitations of the included studies. These results support the conclusions of the published report of the intensive care synthesis, which calls for further research across intervention types, even where meta-analysis demonstrated significant intervention effects (pp. 110 of this chapter).

Table 4.2: Summary of findings: Prophylactic heel dressings

Summary of findings:

Prophylactic heel dressings compared to standard care for adults admitted to intensive care settings

Patient or population: Adult inpatients
Setting: Intensive care settings
Intervention: Prophylactic heel dressings
Comparison: Standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with standard care	**Risk with prophylactic heel dressings**				
Pressure injury	41 per 1,000	**13 per 1,000** (5 to 33)	**RR 0.31** (0.12 to 0.80)	915 (2 RCTs)	⨁⨁◯◯ Low[a,b,c,d,e]	Publication bias unable to be assessed

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. 1 of 2 studies had a risk of bias criterion judgment of high risk
b. No heterogeneity (I^2 0%)
c. 1 study included limited to high/very high risk patients and patients expected for > 3 days
d. Optimal Information Size met
e. Large effect (RR < 0.5); no change to rating as not observational

4.3 Conclusion

This chapter has presented the intensive care setting-specific synthesis of the systematic review and meta-analysis undertaken in Phase One. The synthesis has identified randomised controlled trials which assessed the effectiveness of interventions (single or bundled) to prevent PI in adults admitted to intensive care settings and assessed the effectiveness of the reported interventions.

The completion of Phase One of this program of research, which comprises the syntheses presented in both Chapter Three (acute hospital setting-specific synthesis) and this chapter, has for the most part addressed the research objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.* However, these syntheses were limited to literature published prior to the year 2020. To fully address this research objective and present the most up-to-date overview of the relevant interventions within this thesis, the searches were updated to include the years 2020 and 2021. The next chapter (Five) presents the updated search results.

Chapter Five: Phase One: An update to the systematic review and meta-analysis

5.1 Introduction

In Phase One, a systematic review and meta-analysis was undertaken to address the overall research objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings*. The two previous chapters present the published reports of the systematic review and meta-analysis in acute (Chapter Three) and intensive care (Chapter Four) settings, of which both included studies published in 2019 and prior. For the purposes of contemporaneity and this thesis, the searches were rerun in January 2022 by the PhD candidate to present further research articles meeting the inclusion criteria which were published in 2020 and 2021. This chapter presents a brief overview of the searches and relevant articles identified.

5.2 Updated searches

The systematic review searches were updated using the main systematic review search strategy (pp. 60-62, 66, 79, 97), with the only change being the limitation of searches to the years 2020 and 2021. Search results were collated in EndNote™ X9, duplicates were removed, and the remaining citations were uploaded into Covidence™. The PhD candidate screened abstracts, and then full-texts against the eligibility criteria applied within the main review (pp. 45-46, 66, 97) to identify relevant articles. Data were then extracted directly from the identified full-text articles and summarised in a table (Table 5.1).

5.3 Results

5.3.1 Study selection

The study selection process is displayed in Figure 5.1 (Page, McKenzie *et al.*, 2021). Overall, 12 further articles relevant to the systematic review were identified. Of which, five were acute care setting trials, six were intensive care setting trials and one included both acute and intensive care units.

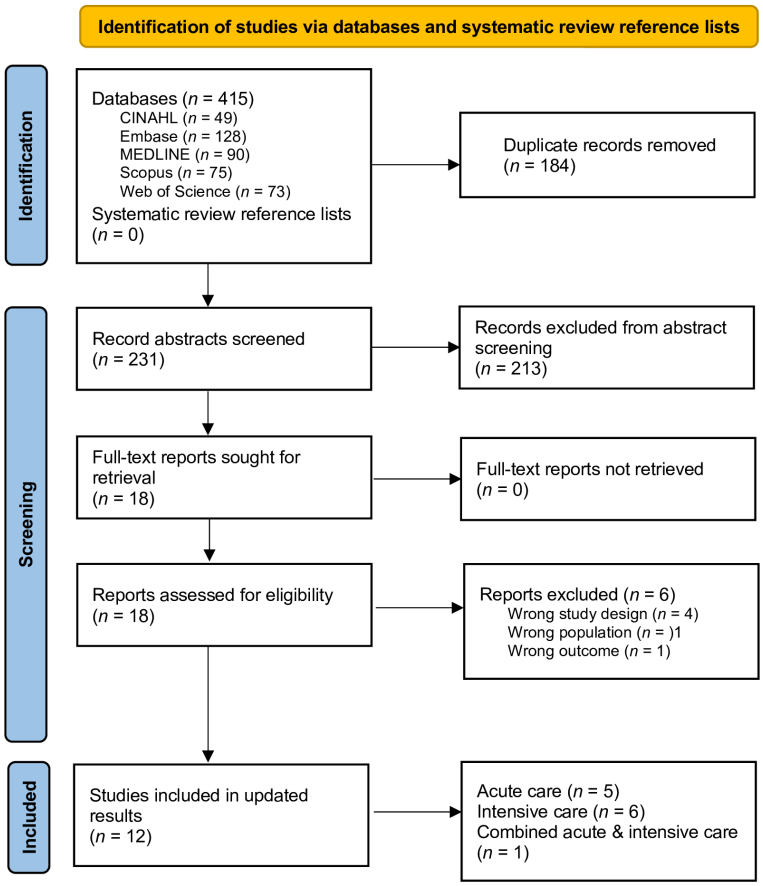


Figure 5.1: Updated 2020 and 2021 search flow diagram

5.3.2 Summary of interventions

Table 5.1 provides a summary of the 12 studies identified in the 2020 and 2021 searches, and the interventions tested. No additional interventions to the earlier systematic reviews were identified. However, variations of the interventions (i.e. different topical applications, bundles with varying components and support surface and repositioning combinations) were evident. Five prophylactic dressing trials were identified. Consistent with trials identified in the earlier searches, the majority (*n* = 4/5) demonstrated effectiveness for preventing PI at the dressing location. Four topical application trials were found, but similar to the earlier searches, the types of applications were heterogenous and limited to single studies. Nonetheless, one trial demonstrated that the topical application was effective in preventing PI when compared to standard care, and one in comparison to a placebo but not standard care (3-arm trial). The three bundle trials were also heterogenous in terms of bundle composition, but all were found to be effective.

Table 5.1: 2020 and 2021 trial characteristics and outcomes

Authors, Year Country	Acute or ICU	Setting Sample	Intervention	Comparison	ITT or PP	PI incidence	Reported significance *p*	Time to PI	Comments
Prophylactic dressings (*n* = 5)									
Beeckman *et al.*, 2021 Belgium	Acute & ICU	8 hospitals, ICU & 'non-ICU' wards >18 years; Braden < 17; admitted within last 48h; without sacral PI stage II or worse; no IAD or skin condition contraindicating intervention	1. Prophylactic sacral, heel & trochanteric dressings (Mepilex® brand) plus standard care 2. Prophylactic sacral, heel & trochanteric dressings (Allevyn® brand) plus standard care	Standard care (regular risk assessment, skin assessment, repositioning plan, pressure redistributing devices, offloading heels, nutritional status monitoring, skin care)	States ITT but PP	Interventions 43/1066 (4%) Control 34/539 (6.3%)	*p* = 0.04 (reported ITT, includes stage II PI & worse only)	Not reported	14 day follow up Staging not reported Patients still included if prevention could be applied or PIs stage II or worse at ¾ of other sites (heel left/right; trochanter left/right) PI incidence stage II & worse
Eberhardt *et al.*, 2021 Brazil	Acute	Perioperative units Elective digestive/cardiac surgery; > 18 years; expected LOS ≥ 48h; no lower limb amputation, fracture preventing heel access, heel PI, impaired LOC & communication	Prophylactic multi-layered silicone foam dressings (Mepilex® Border Heel) to heels plus standard care	Prophylactic transparent polyurethane film dressing (Advanced, Cremer) to heels plus standard care (post-operative: floating heels, daily risk/skin assessments, PI change 2 hourly; intra-operative: no PI prevention)	PP	Intervention 36/135 (26.7%) Control 63/135 (46.7%)	*p* = 0.001	Kaplan-Meyer: Intervention 57.5h Control 43.9h *p* < 0.001	Follow up to 72h, heels assessed immediately post-operative, first and second post-operative day NPUAP 2016 staging (Edsberg *et al.*, 2016; EPUAP *et al.*, 2019) Unclear which pre- and post-operative units involved, wards only or ICU also? Comparison dressing was standard care
Gazineo *et al.*, 2020 Italy	Acute	Unit/wards not described ≥ 65 years; admitted from ED with fragility hip fracture; without sacral PI, different fracture type, intervention dressing allergy, skin diseases	Prophylactic sacral dressing (Allevyn® Life) plus standard care	Standard care (regular risk/skin assessments, active support surface for Braden < 18, 4 hourly repositioning, heel off-loading, head of bed elevation limit, incontinence skin care)	ITT	Intervention 7/34 (20.6%) Control 1/34 (2.9%)	*p* = 0.54	Intervention mean 5.9 days Control mean 2.7 days *p* = 0.003	PI

Hahnel *et al.*, 2020 Germany	ICU	7 ICUs (surgical, cardiovascular, gastroenterology, nephrology, anaesthesiology, neurology) ≥ 18 years; within 6h of admission; high to very high PI risk; expected LOS ≥ 3 days; without PI, trauma to heels or sacrum, intervention dressing allergies; not at end of life, on air-fluidised beds and unable to be repositioned	Prophylactic sacral & heel dressings (Mepilex® Border Sacrum & Heel) plus standard care	Standard care (PI risk assessment, regular skin inspection, patient information, mobilisation, support surface use, repositioning, heel flotation)	States ITT but PP	Intervention 6/212 (2.8%) Control 28/210 (13.3%)	$p < 0.001$	Stage II+: Intervention mean 10.8 days Control mean 13.5 days $p = 0.025$	Follow up to decrease in risk status, sacral or heel PI developed and healed, adverse dressing event, withdrawal, protocol violation, death, transfer, discharge PI incidence reporting for all stages, time to PI only Stage II and worse NPUAP *et al.*, 2014 staging
Oe *et al.*, 2020 Japan	Acute	3 hospitals/medical centres (units not described) ≥ 20 years; with persistent diarrhea and/or fragile skin (low birth weight baby, graft versus host disease, jaundice); without PI	Prophylactic foam dressing (Mepilex® Border) to sacrum & coccyx plus standard care	Standard care (risk screening, skin inspection & care, repositioning 2 hourly, support surfaces)	ITT	Intervention 5/300 (1.7%) Control 22/300 (7.3%)	$p = 0.001$	Intervention mean 13.9 days Control mean 13.7 days $p = 0.002$	2 week follow up or to death or discharge NPUAP staging, year unclear
Topical Applications (*n* = 4)									
Borzou *et al.*, 2020 Iran	ICU	ICU (mostly trauma) 18-85 years; with IDC; Braden ≤ 18; no skin allergies, diseases, PI, topical applications, sensitivity to intervention, diabetes, bed rest, quadra/ paraplegia	Topical sweet almond oil to sacrum, heels & shoulders plus standard care	Placebo plus standard care OR Standard care only	PP	Intervention 2/36 (5.6%) Placebo 5/36 (13.94%) Control 9/36 (25.14%)	3-arm comparison $p = 0.06$ Placebo comparison $p = 0.024$ Control comparison $p = 0.189$	Intervention 5.4 days versus Placebo 5 days ($p = 0.196$) Control 4.22 days ($p = 0.023$)	7 day follow up NPUAP *et al.*, 2014 staging
Choi & Kim, 2021	ICU	Neurological ICU >20 years; repos-itioning needed (paralysis, paresis, lowered LOC); without sacral PI/wounds, body temperature > 38°C, persistant diarrhea, haemodynamic instability, do not resuscitate status	Uncoated paper (WYPALL™) to sacrum for 5 days plus standarc care	Standard care (repositioning 2 hourly & active mattress)	PP	Intervention 1/68 (1.5%) Control 3/67 (4.5%)	$p = 0.366$	Intervention group: case on day 5 Control group: 1 case on day 3, 2 cases on day 5	Outcome measured on days 1, 3, 5 NPUAP 2016 staging (Edsberg *et al.*, 2016)
Karimi *et al.*, 2020	ICU	Surgical, medical & trauma ICU ≥ 18 years; moderate to high	1. Olive oil soaked gauze applied to heels plus standard	*Comparison of two interventions, not applicable*	ITT	Olive oil 0/11 (0%) Fish oil 0/13	Not significant		7 day intervention period NPUAP staging (Edsberg *et al.*,

Iran		PI risk (Braden); without heel PI, allergy to oils	care 2. Fish oil soaked gauze applied to heels plus standard care			(0%)			2016)
Sönmez & Yapucu, 2020 Turkey	ICU	2 ICUs (anaesthesia & neurosurgery) ≥ 18 years; Braden ≤ 12; LOS ≥ 5 days; without PI, brain death, positioning contraindications, medical disability, vasoconstrictive therapy, terminal period, casts or bandages on lower limbs	Extra virgin olive oil to sacrum, trochanters & heels plus standard care	Standard care (skin assessments at position change, support surfaces, tight fitting sheets, risk assessment, skin barrier protection product)	PP	Intervention 11/65 (16.9%) Control 21/64 (32.8%)	$p = 0.037$	Intervention mean 10.45 days Control mean 7.50 days	Follow up 5-days to four weeks or to Stage II PI development EPUAP & NPUAP 2009 staging
Bundled interventions ($n = 3$)									
Jiang *et al.*, 2020 China	ICU	7 acute hospitals, 13 ICUs (medical, surgical, trauma) ≥ 18 years; admission in last 24h; expected LOS ≥ 7 days; limited mobility or Braden < 17; without PI, erythema, bruising, terminal illness, refusal/limitation of pressure redistribution mattress, limitation of repositioning, mental/psychiatric symptoms, other study participation	4-hourly repositioning with reactive mattress	2-hourly repositioning with active mattress (standard care)	States ITT but PP	Intervention 2/596 (0.3%) Control 11/598 (1.5%)	$p = 0.022$	Intervention median 2 days Control median 5 days $p = 0.231$	Follow up to discharge, death, at least 7 days, to 3-months for developed PI 2009 NPUAP & EPUAP staging
Kathirvel *et al.*, 2021 India	Acute	Orthopaedic wards ≥ 18 years; immobile; with Stage I PI or Braden ≤ 12	Full intervention educational bundle (patient/caregiver education using self-instruction manual, one-to-one explanation/demonstration, counselling)	Minimal interventional education bundle (patient/caregiver education using self-instruction manual only)	ITT	Intervention4 /46 8.7% Control 10/46 21.7%	$p = 0.043$	Intervention mean 26.4 days Control mean 35.3 days $p = 0.045$	
Xiao *et al.*, 2021 China	Acute	Hospital, units not described 60-85 years; bedridden (cerebral infarction, dementia, diabetic encephalopathy) for > 1 week; without severe heart, lung, liver or kidney damage, mental illness, failure to	'Seamless nursing care' bundle (detailed procedure for admission, pre- and post-operative care, including health, condition & skin assessments, health management, body temperature control, anti-PI	Standard care (routine pre- & post-operative education/care, postoperative dressing change as per medical advice, caregiver assistance for turning, patient and caregivers	ITT	Intervention 2/66 (3.03%) Control 14/66 (21.21%)	$p = 0.001$	Not reported	States surgical patients throughout paper but not defined in eligibility criteria Follow up during hospitalisation & 15 days post PI incidence during hospitalisation presented

		cooperate, history of or current PI	pad intraoperatively, PI management) plus standard care	asked to use turning pad)					Young 1996 PI staging
Emergency Department = ED, Hours = h, Intensive care unit = ICU, Intention-to-treat = ITT, LOC = level of consciousness, LOS = length of stay, Per protocol = PP									

5.4 Conclusion

This chapter has detailed the update of earlier systematic review searches to briefly summarise trials published more recently, in the years 2020 and 2021, for the purposes of this thesis. The updated searches complete Phase One of this program of research. Overall, Phase One comprised the published systematic searches and syntheses presented in Chapter Three (acute hospital setting-specific synthesis), Chapter Four (intensive care setting-specific synthesis) and this chapter, fully addressing the research objective *to identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.*

Within this program of research, Phase One was performed to inform Phase Two by determining which PI preventative interventions have demonstrated effectiveness in acute hospital and intensive care settings in randomised controlled trials, and thus may be potentially included in the minimum PI preventative intervention set developed in Phase Two. The next part (Two) of this thesis presents Phase Two of the program of research. Specifically, it provides an overview of the methodology and extended methods of Phase Two (Chapter Six), the selection of interventions from those identified in Phase One, for use in Phase Two (Chapters Seven) and the published modified Delphi study (Chapter Eight).

PART TWO: PHASE TWO

Chapter Six: Phase Two: Methodology

6.1 Introduction

The research problem was established in Chapter One, within the context of the theoretical background. Based on the established research problem, a research question, aim and objectives were developed, which were subsequently addressed by a three-phase program of research.

1. Phase One: Systematic review and meta-analysis
2. **Phase Two: Modified Delphi study**
3. Phase Three: Translation and concurrent validity study.

Part One of this thesis (Chapters Two to Five) presented Phase One of the overall program of research. This chapter introduces **Phase Two** and presents the methodology and rationale for this phase. Additionally, extended methods are also presented to support the full methods described in the corresponding publication.

To set the scene for this chapter, the overall research question, aim and objectives are re-presented, and the research design of Phase Two is situated against the overall design of the program of research. Further detail on the remaining phase is provided in future chapters.

6.2 Overall research question

What interventions should be applied relative to critically ill patients' PI level of risk, as determined by an intensive care-specific risk assessment scale (the COMHON Index), as part of a minimum set of PI preventative interventions for international use within intensive care units?

6.2.1 Overall research aim and objectives

The overall aim of this program of research is to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care units.

This encompasses the following objectives:

1. To identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.
2. To develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index.
3. To translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale.

6.3 Research design

In order to address the overall research question and aim, an interlinked three-phase program of quantitative research was designed with each phase addressing one of the research objectives. Prior to establishing international consensus about a minimum PI prevention set, PI preventative interventions which are effective in preventing PI in adults admitted to acute hospital and intensive care settings needed to be identified, to form the basis of the minimum intervention set. Once developed, the minimum PI preventative intervention set would require testing on an international scale, but the COMHON Index is not yet available in one of the most commonly spoken languages globally, Chinese Mandarin. To this end, the three-phase program of research was developed.

Phase One addressed the first research objective through a systematic review and meta-analysis of randomised controlled trials undertaken to identify and synthesise high level evidence demonstrating the effect of PI preventative interventions in adult acute hospital and intensive care inpatients. Phase One is presented in Part One, Chapters Two to Five, of this thesis. The results of Phase One were then used to inform the development of the intervention set in Phase Two.

For **Phase Two**, the development of a minimum PI preventative intervention set based on those interventions identified in Phase One, was required. Evidence surrounding the use of interventions relative to assessed level of PI risk in intensive care patients is lacking. As such, it was appropriate to

obtain consensus representative of international expertise to establish an applicable minimum PI preventative intervention set, using a recognised consensus method (Fink *et al.*, 1984; Vernon, 2009; Waggoner *et al.*, 2016). While expert consensus is low level evidence according to The Joanna Briggs Institute (Level 5.b, 2014), and is not classified within the evidence levels by NHMRC (2000), use of a consensus method was appropriate to address the second research objective. Of the consensus methods available, a modified Delphi design was selected, as it was most suitable to facilitate international collaboration and integration of expert consensus with the evidence-based interventions identified in the first phase of this research. Further details of the Phase Two rationale and methodology are now provided in this chapter (pp. 127-140). The results of Phase One are then linked to the development of the intervention set in Chapter Seven. To conclude Phase Two, the published study report (Lovegrove, Fulbrook & Miles, 2020) is presented in Chapter Eight.

6.4 Phase Two methodology

6.4.1 Consensus designs and rationale

Phase Two was undertaken to address the objective *to develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index*. To do so, it was necessary to employ a research design which enabled the convergence of international expert opinion to obtain consensus. Since their inception in the mid-1900s (Fink *et al.*, 1984), consensus designs have become widely used in health care (Fink *et al.*, 1984; Halcomb *et al.*, 2008; Vernon, 2009; Waggoner *et al.*, 2016). These designs allow for the synthesis of evidence-based literature and the convergence of expert opinion to address complex health issues and research questions. Such designs are used to for issues and questions for which there is not yet a standard of care or guideline (Halcomb *et al.*, 2008; Waggoner *et al.*, 2016) or for which little is known or there is conflicting evidence (Fink *et al.*, 1984; Vernon, 2009; Waggoner *et al.*, 2016). There are several designs which are used to obtain consensus and agreement outcomes; including consensus development conferences (or panels), the nominal group technique and the Delphi technique (Fink *et al.*, 1984; Waggoner *et al.*, 2016). These are now discussed to rationalise the design chosen for Phase Two.

6.4.1.1 Consensus development conferences

Consensus development conferences are used as an approach to evaluate, interpret and summarise scientific evidence to provide a statement of recommendations for guiding practice and policies (Halcomb *et al.*, 2008; National Institutes of Health, 2013b; Waggoner *et al.*, 2016). The National Institutes of Health (2013a) has widely used this design since 1977 to examine a variety of health issues (Fink *et al.*, 1984; Halcomb *et al.*, 2008; National Institutes of Health, 2013a; Waggoner *et al.*, 2016). More recently, consensus development conferences have been used to explore the evidence

surrounding contemporary complex health issues such as unavoidable PI (Edsberg *et al.*, 2014) and antimicrobial-resistant organisms (Buick *et al.*, 2015). A consensus development conference usually consists of a review of the topical evidence, a multi-day face-to-face conference at which the evidence is considered and debated by conference participants, and the production of a statement summarising the resulting recommendations and consensus outcomes (Buick *et al.*, 2015; Edsberg *et al.*, 2014; Halcomb *et al.*, 2008; Waggoner *et al.*, 2016). Participants are not necessarily experts in the field of interest, but may instead be stakeholders such as clinicians, policy makers or consumers (Halcomb *et al.*, 2008). This design combines the synthesis of supporting evidence and participant opinion and promotes greater time efficiency as outcomes are reached by the end of the conference (Waggoner *et al.*, 2016). However, while the face-to-face component of this design enables focused participant involvement, robust discussion and debate, there is a risk of bias due to lack of anonymity, group dominance and peer pressure (Halcomb *et al.*, 2008; Waggoner *et al.*, 2016). Furthermore, the face-to-face group meeting associated with this design requires costly resources and a high level of organisation (Waggoner *et al.*, 2016).

6.4.1.2 Nominal group technique

A nominal group technique is employed to generate innovative ideas aimed at solving the identified problem or research question (McMillan *et al.*, 2014). The technique has been used in health care research recently to address knowledge gaps, including identifying key treatment priorities for paediatric chronic pain rehabilitation (Hurtubise *et al.*, 2019) and determining solutions to the barriers of exercise for moderately disabled individuals with multiple sclerosis (Moffat & Paul, 2018). The nominal group technique is a structured group interaction, in which researchers firstly pose a question or questions to a panel of experts (Foth *et al.*, 2016; McMillan *et al.*, 2016; Waggoner *et al.*, 2016). Panel members independently generate ideas related to the question(s) and the ideas are then presented (often anonymously) at a face-to-face group meeting (Foth *et al.*, 2016; McMillan *et al.*, 2016; Waggoner *et al.*, 2016). The ideas are then discussed and either ranked or voted on to establish consensus (Foth *et al.*, 2016; McMillan, *et al.*, 2016; Waggoner *et al.*, 2016). While the nominal group technique does introduce some anonymity in the early stages of the process, similar to the consensus development conference, it also includes face-to-face contact by an expert panel, and thus carries the same associated advantages and disadvantages (Foth *et al.*, 2016, Waggoner *et al.*, 2016). Moreover, evidence-based literature may not always be integrated into the approach to support the outcomes (Vakil, 2011).

6.4.1.3 Delphi technique

The Delphi technique, however, does not require face-to-face meetings, and has the potential to integrate evidence through the inclusion of a literature review in the technique (Foth *et al.*, 2016; Hsu

& Sandford, 2007; Keeney *et al.*, 2011; McMillan *et al.*, 2016; Trevelyan & Robinson, 2015). While this does not allow for discussion and debate between panel members, a recognised limitation of the Delphi technique (Foth *et al.*, 2016), it does grant anonymity to reduce the risk of dominance and intimidation within the panel (Brown, 1968; Keeney *et al.*, 2011; Vernon, 2009). It also supports the inclusion of experts who may not be able to attend face-to-face meetings (Keeney *et al.*, 2011; McMillan *et al.*, 2016; Vernon, 2009), which increases cost effectiveness as there is no requirement for meeting resources (James & Warren-Forward, 2015; Keeney *et al.*, 2011). To address the identified research problem or question, the Delphi technique uses questionnaires, or surveys, to obtain a convergence of opinion of a panel of experts in the field of interest (Foth *et al.*, 2016; Hsu & Sandford, 2007; Keeney *et al.*, 2011; Linstone & Turoff, 1975; McMillan *et al.*, 2016; Vernon, 2009). For example, Delphi techniques have been used to identify clinical indicators of risk of death or deterioration in people with haematological malignancy (Button *et al.*, 2019), identify metrics for assessing patient-level antimicrobial stewardship interventions in acute-care settings (Moehring *et al.*, 2019) and to establish priorities in orthopaedic oncology research (Schneider *et al.*, 2017). The Delphi technique incorporates the identification of a research problem, the development of a questionnaire, a series of iterations in which the questionnaire (amended after each iteration) is sent to the expert panel members for completion and the calculation of expert panel agreement in each iteration (Foth *et al.*, 2016; Hsu & Sandford, 2007; Keeney *et al.*, 2011; Linstone & Turoff, 1975; McMillan *et al.*, 2016; Vernon, 2009). Iterations cease once consensus is achieved for each questionnaire statement or when a pre-determined number of rounds has been met (Foth *et al.*, 2016; Keeney *et al.*, 2011).

6.4.1.4 Phase Two considerations

The consensus development conference, the nominal group technique and the Delphi technique are all recognised as viable designs to obtain data from conference participants or panels of experts in the field of interest, and form a convergence of opinion and agreement to address a specific research problem (Halcomb *et al.*, 2008; McMillan *et al.*, 2016; Vernon, 2009; Waggoner *et al.*, 2016). There are recognised limitations specific to each design, and to consensus designs in general, due to a lack of consistency and clarity in various modifications that have been made to the methodology used across studies (Foth *et al.*, 2016; Waggoner *et al.*, 2016). In consideration of Phase Two, to obtain international consensus, it was impractical to use face-to-face meetings, given the intended global dispersion of the expert panel. Furthermore, there is a lack of evidence surrounding the topic. Therefore, a Delphi technique was selected for Phase Two to enable inclusion of an internationally dispersed panel of experts and the integration of the systematic review of identified PI preventative intervention evidence.

6.4.2 Classical and modified Delphi techniques

The Delphi technique was originally developed to obtain consensus from a group of experts by The RAND Corporation in the 1950s (Brown, 1968). Consensus was achieved through a structured process with three key elements; anonymous response, iteration and feedback, and statistical group response (Dalkey, 1969). When developed, the technique was used for defence related forecasting (Dalkey & Helmer, 1962; Linstone & Turoff, 1975); however, since then, the technique has been used for various applications across diverse fields of research (Brown, 1968; Dalkey, 1969; Keeney *et al.*, 2011; Linstone & Turoff, 1975; Vernon, 2009). The classical (Keeney *et al.*, 2011), or conventional (Linstone & Turoff, 1975), Delphi technique comprises the selection of an expert panel, followed by the distribution of a series of questionnaires to the expert panel members by post, who then complete and return the questionnaires (Brown, 1968; Keeney *et al.*, 2011; Linstone & Turoff, 1975). The first questionnaire contains focused open-ended questions to elicit the experts' opinions, the answers to which are analysed on return to the researchers (Brown, 1968; Helmer, 1967; Keeney *et al.*, 2011). Follow up questionnaires contain an aggregated summary of the previous questionnaire's results with further questions or statements (Brown, 1968; Helmer, 1967; Keeney *et al.*, 2011; Linstone & Turoff, 1975). Expert panel members then reconsider their answers, and respond to the questions or rate the statements, and may also be asked to justify their responses (Brown, 1968; Helmer, 1967; Keeney *et al.*, 2011; Linstone & Turoff, 1975). The iterations continue until consensus is achieved (Keeney *et al.*, 2011), or until a set number of iterations is met and then the median of responses is used to indicate consensus (Brown, 1968; Helmer, 1967).

The classical Delphi process has been modified in a number of ways since its development (Keeney *et al.*, 2011; Linstone & Turoff, 1975; Waggoner *et al.*, 2016). Such modifications are then applied selectively by researchers as appropriate to address the needs of the research (Keeney *et al.*, 2011; Linstone & Turoff, 1975; Waggoner *et al.*, 2016), highlighting the flexibility of the Delphi technique (Keeney *et al.*, 2011). Some modifications include the use of group meetings, focus groups, seminars or other methods of communication, and revealing identities amongst the panel (Keeney *et al.*, 2011; Linstone & Turoff, 1975). The RAND Corporation itself has modified the Delphi technique in this manner, developing The RAND/UCLA Appropriateness Method (RAM) in the 1980s (Fitch *et al.*, 2001). The RAM incorporates an extensive literature review, followed by a two-round modified Delphi, in which the expert panel members rate 'indications' identified in the literature review individually in the first round, and meet face-to-face for discussion in the second round before re-rating the indications again individually (Fitch *et al.*, 2001). This approach has been described as a cross between the Delphi technique and nominal group technique (Foth *et al.*, 2016; McMillan *et al.*, 2016). However, the inclusion of face-to-face iterations eliminates the advantages of anonymity as described by Brown (1968) and Dalkey (1969).

Other modifications may be used specific to the research aims, such as modifications to develop future policy (Policy Delphi), make decisions (Decision Delphi) or to identify applicable factual arguments (Argument Delphi) (Keeney *et al.*, 2011). Technological advancements have also influenced modifications to the Delphi process, including the use of computer systems to analyse and compile iteration responses in rapid time frames (Keeney *et al.*, 2011; Linstone & Turoff, 1975) and the use of email or online questionnaires (Keeney *et al.*, 2011; Vernon, 2009). Courtenay *et al.* (2018) used online questionnaires when sampling experts nationally in the United Kingdom to establish priorities for conditions managed by community nurse prescribers. Taylor *et al.* (2016) also sampled international experts using an online survey to define professional competencies associated with working with teenagers and young adults with cancer. These studies also adapted the structure of the round one questionnaire (Courtenay *et al.*, 2018; Taylor *et al.*, 2016), a further modification of the Delphi technique (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Vernon, 2009).

Phase Two of this program of research also employed modifications as appropriate to address the second research objective. Given the international distribution of expert panel members, an e-Delphi technique was used, meaning correspondence and questionnaire distribution and return was undertaken via email and, or, based online (Keeney *et al.*, 2011). The use of email and online based questionnaires also increases time efficiency, as opposed to postage of questionnaires which are more time consuming and costly (Vernon, 2009). Moreover, using this modification maintains a key feature of the Delphi technique, anonymity (Dalkey, 1969; Hsu & Sandford, 2007). A further modification which was applied to this study was the use of a structured round one questionnaire, which was appropriate given the availability of evidence supporting singular PI preventative interventions identified in Phase One (Hsu & Sandford, 2007). These modifications are presented in the published study report (Chapter Eight, pp. 154-169).

6.4.3 Expert panel sample

The composition of the Delphi expert panel is considered crucial to the quality of the study outcomes (Hsu & Sandford, 2007). However, a critique of the Delphi is the lack of an agreed definition which can be applied to 'expert' (Foth *et al.*, 2016; Trevelyan & Robinson, 2015), given the subjective nature of labelling an individual's expertise (Helmer, 1967). Panels may be multidisciplinary and heterogeneous in studies with a broader focus; while in studies with a narrower focus, panel members may be specific to a discipline or have specialised knowledge (Fitch *et al.*, 2001; Hsu & Sandford, 2007; Vernon 2009). Therefore, it is necessary to consider the context and needs specific to a study when determining the criteria of experts to be purposefully sampled (Vernon, 2009), and the method in which experts will be identified (Keeney *et al.*, 2011). Similarly, the ideal sample size of an expert panel is also unclear (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Vernon, 2009). Smaller sample sizes may not be representative or generalisable, while larger sample sizes may be more reliable but unmanageable (Hsu & Sandford,

2007; Vernon, 2009). Recent international Delphi studies have reported sample sizes of 19 (Moehring *et al.*, 2019), 31 (Button *et al.*, 2019), 65 to 80 (Courtenay *et al.*, 2018) and 136 to 158 across rounds (Taylor *et al.*, 2016). Given these inconsistencies, expert panel size should also be considered in relation to the intended study and its design (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Vernon, 2009).

Within the context of Phase Two, it is primarily nurses who assess PI risk and implement PI preventative interventions within an intensive care environment. Furthermore, nurses are at the bedside of intensive care patients 24 hours a day, and advocate for their patients who are often too critically ill to communicate. Therefore, the inclusion criteria were developed to select nurses with sufficient intensive care experience to represent expertise in intensive care practices, with additional knowledge in PI prevention. To ensure the expert panel was representative of the world, expert panel members were identified through an international body relevant to the inclusion criteria. Nurses associated with all levels of intensive care, as defined in Australia and New Zealand (College of Intensive Care Medicine, 2016), the United Kingdom (Intensive Care Society, 2009) and internationally by the World Federation of Societies of Intensive and Critical Care Medicine (Marshall *et al.*, 2017) were included. Given this, and the need for international representation, the sample size was reliant on the number of member associations of the international body used for expert identification. Use of an e-Delphi technique, described in section 6.4.2 (pp. 131-132) enabled the inclusion of a larger, international sample (Boulkedid *et al.*, 2011; Keeney *et al.*, 2011). However, to ensure the sample was not too large and unmanageable (Hsu & Sandford, 2007; Vernon, 2009), member associations were limited to nomination of two potential experts. It was also necessary, logistically speaking, to restrict the expert panel to those who were fluent in English, the language of the researchers. These considerations were taken into account in the Phase Two methods (Chapter Eight, pp. 156-159).

6.4.4 Questionnaire content

As previously discussed in section 6.4.2 (pp. 131-132), traditionally, the Delphi technique begins with a questionnaire containing open-ended questions in the first iteration, followed by subsequent questionnaires with further enquiries, or statements requiring rating (Brown, 1968; Helmer, 1967; Keeney *et al.*, 2011). Open-ended questions may be appropriate in the first-round questionnaire to generate ideas and identify key issues, statements or indicators relevant to the research (Hsu & Sandford, 2007; Keeney *et al.*, 2011). However, open-ended questions may result in a large amount of data which requires analysis (Keeney *et al.*, 2011). Alternatively, the first-round questionnaire may be structured with closed questions based on an extensive literature review that identifies supporting evidence (Hsu & Sandford, 2007). It is important to note however, that while open-ended questions may result in large sets of data, structured closed questions may introduce bias through limiting responses (Keeney *et al.*, 2011). Regardless of the design of the first-round questionnaire, the results of the preceding questionnaire inform the design and content of subsequent questionnaires (Hsu &

Sandford, 2007; Keeney *et al.*, 2011; McMillan *et al.*, 2016; Vernon, 2009).

Where the preceding questionnaire contains open-ended questions, the subsequent questionnaire may contain a summary of the responses generated in round one in the form of closed statements, which expert panel members may then be required to rate (Keeney *et al.*, 2011). In these cases, the subsequent questionnaire may also contain some open-ended questions to enable experts to add additional ideas or provide a response rationale (Keeney *et al.*, 2011). Where the preceding questionnaire contained structured closed statements, which were rated by expert panel members, subsequent questionnaires may contain further or repeated structured statements and their associated aggregated results to date (Keeney *et al.*, 2011; McMillan *et al.*, 2016). The questionnaires may also contain options for open responses and feedback (Keeney *et al.*, 2011). There are two variations to this; either all statements and their associated results from a preceding questionnaire are presented for re-rating (Keeney *et al.*, 2011; McMillan *et al.*, 2016), or only the statements and the associated results of those not reaching consensus in the preceding questionnaire are presented for re-rating (Keeney *et al.*, 2011). In both of these variations, each expert panel member may also receive their own individual questionnaire responses along with the aggregated results of the panel for comparison (Boulkedid *et al.*, 2011; Hsu & Sandford, 2007; Keeney *et al.*, 2011; Vernon, 2009).

Further questionnaires may continue in either of these ways or a combination of both (Hsu & Sandford, 2007), or may be further modified, such as the introduction of a face-to-face meeting in the third round (Keeney *et al.*, 2011). These variations once again highlight the flexibility of the Delphi design; thus, researchers must consider approaches within the context of their study (Keeney *et al.*, 2011; Vernon, 2009). While including all statements and results in each round may give each statement the chance to reach the highest level of consensus possible, each questionnaire may remain lengthy, potentially resulting in expert panel drop out and negatively impacting response rates in subsequent questionnaires (Keeney *et al.*, 2011). Removing statements as they reach consensus will combat this and potentially maximise response rate, although experts will not get the opportunity to re-rate these statements (Keeney *et al.*, 2011).

Phase Two of this research used a modified Delphi technique to group singular PI preventative interventions for application relative to identified level of risk. As previously noted (section 1.3, pp. 32-35), such a risk-stratification of interventions using a setting specific PI risk assessment scale has several key functions. This includes setting-specific risk assessment to promote assessment of relevant risk factors and subsequently appropriate risk categorisation; implementation of PI preventative interventions relative to assessed risk thus ensuring individuals have a *minimum* level of PI prevention in place to prevent harm; and targeted resourcing to prevent under- and over-utilisation of resources. To identify evidence-based singular PI preventative interventions for Phase Two, an extensive systematic review was undertaken in Phase One. Based on this review and the identification of

sufficient supporting evidence, a structured closed statement questionnaire was developed for the first round (Hsu & Sandford, 2007). However, there were two areas identified where supporting evidence was lacking. In these areas, recommendations from international guidelines (NPUAP *et al.*, 2014) were used to inform the questionnaire. Subsequent questionnaires were also structured with closed statements as appropriate, and only included those items not yet reaching consensus to ensure time efficiency and continued expert panel member engagement (Keeney *et al.*, 2011). To enable comparison with the group prior to responding, the subsequent questionnaires contained the aggregated results of the panel from the preceding survey (Boulkedid *et al.*, 2011; Keeney *et al.*, 2011; McMillan *et al.*, 2016). The questionnaire content methods used for Phase two are presented in the published study report (Chapter Eight, pp. 156-159), and the questionnaires are presented in Appendices B, C and D.

6.4.5 Rating scales

As mentioned previously in section 6.4.4 (pp. 133-135), Delphi questionnaires contain statements that require rating (Hsu & Sandford, 2007; Keeney *et al.*, 2011; McMillan *et al.*, 2016). Rating scales are used as an instrument to quantitatively measure expert opinion (Waltz *et al.*, 2010). However, the evidence surrounding the ideal number of points for a rating scale is conflicting (Robinson, 2018). Lozano *et al.* (2008) suggest that fewer than four points on a rating scale decreases reliability and validity, and that the ideal number of points ranges between four and seven. Similarly, Preston and Colman (2000) found that two, three and four-point scales carried less validity and reliability that those with a greater number of points, indicating that rating scales should have at least five points. Based on a study which considered participants' reaction and response times, Chen *et al.* (2005) support the use of a five-point scale but this study did not examine validity and reliability. In relation to sensitivity, Contractor and Fox (2011) indicated that five- and six-point scales may be more sensitive than those with a greater number of points, and also found that respondents preferred scales of this size. However, this was based on interviews undertaken for a small sample size across two studies. Preston and Colman (2000) also reported on the preferred scale sizes of their respondents while maintaining validity and reliability, finding that in a questionnaire form, scales of ten points, followed by seven and nine points, were preferred. Given that participant drop out and poor response rates are a concern when undertaking a Delphi study (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Trevelyan & Robinson, 2015), this may be advantageous.

However, the evidence discussed in relation to the number of scale points is not specific to Delphi studies. Within Delphi studies, the use of five-point (Courtenay *et al.*, 2018; Schneider *et al.*, 2017), seven-point (Button *et al.*, 2019) and nine-point (Fitch *et al.*, 2001; Moehring *et al.*, 2017; Taylor *et al.*, 2016) scales has been demonstrated. A further consideration in the design of a scale is the method in which the points will be labelled or anchored, which indicates the direction of the scale (Robinson,

2018; Waltz *et al.*, 2010). Labels may be adapted within the context of a study, such as the use of 'entirely disagree' and 'entirely agree' as endpoints (Button *et al.*, 2019), 'strongly disagree' to 'strongly agree' (Schneider *et al.*, 2017) and 'not important' to 'extremely important', with a midpoint of 'moderate importance' (Taylor *et al.*, 2016). Labelling each point with a verbal anchor (e.g. strongly disagree, disagree, agree and strongly agree) provides clarity (Robinson, 2018), while using numerical points (e.g. 1 to 9) with an explanation of their value at the beginning of a questionnaire removes the need for labels, while still coordinating the values with the numeric (Waltz *et al.*, 2010). Alternatively, a combination of both may be used by only labelling the endpoints (e.g. strongly disagree, 2, 3, 4, strongly agree), which also removes the need to label all points, but may decrease clarity for participants (Robinson, 2018). This further highlights the inconsistencies present in the use of the Delphi technique, and the need to consider the appropriate approach within the context of a particular study (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Vernon, 2009).

For Phase Two, all questionnaires distributed for the modified Delphi study were structured with closed statements for rating. Given this, it was necessary to identify an appropriate rating scale for consistent use across iterations. A nine-point ordinal scale was selected to indicate strength of agreement, as a nine-point scale has been shown to be a preference of respondents (Preston & Colman, 2000), and successful use of the nine-point scale has been demonstrated in other Delphi studies (e.g. Moehring *et al.*, 2017; Sahnan *et al.*, 2018; Taylor *et al.*, 2016). The selection of a nine-point scale was also influenced by the demonstration of consensus level analysis undertaken in previous studies, which will be discussed further in section 6.4.6 (pp. 136-137). However, using a nine-point scale increased the number of possible labels; therefore, only end points were labelled to indicate the direction of the scale (i.e. strongly disagree [1] to strongly agree [9]). Moreover, the English language was the second language to many participants in Phase Two of this program of research, and as such, it was deemed appropriate to minimise the use of wording to avoid confusion.

6.4.6 Consensus level and data analysis

Overall, the Delphi technique is undertaken to obtain consensus through the convergence of opinion of a panel of experts in the field of interest (Foth *et al.*, 2016; Hsu & Sandford, 2007; Keeney *et al.*, 2011; Linstone & Turoff, 1975; McMillan *et al.*, 2016; Vernon, 2009). Keeney *et al.* (2011, p. 14) suggest consensus may be defined as 'collective agreement' in the context of Delphi studies. The criteria which determines when consensus has been achieved in a study should be clearly defined and predetermined (Keeney *et al.*, 2011; McMillan *et al.*, 2016; Vernon, 2009). This is referred to as level of consensus (Keeney *et al.*, 2011; Vernon, 2009). As with many other facets of the Delphi technique, the level of consensus applied varies greatly across studies (Diamond *et al.*, 2014). Two commonly used level of consensus approaches involve the use of percentages or proportions, and central tendency statistical analyses (Diamond *et al.*, 2014; Hsu & Sandford, 2007; Keeney *et al.*, 2011).

Percentages refers to a certain percentage of the expert panel rating a questionnaire item the same (Diamond *et al.*, 2014), or within a predetermined range (Hsu & Sandford, 2007; Keeney *et al.*, 2011), which may also be referred to as proportion within a range (Diamond *et al.*, 2014). Alternatively, statistical analyses using central tendencies may be used (Diamond *et al.*, 2014; Hsu & Sandford, 2007; Keeney *et al.*, 2011). Such approaches not only measure the convergence of individual responses or group opinion, often using the mean or median, but may also measure the extent to which the expert panel agrees with each other by taking into account the dispersion of responses (Becker & Roberts, 2009; Diamond *et al.*, 2014; Hsu & Sandford, 2007). Courtenay *et al.* (2018) measured group consensus using medians, and interquartile ranges to assess the spread of responses. Responses were retained if they met a pre-defined median and interquartile range indicating agreement (Courtney *et al.*, 2018). Moehring *et al.* (2017) defined consensus using mean upper 95% CI bounds and retained or rejected studies based on this definition. The RAM rates indicators as appropriate, uncertain or inappropriate using medians (Fitch *et al.*, 2001). Taylor *et al.* (2016), however, defined both group consensus using medians, referred to as 'level of support', and the dispersion of responses using mean absolute deviation from the median (MADM), referred to as 'level of agreement'. Using a nine-point scale, a median of seven to nine indicated strong support, four to 6.5 indicated moderate support and one to 3.5 indicated weak support (Taylor *et al.*, 2016). Mean absolute deviation from the median was also calculated to describe the dispersion of responses, and was referred to as 'level of agreement' (Taylor *et al.*, 2016). For example, a median of 7 would indicate strong group support for the relevant item or intervention. However, the MADM represents the average distance of the participants rating from the overall median (Hutchings *et al.*, 2005; Taylor *et al.*, 2016).

Given that Phase Two used a scale to measure strength of agreement and the consensus definition of collective 'agreement' suggested by Keeney *et al.* (2011, p.14), the use of statistical analyses to measure level of support with medians and the use of MADM to describe the dispersion of responses (Taylor *et al.*, 2016) was particularly relevant. Furthermore, such an approach to analysis has been demonstrated with the use of a nine-point scale (Taylor *et al.*, 2016). This approach has also been employed in a nominal group technique by Vella, Goldfrad, Rowan Bion and Black (2000) and to assess participant disagreement within guideline development groups (Hutchings *et al.*, 2005). Therefore, based the quantitative nature of closed statement surveys and the nine-point scale used in Phase Two, this approach (Hutchings *et al.*, 2005; Taylor *et al.*, 2016; Vella *et al.*, 2000) was applied with the median scores described by Taylor *et al.* (2016) and Vella *et al.* (2000), as well as use of the MADM to describe response dispersion, as detailed in the published study report (Chapter Eight, pp. 159-160).

6.4.7 Number of rounds

A key feature of a Delphi study is controlled iterations. By definition a Delphi must have multiple rounds; however, the number of actual rounds varies (Hsu & Sandford, 2007; Keeney *et al.*, 2011).

Studies often use two (McMillan *et al.*, 2016; Taylor *et al.*, 2016) or three rounds (Button *et al.*, 2019; Courtenay *et al.*, 2018). This is consistent with recommendations to limit Delphi studies to two (Boulkedid *et al.*, 2011; Waggoner *et al.*, 2016) or three rounds (Boulkedid *et al.*, 2011; Trevelyan & Robinson, 2015). Not only is consensus often reached within a smaller number of rounds (Hsu & Sandford, 2007), limiting the number of rounds helps to promote ongoing panel participation and time efficiency; whereas having more rounds may result in panel attrition and lack of engagement (Boulkedid *et al.*, 2011; Keeney *et al.*, 2011; Trevelyan & Robinson, 2015). To further encourage participation and time efficiency, expert panel members may be given a deadline for completing each questionnaire (Hsu & Sandford, 2007; Trevelyan & Robinson, 2015), with regular reminders sent to maximise response rates (Keeney *et al.*, 2011). To this end, the time frame between rounds should also be kept to a minimum (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Trevelyan & Robinson, 2015).

Therefore, Phase Two was undertaken in three rounds (Boulkedid *et al.*, 2011; Trevelyan & Robinson, 2015). To ensure timely completion, from the day of distribution of each round, panel members were given a response deadline with regular reminders sent via email (Hsu & Sandford, 2007; Keeney *et al.*, 2011; Trevelyan & Robinson, 2015), with a minimum response rate of 75% targeted. As noted in section 6.4.4 (pp. 133-135), the timely completion of rounds was further facilitated by the removal of statements from subsequent questionnaires as consensus was reached, making each subsequent survey smaller. Furthermore, the inclusion of closed statements promoted timely data analysis and subsequent survey distribution.

6.5 Methods

The methods of Phase Two are provided in full within the study report published in the *International Wound Journal* (Lovegrove *et al.*, 2020), which is presented in Chapter Eight (pp. 153-169). While the aim was detailed in the published report (Lovegrove *et al.*, 2020), the associated research question was not; thus, it is presented below. Furthermore, supplementary information on the security of the online platform used for questionnaires is provided.

6.5.1 Research question

What is the minimum PI preventative intervention set that should be implemented relative to intensive care patients' COMHON Index level of risk?

6.5.2 Questionnaire confidentiality

Questionnaires were undertaken on a secure online platform, SurveyMonkey™ (SurveyMonkey, 2020a; SurveyMonkey, 2020b), in which data are stored in line with relevant privacy regulations (SurveyMonkey, 2018). Data is encrypted when received, stored and transferred, and is only accessible via secure connectivity and the password protected account (SurveyMonkey, 2020a; SurveyMonkey, 2020b). Use of this platform was included within the ethical clearance for the study.

6.6 Conclusion

This chapter has introduced Phase Two and has presented the research design and methodology of this phase.

Phase Two was justified as appropriate for addressing the relevant objective *to develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index*.

In the next chapter (Seven), the results of Phase One (a systematic review and meta-analysis previously presented in Chapters Three to Five) are reviewed to identify interventions which have demonstrated effectiveness and can be used as part of the minimum PI preventative intervention set for use in a Delphi consensus study (Phase Two). The following Chapter (Eight) presents the published report of the Delphi consensus study.

Chapter Seven: Selection of interventions from Phase One (systematic review and meta-analysis) for Phase Two (modified Delphi study)

7.1 Introduction

The previous chapter detailed the methodology of Phase Two of this program of research and noted (pp. 127-128, 134-135) that the results of Phase One were used to inform intervention selection for Phase Two. The transition of results from Phase One to Phase Two are presented herein.

An extensive systematic review and meta-analysis was undertaken in Phase One, which identified evidence which tested the effectiveness of PI preventative interventions in adults admitted to acute (Chapter Three) and intensive care (Chapter Four) settings. While the setting focus of this program of research is intensive care, previous research (Alshahrani *et al.*, 2021; Tayyib & Coyer, 2016) has indicated that the testing of interventions within intensive care has been notably limited. Thus, as previously rationalised (pp. 35, 55, 60), Phase One included reviews of interventions in both acute and intensive care settings for potential use in the following phase.

In Phase Two, a modified Delphi study was conducted to identify which PI preventative interventions should be applied relative to each COMHON Index level of PI risk in a minimum PI preventative intervention set (reported in Chapter Eight). The syntheses of results revealed that, in both settings, further high-level research is required to establish the effectiveness of PI preventative interventions. Within acute care, meta-analysis indicated that the only intervention which has demonstrated effectiveness (using intention-to-treat data) was Australian medical sheepskin overlays (compared to other standard care surfaces, p. 85). At a per-protocol level, meta-analyses suggested active (versus other comparison and standard surfaces) and reactive (versus other comparison surfaces) support surfaces and heel protection devices (versus standard care) were effective in decreasing PI (pp. 86-87). Within intensive care, intention-to-treat meta-analyses supported the use of sacral and heel prophylactic dressings (p. 109).

While the number of interventions identified in meta-analyses that demonstrated effectiveness was limited, and further research is required, it was also identified that a number of individual randomised controlled trials had demonstrated the effectiveness of a PI preventative intervention in the acute and/or intensive care setting. Phase Two required the identification of interventions which have demonstrated effectiveness and can be used as part of the minimum PI preventative intervention set for use in a Delphi consensus study. Thus, interventions which had demonstrated effectiveness in an individual randomised controlled trial were identified for use in Phase Two. This interlinking Chapter (Seven) provides an overview of the identification and selection of interventions identified in Phase One, for use in Phase Two, which is reported in Chapter Eight.

7.2 Intervention identification and selection

7.2.1 Initial intervention identification and selection

Following study selection from the initial systematic review searches in May and June 2019, the randomised controlled trials which demonstrated that a trialled singular intervention was effective in preventing PI were identified. For the purposes of identifying interventions for use in Phase Two, interventions were considered to have demonstrated effectiveness where the reported statistical significance of the difference in PI incidence between the intervention and comparison groups was $p < 0.05$. Where statistical significance was not reported for PI incidence differences between groups, it was calculated using Fishers Exact Test. Overall, 33 of the 64 included randomised controlled trials demonstrated that the trialled intervention was effective in reducing PI incidence.

Once these trials (n = 33) were identified, the trialled interventions were examined in detail. Since Phase Two was planned to develop a globally relevant minimum PI preventative intervention set for international use in intensive care units, included interventions were required to be replicable and generally applicable to everyday intensive care practice. As such, interventions not meeting this requirement were excluded. Similarly, since Phase Two required singular interventions to be comprised within the intervention set, bundled interventions where singular interventions were unable to be extrapolated were excluded. Following these exclusions, 21 trials were retained for use in Phase Two.

Table 7.1 presents the trials included in Phase Two grouped by intervention type, Table 7.2 presents a list of the trials that demonstrated intervention effectiveness but were excluded from Phase Two and the subsequent rationale for exclusion, and Table 7.3 presents the trials which did not demonstrate intervention effectiveness.

7.2.2 Updated systematic review searches

In April 2020, the main systematic review searches were updated to the end of 2019. These updates were included in the publications of the systematic review syntheses (Chapters Three and Four). At this time, the interventions included in Phase Two had been finalised and the Phase Two modified Delphi study had commenced. The updated 2019 search resulted in a further five trials being included in the systematic reviews, of which two demonstrated the effectiveness of a PI preventative intervention. However, one of these supported interventions was already included in Phase Two, and the other did not meet the inclusion criteria.

Similarly, for the purposes of providing a contemporary overview of relevant PI preventative interventions and supporting trials in this thesis, the searches were again rerun in January 2022 to identify articles published in the years 2020 and 2021 (Chapter Five). The updated 2020 to 2021 search identified a further 12 trials which were relevant to the earlier systematic review and meta-analysis.

Of these, the majority (n = 9; Beeckman et al., 2021; Borzou et al., 2020; Eberhardt et al., 2021; Hahnel et al., 2020; Jiang et al., 2020; Kathirvel et al., 2021; Oe et al., 2020; Sönmez & Yapucu, 2020; Xiao et al., 2021) reported an intervention which demonstrated effectiveness. Nonetheless, four supported interventions were already included in Phase Two (Beeckman et al., 2021; Eberhardt et al., 2021; Hahnel et al., 2020; Oe et al., 2020), and the remainder met the exclusion criteria (Borzou et al., 2020; Jiang et al., 2020; Kathirvel et al., 2021; Sönmez & Yapucu, 2020; Xiao et al., 2021).

Therefore, overall, the updated searches yielded no further interventions which would have been relevant to include in Phase Two. Tables 7.4 and 7.5 present the randomised controlled trials included following the updated systematic review searches (2019 update and 2020 to 2021 update, respectively) and their relevance to Phase Two.

Table 7.1: Trials demonstrating intervention effectiveness

Intervention type	First author, year	Acute or ICU	Intervention	Comparison	Reported significance *p*
Continence	Francis, 2017	Acute	Disposable underpads	Reusable underpads	$p = 0.02$ (ITT)
	Rassin, 2013	ICU	Catheter care protocol 2	Standard care	$p = 0.002$ (post hoc PP)
Heel elevation/ protection	Bååth, 2016	Acute	Heel suspension device boot	Standard care	$p = 0.017$ (PP)
	Donnelly, 2011	Acute	Heel elevation	Standard care	$p < 0.001$ (ITT)
	Meyers, 2017	ICU	Heel protection device	Standard care heel offloading	$p < 0.001$
Nutrition	Bourdel-Marchasson, 2000	Acute	Nutritional oral supplements	Standard diet	$p = 0.033$ (post hoc ITT)
PI preventative dressings (heel, sacral, trochanteric)	Dutra, 2015	Acute & ICU	Comparison of 2 dressing types applied to sacrum & trochanters	Not applicable	$p = 0.038$ (ITT)
	Forni, 2018	Acute & ICU	Prophylactic sacral dressings	Standard care	$p = 0.001$ (ITT)
	Kalowes, 2016	ICU	Prophylactic sacral dressing	Standard care	$p = 0.01$ (ITT)
	Lee, 2019	ICU	Prophylactic sacral dressing	Standard care	$p = 0.006$ (PP)
	Nakagami, 2007	Acute	Prophylactic trochanteric dressings	No dressing	$p = 0.007$ (ITT)
	Santamaria, 2015	ICU	Prophylactic sacral & heel dressings	Standard care	$p = 0.001$ (ITT)
Support surfaces: Medical grade sheepskin	Jolley, 2004	Acute	Australian medical sheepskin overlay	Standard mattress	$p = 0.027$ (post hoc ITT)
	McGowan, 2000	Acute	Australian medical sheepskin overlay	Standard mattress	$p < 0.001$ (post hoc ITT)
Support surfaces: Reactive	Andersen, 1983	Acute	Reactive mattress (also active)	Standard mattress	$p = 0.01$ (post hoc PP)
	Bueno de Camargo, 2018	ICU	Reactive mattress	Standard reactive mattress	$p < 0.001$
	Gray, 1994	Acute	Reactive mattress	Standard mattress	$p < 0.001$ (ITT)
	Park, 2017	Acute	Reactive overlay	Standard mattress	$p = 0.001$ (PP)
	Takala, 1996	ICU	Reactive mattress	Standard mattress	$p < 0.005$ (ITT & PP)
Support surfaces: Active	Andersen, 1983	Acute	Active mattress (also reactive)	Standard mattress	$p = 0.009$ (post hoc PP)
	Aronovitch, 1999	Acute	Active air pad	Standard care	$p < 0.005$ (PP)
	Sanada, 2003	Acute	Active mattress – 2-cell Active mattress – 1-cell	Standard mattress	$p = 0.003$ (post hoc ITT) $p = 0.155$ (post hoc ITT)
Intensive care unit = ICU, Intention-to-treat = ITT, Per protocol = PP					

Table 7.2: Trials demonstrating intervention effectiveness but excluded

First author, year	Acute or ICU	Intervention	Comparison	Reported significance *p*	Exclusion rationale
Bharucha, 2018	Acute & ICU	Non-invasive perfusion enhancement system	Standard care	$p = 0.024$ (PP)	System not widely available
Chaboyer, 2016	Acute	PI prevention care bundle	Standard care	$p = 0.002$ (post hoc ITT)	Non-singular intervention
Gregoretti, 2002	ICU	Prototype face mask	Conventional face masks	$p < 0.01$ (PP)	Prototype face mask not widely available
Hekmatpou, Ahmadian, 2018	ICU	Henna ointment	Standard care	$p = 0.001$ (PP)	Ointment not replicable or widely available
Hekmatpou, Mehrabi, 2018	Acute	Aloe vera gel	Placebo	$p = 0.047$ (PP)	Gel not replicable or widely available
Hofman, 1994	Acute	Cubed intervention mattress	Standard mattress	$p = 0.008$ - 0.013 (PP)	Mattress not widely available
Inman, 1993	ICU	Air suspension bed	Standard bed	$p < 0.001$ (post hoc ITT)	Unclear whether active or reactive support surface
Madadi, 2015	ICU	Olive oil	Standard care	$p = 0.03$ (PP)	Not internationally used or available
Pickham, 2017	ICU	Wearable patient sensor	Wearable patient sensor control	$p = 0.025$ (post hoc ITT)	Sensor not widely available
Shakibamehr, 2019	ICU	Tragacanth gel cushion	Foam cushion	$p = 0.008$ (PP)	Not replicable or widely available
Tayyib, 2015	ICU	PI prevention care bundle	Standard care	$p < 0.001$ (ITT)	Non-singular intervention
Intensive care unit = ICU, Intention-to-treat = ITT, Per protocol = PP					

Table 7.3: Trials which did not demonstrate intervention effectiveness

First author, year	Acute or ICU	Intervention	Comparison	Reported significance *p*
Aloweni, 2017	Acute	Prophylactic sacral dressing Fatty acids oil spray	Standard care	*p* = 0.789 (post hoc ITT) Not significant (ITT)
Bennett, 1998	Acute	Low-air-loss hydrotherapy bed	Standard bed & mattress	*p* = 0.11 (PP)
Berthe, 2007	Acute	Reactive mattress	Standard mattress	*p* = 0.154 (ITT)
Cobb, 1997	Acute & ICU	Reactive overlay	Low-air-loss bed	*p* = 0.338 (post hoc ITT)
Cooper, 1998	Acute	Reactive mattress	Reactive mattress (2nd intervention)	*p* = 0.483 (post hoc ITT)
Demarré, 2012	Acute	Active intervention mattress	Active standard mattress	*p* = 0.97 (ITT)
Gilcreast, 2005	Acute & ICU	Comparison of 3 heel protection devices	Not applicable	*p* = 0.416 (PP)
Gray, 2000	Acute	Reactive mattress	Reactive control mattress	Not significant (ITT)
Gunningberg, 2000	Acute	Reactive mattress/overlay	Standard mattress	*p* = 0.511 (post hoc PP)
Gunningberg, 2017	Acute	Continuous bedside pressure mapping system	Control (inactive intervention)	*p* = 0.3 - *p* = 0.7 (PP)
Hartgrink, 1998	Acute	Tube feeding	Standard diet	*p* = 0.26 - 0.69 (PP)
Houwing, 2003	Acute	Nutritional supplementation	Placebo supplementation	*p* = 0.420 (ITT)
Inman, 1999	ICU	Purchased bed protocol	Rented & purchased bed protocol	*p* = 0.667 (post hoc ITT)
Irvine, 1961	Acute	Norethandrolone tablets	Placebo	Not significant (PP)
Jafary, 2018	Acute & ICU	PI prevention care bundle	Standard care	*p* = 0.08 (post hoc PP)
Jiang, Li, Zhang 2014	Acute & ICU	Active mattress	Reactive mattress	*p* = 0.882 (PP)
Keogh, 2001	Acute	Profiling bed	Standard bed	Not significant (ITT & PP)
Manzano, Colmenero, 2014	ICU	2-hourly repositioning	4-hourly repositioning	*p* = 0.496 (post hoc ITT)
Nixon, Nelson, 2006	Acute	Active mattress	Reactive mattress	*p* = 0.75 (reported ITT)
Ozyurek, 2015	ICU	Comparison of 2 reactive mattress interventions	Not applicable	*p* = 0.44 (PP)
Peña Otero, 2017	ICU	Prophylactic dressings under oro-nasal mask Hyperoxygenated fatty acids	Direct-to-skin mask application	*p* = 0.057 - 0.177 (post hoc ITT) *p* = 0.055 (PP)
Pittman, 2012	ICU	Bowel management catheter Rectal trumpet	Standard care	Not significant (PP)
Price, 1999	Acute	Active mattress and cushion	Reactive mattress and cushion	Not significant (reported ITT)
Russell, 2000	Acute	Active mattress	Standard care	*p* = 0.170 (ITT)
Russell, 2003	Acute	Reactive mattress & cushion	Standard mattress & cushion	*p* = 0.17 (PP)
Serra, 2015	ICU	Intravenous albumin	No intravenous albumin	*p* = 0.086 (ITT)

Theaker, 2005	ICU	Active bed	Active bed	$p = 0.35$ (PP)
Tymec, 1997	Acute	Heel elevation with foot waffle	Standard care	$p = 0.249$ (ITT)
Vanderwee, 2005	Acute	Active overlay	Reactive mattress	$p = 1$ (ITT)
Verdú, 2020	Acute	Hyperoxygenated fatty acids	Placebo	$p = 0.94$ (ITT)
Vermette, 2012	Acute & ICU	Reactive overlay	Standard care	$p = 0.271$ (ITT)
Young, 2004	Acute	30-degree tilt position	Standard repositioning	$p > 0.05$ (ITT)
Intensive care unit = ICU, Intention-to-treat = ITT, Per protocol = PP				

Table 7.4: Updated 2019 search randomised controlled trials

First author, year	**Acute or ICU**	**Intervention**	**Comparison**	**Reported significance *p***	**Relevance to Phase Two**
Babamohamadi, 2019	ICU	Peppermint gel	Placebo gel	$p < 0.001$ (PP)	Gel not replicable or widely available
da Silva Augusto, 2019	Acute & ICU	Comparison of 2 dressing types applied to sacrum & trochanters	Not applicable	Not significant (PP)	Not effective, comparison of two dressing types, unable to separate for Phase Two interventions
Hahnel, 2019	ICU	Prophylactic sacral & heel dressings	Standard care	$p < 0.001$ (PP)	Supports Phase Two interventions
Landsperger, 2019	ICU	Comparison of 2 endotracheal tube securement methods	Not applicable	$p = 0.05$ (PP)	Not effective
Nixon, Smith, 2019	Acute	Active mattress	Reactive mattress	unadjusted p =0.1148 (reported ITT)	Not effective
Intensive care unit = ICU, Intention-to-treat = ITT, Per protocol = PP					

Table 7.5: Updated 2020 to 2021 search randomised controlled trials

First author, year	Acute or ICU	Intervention	Comparison	Reported significance *p*	Relevance to Phase Two
Beeckman, 2021	Acute & ICU	Prophylactic sacral, heel & trochanteric dressings (two brand arms)	Standard care	$p = 0.04$ (reported ITT)	Supports Phase Two interventions
Borzou, 2020	ICU	Topical almond oil to sacrum, heels & shoulders	Placebo OR standard care only	Placebo comparison $p = 0.024$ Control comparison $p = 0.189$ (PP)	Oil not replicable or widely available
Choi, 2021	ICU	Uncoated paper to sacrum	Standard care	$p = 0.366$ (PP)	Not effective, not widely available
Eberhardt, 2021	Acute	Prophylactic multi-layered silicone foam dressings to heels	Prophylactic transparent polyurethane film dressing to heels (standard care)	$p = 0.001$ (PP)	Supports Phase Two interventions
Gazineo, 2020	Acute	Prophylactic sacral dressing	Standard care	$p = 0.54$ (ITT)	Not effective
Hahnel, 2020	ICU	Prophylactic sacral & heel dressings	Standard care	$p < 0.001$ (PP)	Supports Phase Two interventions
Jiang, 2020	ICU	4-hourly repositioning with reactive mattress	2-hourly repositioning with active mattress	$p = 0.022$ (PP)	Effective but unable to separate repositioning and support surface for Phase Two; non-singular intervention
Karimi, 2020	ICU	Comparison of olive oil heel dressings & fish oil heel dressings	Not applicable	Not significant (ITT)	Not effective, comparison of two dressing types, unable to separate for Phase Two interventions
Kathirvel, 2021	Acute	Full intervention educational bundle	Minimal interventional education bundle	$p = 0.043$ (PP)	Non-singular intervention
Oe, 2020	Acute	Prophylactic foam dressing to sacrum & coccyx	Standard care	$p = 0.001$ (ITT)	Supports Phase Two interventions
Sönmez, 2020	ICU	Extra virgin olive oil to sacrum, trochanters & heels	Standard care	$p = 0.037$ (PP)	Oil not widely available
Xiao, 2021	Acute	'Seamless nursing care' bundle	Standard care	$p = 0.001$ (ITT)	Non-singular intervention
Intensive care unit = ICU, Intention-to-treat = ITT, Per protocol = PP					

7.3 Final interventions

7.3.1 Interventions from randomised controlled trials

From the randomised controlled trials identified which demonstrated intervention effectiveness (Table 7.1), the following interventions were included in the Phase Two consensus study:

- *Continence:* Indwelling urinary catheter entry points should be washed with soap and water, and the catheter should be repositioned to the opposite thigh and secured, three times daily (Rassin *et al.*, 2013)
- *Continence:* For intensive care patients who are incontinent of urine and/or faeces, disposable adult incontinence pads should be used (Francis *et al.*, 2017)
- *Heel elevation:* Pressure should be offloaded from the heels using a heel offloading device (Bååth *et al.*, 2015; Donnelly *et al.*, 2011; Meyers, 2017)
- *Nutrition:* For intensive care patients who are able to eat food orally, oral nutritional supplements should be provided in addition to standard nutrition (Bourdel-Marchasson *et al.*, 2000)
- *PI preventative dressings:* A preventative sacral dressing should be applied (Dutra *et al.*, 2015; Forni *et al.*, 2018; Kalowes *et al.*, 2016; Lee *et al.*, 2019; Santamaria *et al.*, 2015)
- *PI preventative dressings:* Preventative heel dressings should be applied (Santamaria *et al.*, 2015)
- *PI preventative dressings:* Preventative trochanteric dressings should be applied (Dutra *et al.*, 2015; Nakagami *et al.*, 2007)
- *Support surfaces (bed/mattress):* Medical grade sheep skin overlays should be used (Jolley *et al.*, 2004; McGowan *et al.*, 2000)
- *Support surfaces (bed/mattress):* Reactive mattress support surfaces should be used (Andersen *et al.*, 1983; Bueno de Camargo *et al.*, 2018; Gray & Campbell, 1994; Park & Park, 2017; Takala *et al.*, 1996)
- *Support surfaces (bed/mattress):* Active mattress support surfaces should be used (Andersen *et al.*, 1983; Aronovitch *et al.*, 1999; Sanada *et al.*, 2003)

Additionally, one further study was identified and used in support of active mattress support surfaces as an intervention (Gebhardt, 1994). However, during the systematic review process, it was identified that the study, presented in a conference abstract, was not truly randomised. Rather, participants were allocated to a study group based on patient hospital number, as reported in a full report of an intensive care sub-study (Gebhardt *et al.*, 1996). Thus, the study was excluded from the systematic review and meta-analysis after the interventions for Phase Two had been finalised. Nonetheless, the study did demonstrate the effectiveness of an active mattress support surface when compared to a reactive surface in both acute (reported $p = 0.002$; Gebhardt, 1994) and intensive care (reported $p < 0.001$; Gebhardt *et al.*, 1996) settings.

7.3.2 Certainty of evidence

Certainty of evidence was assessed using the GRADE approach (Schünemann *et al.*, 2013) for intervention types which demonstrated effectiveness in intention-to-treat meta-analysis (see section 2.4.10, pp. 57-60). This included Australian medical sheepskin overlays compared to standard care (acute hospital setting synthesis), and prophylactic sacral and heel dressings compared to standard care (intensive care setting synthesis). The evidence for these intervention types was judged to be of very low, low and low certainty, respectively (see section 3.2, p. 93; section 4.2, pp. 114-115). Thus, as noted in the chapter introduction (p. 141), not only were there few intervention types for which meta-analysis could be undertaken and even fewer meta-analyses which demonstrated a significant effect, but the pooled studies with a significant effect were also limited. Subsequently, while it may be argued that only effective interventions which were underpinned by a moderate- or high-quality body of evidence should be included, the results of Phase One demonstrate that this would not be pragmatic.

This necessitated the need for the use of results of individual randomised controlled trial to identify interventions for use in Phase Two. Furthermore, in the absence of a strong supporting body of literature for PI preventative interventions in acute hospital and intensive care settings, guidance for clinical practice and guidelines must be drawn from the limited hierarchal evidence available and expert consensus as the most robust approach. Indeed, consensus designs allow for the synthesis of the available evidence and the convergence of expert opinion to address complex health issues and research questions where there is not yet a standard of care or guideline (Halcomb *et al.*, 2008; Waggoner *et al.*, 2016) or for which little is known or there is conflicting evidence (Fink *et al.*, 1984; Vernon, 2009; Waggoner *et al.*, 2016). As such, the results of Phase One and the certainty of evidence assessments support the underpinning consensus methodology of Phase Two, which is detailed in Chapter Six (pp. 126-140).

7.3.3 Additional interventions

From the selected randomised controlled trial interventions, it was evident that two widely recognised PI preventative interventions were not included. While not supported by high-level research, repositioning as a PI preventative intervention is underpinned by a strong theoretical background associated with the aetiology of PI (Avsar *et al.*, 2020; Gillespie, Walker *et al.*, 2021), and is recommended internationally for at risk individuals (EPUAP *et al.*, 2019; NPUAP *et al.*, 2014). Regular repositioning redistributes the sustained loading, or pressure, present between body tissues and the surface, to other areas, thus minimising the duration of sustained loading to one area of the body (Avsar *et al.*, 2020). Similarly, use of a seating support surface is recommended, given that the body is supported on a small area when seated, predisposing the area to high pressures (EPUAP *et al.*, 2019; NPUAP *et al.*, 2014). Subsequently, based on the international recommendations current at the time (NPUAP *et al.*, 2014), repositioning and use of a seating support surface were included as interventions

in Phase Two. However, how often an individual should be repositioned was unclear in the evidence. Thus, the frequency of repositioning was addressed through international consensus in Phase Two. Specifically, these additional interventions were included in Phase Two as:

- *Repositioning:* Patients should be repositioned at least two-, three- or four-hourly (NPUAP *et al.*, 2014)
- *Support surfaces (seating):* When a patient is sat out of bed, a pressure redistributing seat cushion should be used (NPUAP *et al.*, 2014)

7.3.4 Risk assessment

While risk assessment with COMHON Index underpinned the minimum PI preventative intervention set developed for Phase Two, the frequency with which risk should be assessed was unclear. The international guideline at the time recommended a structured risk assessment be performed as soon as possible, but within eight hours of admission, and be repeated as required by the individual and with any significant change in individual condition (NPUAP *et al.*, 2014, p. 47). However, as previously noted (p. 3), tissue damage which may lead to PI can begin to occur within minutes of sustained loading (Gefen, 2018). As such, there is justification for including options for earlier PI risk assessment following admission, as suggested elsewhere (Fulbrook, Miles & Coyer, 2019), and time frames for reassessment. Therefore, risk assessment frequency within the recommended time frame was also addressed through international consensus in Phase Two, with the following put forth:

- *Risk assessment:* Following admission, PI risk assessment should be completed within two, four, six, or eight hours (NPUAP *et al.*, 2014)
- *Risk assessment:* Patients should be reassessed for PI risk once every eight, 12 or 24 hours, or when there is a significant change in patient condition (NPUAP *et al.*, 2014).

7.4 Conclusion

In conclusion, this chapter has provided an overview of the PI preventative interventions identified in Phase One, and the selection process of interventions for use in Phase Two. The rationale for the exclusion of interventions from Phase Two has also been outlined. The included interventions outlined in this chapter are comprised within the first-round questionnaire (Appendix B) of the Phase Two modified Delphi study, which was followed by two further questionnaires (Appendices C, D). The next chapter (Eight) will present the Phase Two modified Delphi study about the included interventions.

Chapter Eight: Phase Two: A modified Delphi study

8.1 Introduction

In Phase Two, a modified Delphi study was undertaken to address the overall research objective *to develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index.*

To address this research objective, PI preventative interventions for use in the minimum PI preventative intervention set first needed to be identified in Phase One. The previous chapter (Seven) outlined the selection of interventions identified in Phase One, for use in Phase Two. This chapter presents the subsequent modified Delphi study (Phase Two), which was published in the *International Wound Journal* (Lovegrove *et al.*, 2020). The Delphi study questionnaires are presented in Appendices B, C and D. The study was approved by the Australian Catholic University Human Research Ethics Committee (2019-25E; Appendix E).

The *International Wound Journal* was selected for publication of Phase Two based on its ongoing dissemination of relevant pressure injury prevention research and international reach. In the year of publication (2020), it had an Impact Factor of 3.315 (Clarivate™, 2021) and was a Q1 journal (Scimago, 2021) with Scimago Journal Rankings (2021) of 23/138 Medicine – Dermatology and 94/456 Medicine – Surgery. As of 2021, the *International Wound Journal* is fully open access, and the publication is freely available (Wiley Online Library, 2021). Permission to present the published paper within this thesis in PDF form was also provided in writing (email; Research Portfolio Appendix E). The PDF of the published paper is now presented herein (pp. 154-169).

8.2 Certainty of evidence

Certainty of evidence was previously assessed using the GRADE approach (Schünemann *et al.*, 2013) for intervention types which demonstrated effectiveness in intention-to-treat meta-analysis (see section 2.4.10, pp. 57-60). This included Australian medical sheepskin overlays compared to standard care (acute hospital setting synthesis) (see section 3.2, p. 93), and prophylactic sacral and heel dressings compared to standard care (intensive care setting synthesis) (section 4.2, pp. 114-115). Of the three intervention types, only one was rejected from the minimum PI preventative intervention set in Phase Two, Australian medical sheepskin overlays, which was also the only intervention to be rated at the lowest grading of evidence certainty (very low). Such a result may represent the limitations of the intervention, which are discussed fully in the Phase Two publication (p. 164 of this chapter). The remaining two interventions (sacral and heel prophylactic dressings) were rated higher in terms of certainty of evidence, although the rating was still 'low'. Nonetheless, both dressing interventions retained for individuals assessed to be at high risk of PI in the minimum intervention set, suggesting expert clinicians view them as clinically applicable even where the evidence is limited.

8.3 Conclusion

This chapter has presented a modified Delphi study, in which a minimum PI preventative intervention set for implementation relative to COMHON Index PI level of risk, has been developed. The intervention set was developed based on international consensus and is globally relevant.

The completion of Phase Two of this program of research has addressed both the research objective *to develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index*, and the overall research aim *to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care unit*s.

However, the minimum PI preventative intervention set still requires testing on an international scale to establish its effectiveness. The next part of this thesis (Part Three) details Phase Three of this program of research, a translation of the COMHON Index into Chinese Mandarin in preparation for international testing.

PART THREE: PHASE THREE

Chapter Nine: Phase Three methodology

9.1 Introduction

The research problem was established in Chapter One, within the context of the theoretical background. Based on the established research problem, a research question, aim and objectives were developed, which were subsequently addressed by a three-phase program of research.

1. Phase One: Systematic review and meta-analysis
2. Phase Two: Modified Delphi study
3. **Phase Three: Translation and concurrent validity study.**

Part One of this thesis (Chapters Two to Five) presented Phase One of the overall program of research, while Part Two (Chapters Six to Eight) set forth Phase Two. This chapter introduces **Phase Three** and presents the methodology and rationale for this phase. Additionally, extended methods of the translation component are presented to support the full methods described in the corresponding publication, while the full methods of the concurrent validity study are also described.

To set the scene for this chapter, the overall research question, aim and objectives are re-presented, and the research design of Phase Three is situated against the overall design of the program of research. Further detail on the remaining phase is provided in future chapters.

9.2 Overall research question

What interventions should be applied relative to critically ill patients' PI level of risk, as determined by an intensive care-specific risk assessment scale (the COMHON Index), as part of a minimum set of PI preventative interventions for international use within intensive care units?

9.2.1 Overall research aim and objectives

The overall aim of this program of research is to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care units.

This encompasses the following objectives:

1. To identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.
2. To develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index.
3. To translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale.

9.3 Research design

In order to address the overall research question and aim, an interlinked three-phase program of quantitative research was designed with each phase addressing one of the research objectives. Prior to establishing international consensus about a minimum PI prevention set, PI preventative interventions which are effective in preventing PI in adults admitted to acute hospital and intensive care settings needed to be identified, to form the basis of the minimum intervention set. Once developed, the minimum PI preventative intervention set would require testing on an international scale, but the COMHON Index is not yet available in one of the most commonly spoken languages globally, Chinese Mandarin. To this end, the three-phase program of research was developed.

Phase One addressed the first research objective through a systematic review and meta-analysis of randomised controlled trials undertaken to identify and synthesise high level evidence demonstrating the effect of PI preventative interventions in adult acute hospital and intensive care inpatients. Phase One is presented in Part One, Chapters Two to Five, of this thesis. The results of Phase One were then used to inform the development of the intervention set in Phase Two.

For Phase Two, the development of a minimum PI preventative intervention set based on those interventions identified in Phase One, was required. A modified Delphi study was undertaken to identify which PI preventative interventions identified in Phase One should be applied relative to each

COMHON Index level of PI risk using the international consensus of experts. Phase Two is detailed in Part Two, Chapters Six to Eight, of this thesis.

Following international consensus, the developed minimum PI preventative intervention set applied relative to COMHON Index level of PI risk would require international testing within intensive care units. However, cross-cultural and international research requires the translation of quantitative measures (Cha *et al.*, 2007; Maneesriwongul & Dixon, 2004). Thus, there was a need for access to reliable and valid translations of the COMHON Index. While the COMHON Index was available and had been tested in Spanish and English, and work has been undertaken to translate the instrument into Japanese (Y. Ikematsu, personal communication, 18 May, 2021), it required translation into Chinese Mandarin. Translation with sound methodology is then followed by the testing of the translated instrument (Brislin, 1970; Cha *et al.*, 2007; Maneesriwongul & Dixon, 2004; Ortiz-Gutiérrez & Cruz-Avelar, 2017) and its psychometric properties (Beaton *et al.*, 2000; Cha *et al.*, 2007; Enberg & Berben, 2012; Sousa & Rojjanasrirat, 2011; Streiner & Kottner, 2014). Psychometric testing in this context refers to reliability and validity (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020), which may be undertaken using an observational design (LoBiondo-Wood & Haber, 2018b), such as using observational data to correlate a new instrument with an established measurement of the same construct. Although observational research without a control group is Level 3.e evidence as per The Joanna Briggs Institute (2014) and Level IV NHMRC (2000) evidence, it was an appropriate means of addressing the third research objective. Therefore, a concurrent validity study of the translated COMHON Index using retrospective observational data was undertaken for **Phase Three**. Further details of the Phase Three rationale and methodology are provided in this chapter below (pp. 175-192). The published report of the Phase Three translation component (Lovegrove, Fulbrook, Miles, Steele & Liu *et al.*, 2022) is presented in Chapter Ten, while Chapter Eleven describes the results of the Phase Three concurrent validity study component.

9.4 Phase Three methodology

9.4.1 Rationale

Phase three was undertaken to address the research objective *to translate the COMHON Index into a commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale*.

In Phase Two, a minimum PI preventative intervention set for implementation relative to COMHON Index level of PI risk, intended for international use across intensive care units, was developed. Subsequently, the COMHON Index combined with the minimum intervention set requires international testing within intensive care units to examine whether it is effective in decreasing PI incidence. Cross-cultural and international research firstly requires the translation of quantitative measures (Cha *et al.*,

2007; Maneesriwongul & Dixon, 2004), in this case, the COMHON Index. Indeed, it has been noted that indiscriminately creating new health assessment instruments within cultures and populations is unjustified (Ortiz-Gutiérrez & Cruz-Avelar, 2017), given that the translation of instruments developed elsewhere is time- and effort-saving (Cha *et al.*, 2007), as well as being more cost effective (Ortiz-Gutiérrez & Cruz-Avelar, 2017). Such a cross-cultural approach generates globally significant knowledge (Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2017).

While the COMHON Index is available and has been tested in Spanish and English, and work has been undertaken to translate the instrument into Japanese (Y. Ikematsu, personal communication, 18 May, 2021), it was not previously available in Chinese Mandarin. Thus, it was appropriate to translate the COMHON Index into Chinese Mandarin, since it is the second most spoken language in terms of native and non-native speakers and is the largest language when only counting native speakers (Eberhard *et al.*, 2022). However, to ensure translation quality, valid and reliable measurement, and to avoid error, it is imperative that instrument translation is undertaken using appropriate methodology (Cha *et al.*, 2007; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Maneesriwongul & Dixon, 2004; Ortiz-Gutiérrez & Cruz-Avelar, 2017; Sousa & Rojjanasrirat, 2010). Similarly, translated instruments should also be tested (Beaton *et al.*, 2000; Cha *et al.*, 2007; Sousa & Rojjanasrirat, 2011). Instruments are tested in terms of psychometric properties, including validity and reliability (Enberg & Berben, 2012; McClure, 2020). Within this context, instrument translation methodology and instrument reliability and validity testing is now discussed to rationalise the approach used in Phase Three.

9.4.2 Translation

Previously, instrument translation has been poorly reported and methods and quality have varied (Maneesriwongul & Dixon, 2004). However, there is consensus that a rigorous and formal approach to instrument translation is required (Brislin, 1970; Cha *et al.*, 2007; Gjersing *et al.*, 2007; Jones *et al.*, 2001; Maneesriwongul & Dixon, 2004; Ortiz-Gutiérrez & Cruz-Avelar, 2017; Sousa & Rojjanasrirat, 2010).

9.4.2.1 Brislin's (1970) approach

In 1970, following a literature review and examination of translation quality and equivalence between source and target language versions of essays, Brislin (1970) recommended a seven-step procedure with back translation for translations from English to other languages. The seven-step procedure entailed (1) writing an English form that is likely to be translatable, (2) securing competent translators familiar with the content involved in the source language materials, (3) instructing one bilingual to translate the form from the source to the target language (forward translation), and the other to blindly translate the translated form back from the target to the source language (back translation), (4) have several raters examine the original, target and/or back translated versions for errors that lead

to differences in meaning, followed by repeated iterations of step three if errors are found and changes to the English language version if necessary (referred to as 'decentering'), (5) when no errors are found in step four, pre-test the translated materials in subjects who speak the target language, make revisions if necessary and have a bilingual critically examine the translation (6) administer the materials to bilingual subjects, and (7) report the experience using the criteria for equivalence (monolingual meaning errors, bilingual meaning errors, questions about a passage, performance task and administration of a questionnaire) (Brislin, 1970, pp. 214-215). However, limitations to Brislin's (1970) approach have since been acknowledged, and others have proposed modifications to the approach (Cha *et al.*, 2007; Jones *et al.*, 2001).

9.4.2.2 Modifications to Brislin's (1970) approach

Jones *et al.* (2001) argued that Brislin's (1970) approach was not efficient or accurate for languages with multiple dialects. The authors (Jones *et al.*, 2001) therefore recommend that (1) at least two independent translators from different regions simultaneously perform the forward translation, (2) the forward translations are then back translated by two new bilingual experts, (3) the (at least) four bilingual experts meet with researchers as a committee to review the back translations and adapt a consensus target language version, (4) the consensus target language version is back translated by two more bilingual experts, (5) another committee of the bilingual experts is held to review the new back translations, with this process continuing until consensus is reached on a final version of the instrument, which is then tested in step (6) validation of the back translated instrument in a sample of bilingual subjects.

Cha *et al.* (2007) recognised that both models suggested by Brislin (1970) and Jones *et al.* (2001) have the potential to require many bilingual translators, which may not be achievable. Further, the bilingual testing approach included in both models is limited, because bilinguals are "acculturated to the host culture" and thus differ from monolinguals (Cha *et al.*, 2007, p. 389). As well, the first step of Brislin's (1970) process includes the development of an original easy-to-translate English version, but this is not possible where the instrument (e.g. the COMHON Index) has already been developed and tested (Cha *et al.*, 2007). These were also considerations for Phase Three of this program of research. Based on these, Cha *et al.* (2007) used a combined back translation, committee and pre-testing approach; in which, (1) three independent bilinguals, including one researcher, forward translated the test instruments, (2) each translated instrument was assessed by the other two independent bilinguals, (3) any differences were discussed in a committee meeting of the three bilinguals, (4) the preceding three steps repeated until all translators agreed on a final version, (5) a fourth bilingual back translated the final version, (6) one to two monolinguals (one was the author of the original instrument) compared the original version and the back translated version, (7) where the monolinguals identified differences, a report was provided to the bilinguals for amendments and retranslations, and (8) the process

continued until the monolinguals agreed the original and back translation were identical.

9.4.2.3 Other approaches and techniques

In addition to the approaches proposed by Jones *et al.* (2001) and Cha *et al.* (2007), and since Brislin's (1970) recommendations, studies have used various approaches for instrument translation. A methods review of 47 studies with instrument translations categorised the included studies as follows; forward translation only (without back translation or translated instrument testing; two studies), forward translation only with testing (seven studies), forward/back translation without testing (13 studies), forward/back translation and monolingual testing (18 studies), forward/back translation and bilingual testing (three studies), and forward/back translation and monolingual/bilingual testing (four studies). Evidently, there is no standard or universal approach for instrument translation as research questions and environments differ across studies. Overall, a combination of techniques may be employed based on the research question and environment (such as availability of bilingual translators) (Cha *et al.*, 2007; Maneesriwongul & Dixon, 2004). Similarly, a review of methods and guidelines for cross-cultural adaption of questionnaires (composite measurement scales) found that, across 31 guidelines, there was no consensus or 'gold standard' approach for cross-cultural adaption (Epstein *et al.*, 2015). Most, however, did include the use of committees, focus groups and back translations, although this is not essential (Epstein *et al.*, 2015).

Indeed, techniques aimed at maintaining content equivalence may include back translations (translation from source to target language [forward], then translation from target to source language [back]), a committee or consensus approach (a group of bilingual experts translate the instrument), a bilingual approach (administration of original and translated instrument to bilingual subjects and comparison of responses to instruments), and pre-testing (pilot study to identify problems with translated instrument) (Cha *et al.*, 2007). Numerous variations of these techniques (and others) have been suggested, including those described by Ortiz-Gutiérrez and Cruz-Avelar (2018) (instrument preparation, forward translation, synthesis back translation, review of back translation, revision of target-language phrasing, harmonization, piloting, completion, final report), Gjersing *et al.* (2010) (investigation of conceptual and item equivalence, original instrument translated, a synthesised translated version, back translations, a synthesised back translated version, expert committee, pre-test, revision, investigation of operational equivalence, main study, analysis, final instrument), Sousa and Rojjanasrirat (2011) (forward translation, comparison, blind back translation, comparison, pilot testing of pre-final version with monolinguals, preliminary psychometric testing with bilinguals, full psychometric testing of pre-final version in intended population) and Beaton *et al.* (2000) (forward translation, synthesis, back translation, committee review, pre-testing). The World Health Organisation (2009) also provides a model for instrument translation and adaption, reported within their management of substance abuse website, which details a combination of techniques (forward

translation, expert panel, back translation, pre-testing and cognitive interview).

9.4.2.4 Approach similarities

While there are many discrepancies in proposed translation methods, which highlight the complexities of translation and differences in recommendations, there are also some overwhelming similarities. Firstly, while technique combinations vary, a back translation technique is included in all of the proposed approaches reviewed (Beaton *et al.*, 2000; Brislin, 1970; Cha *et al.*, 2007; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011; World Health Organisation, 2009). Secondly, with the exception of those approaches proposed by Brislin (1970) and the World Health Organisation (2009), most recommend the use of at least two independent bilinguals for forward translation, followed by a synthesis and back translation (Beaton *et al.*, 2000; Cha *et al.*, 2007; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011). Thirdly, most recommend piloting of the translated instrument in a sample of monolinguals and/or bilinguals (Beaton *et al.*, 2000; Brislin, 1970; Cha *et al.*, 2007; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011; World Health Organisation, 2009). Thus, it would seem that there is consensus that these steps in particular are key to the translation process and should be utilised in Phase Three.

9.4.2.5 Phase Three considerations

The considerations of the translation methodology are discussed in the published study report (Lovegrove, Fulbrook, Miles, Steele & Liu *et al.*, 2022) presented in Chapter Ten. However, they are also more fully detailed here, thus there may be some repetition between these parts of this thesis.

The following considerations were made in the context Phase Three. Translation approaches which included the use of at least two independent bilinguals and included a synthesis and back translation were reviewed for use (Beaton *et al.*, 2000; Cha *et al.*, 2007; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011). As also noted by Cha *et al.* (2007), it was anticipated that there would not be an indiscriminate number of bilingual intensive care nurses available, such as those required by Jones *et al.* (2001). Nor would some of the expert committee requirements, such as large committees with members of various specialties (Beaton *et al.*, 2000; Gjersing *et al.*, 2010) or committees without knowledge of the intended use of the scale (Ortiz-Gutiérrez & Cruz-Avelar, 2018) be achievable in the context of Phase Three. As well, some of the recommendations (e.g. medical and other knowledge, background, locality) given for independent bilinguals were inappropriate for use (Beaton *et al.*, 2000; Jones *et al.*, 2001; Sousa & Rojjanasrirat, 2011), given the specialist nature of the COMHON Index, its components and terminology. Thus, the most fitting approach was that used by Cha *et al.* (2007) which, as previously noted, combined back-translation, a committee approach and piloting with monolinguals. This was also supported by Cha *et*

al.'s (2007) critique of step one of Brislin's (1970) process (re writing an English form that is likely to be translatable), which did not recognise that an instrument for translation may already be developed, such as the COMHON Index.

This approach (Cha *et al.*, 2007) has been followed, or used in part, within other reported research (e.g. Al-Rawajfah & Tubaishat, 2015; Devriendt *et al.*, 2012; Hoang *et al.*, 2017). Cha *et al.* (2007) described their translators but did not specify requirements for translators. Given the nature of the COMHON Index, and that the scale is completed by specialised nurses within intensive care, such nurses that are bilingual would be required for translation in this case for most of the translator roles. Forward translator bilinguals were required to be native speakers of the target language, as recommended by others (Beaton *et al.*, 2000; Gjersing *et al.*, 2010; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011; World Health Organisation, 2009). Converse recommendations are made for back translators, but difficulty was experienced in identifying such translators locally. Thus, bilinguals who lived and practised in an English-speaking country were included for back translation.

While it has been postulated that original instruments should not be identical to back translated versions as cultural language adaptions should occur (Swaine-Verdier *et al.*, 2004), this was part of the final step described by Cha *et al.* (2007) (final step; the process continued until the monolinguals agreed the original and back translation were identical). Given that the COMHON Index incorporates components which should not be adapted regardless of cultural inflection, such as prespecified scoring and cut-off points for haemodynamic criteria within categories, an identical back translation would, in part, be appropriate. However, consideration was also given to inherent differences between languages and interpretations that may present in back translations, and these differences assessed for equivalence (Swaine-Verdier *et al.*, 2004). Indeed, in Cha *et al.*'s (2007) translation approach, forward and back translation continued in iterations until the content of the translation was equivalent to that of the original (referred to as decentering, as also reported by Brislin, 1970). Content equivalence was assessed and reported by Cha *et al.* (2007) in terms of vocabulary (lack of equivalent word in target language), idiomatic (translators require knowledge of source language idiom meanings to maintain equivalence in translation), grammatical-syntactical (individual languages have their own grammar and syntax rules which can impact translational equivalence), experiential (differences in linguistic and cultural translations) and conceptual equivalences (source and target languages have the same word, but meaning differs), which were items of equivalence first identified by Sechrest *et al.* (1972). As such, for Phase Three, equivalence was considered in terms of Sechrest *et al.*'s (1972) items of equivalence (Cha *et al.*, 2007).

Once translated, the instrument would require piloting in a sample of monolinguals and/or bilinguals (Beaton *et al.*, 2000; Brislin, 1970; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011; World Health Organisation, 2009). Cha *et al.* (2007) piloted

(pretested) their translated instruments with a sample of 36 participants, but this was limited to reports of internal consistency. A feedback form was noted but further detail was provided (Cha *et al.*, 2007). The participants were monolinguals, given Cha *et al.*'s (2007) noted limitations to testing with bilinguals. As well, bilingual testing can be resource intensive, and requires the identification of enough bilinguals to complete pilot testing (Maneesriwongul & Dixon, 2004; Sousa & Rojjanasrirat, 2011). Others report various repeated testing, tool amendments and cognitive interview piloting measures with mono- and/or bilinguals for piloting (Beaton *et al.*, 2000; Gjersing *et al.*, 2010; Jones *et al.*, 2001; Ortiz-Gutiérrez & Cruz-Avelar, 2018; Sousa & Rojjanasrirat, 2011; World Health Organisation, 2009).

Overall, the aim of piloting a translated instrument is to assess the clarity of the translation and ensure appropriate understanding (Gjersing *et al.*, 2010; Maneesriwongul & Dixon, 2004; Sousa & Rojjanasrirat, 2011) prior to full psychometric testing (Beaton *et al.*, 2000; Cha *et al.*, 2007; Sousa & Rojjanasrirat, 2011). Therefore, as the final step of translation in Phase Three, pilot testing was planned to assess the clarity of the instrument (Gjersing *et al.*, 2010; Maneesriwongul & Dixon, 2004; Sousa & Rojjanasrirat, 2011). However, an already developed tool to assess the clarity of translated instruments was unable to be found, and thus one was developed for the purposes of this study (Appendix F). Based on the discussed methodology, further detail of the methods employed to assess clarity are detailed in a published study report (Chapter Ten). To ensure the pilot was representative of the intended population, a convenience sample of intensive care nurses was targeted for piloting. While some nurses may have coincidently been bilingual, it was anticipated that most would be monolingual. This was considered appropriate given the limitations of bilingual testing (Cha *et al., 2007*) and difficulties in resourcing a bilingual approach to piloting (Maneesriwongul & Dixon, 2004; Sousa & Rojjanasrirat, 2011). Sample criteria are noted in the published study report (Chapter Ten). Following piloting, the translated instrument was finalised. However, it still required further testing (Beaton *et al.*, 2000; Cha *et al.*, 2007; Sousa & Rojjanasrirat, 2011), the methodology of which is now presented.

9.4.3 Instrument testing

When an instrument or tool is developed, it requires psychometric testing (Enberg & Berben, 2012) which should be adequately reported (Steiner & Kottner, 2014). Similarly, if an existing instrument is modified or used in a different population, it requires retesting given that these circumstances may have affected its psychometric properties (Enberg & Berben, 2012; Streiner & Kottner, 2014). Such recommendations are made following translation (Beaton *et al.*, 2000; Cha *et al.*, 2007; Sousa & Rojjanasrirat, 2011). Psychometric testing in this context refers to reliability and validity (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020), which are used to evaluate the quality of an instrument and its measurements, such as the quality of a PI risk assessment scale (Kottner & Balzer, 2010). Reliability represents the consistency of a measurement, or conversely, the level of error which may be present in a measurement (Pittman & Bakas, 2010). Alternatively, validity demonstrates

whether an instrument is measuring the intended concept (Pittman & Bakas, 2010). There are different types of both reliability (internal consistency, test/retest, interrater, alternate-forms) (Enberg & Berben, 2012; McClure, 2020) and validity (predictive, concurrent or criterion, content, construct) (Enberg & Berben, 2012; McClure, 2020), which are now discussed and then related to Phase Three of this program of research.

9.4.3.1 Reliability

Reliability refers to the consistency of the outcome following multiple measurements with the instrument (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020), and may be expressed in four different forms.

Internal consistency reliability examines how homogenous the internal structures of an instrument (e.g. subscales) are (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c), and how well they relate to an overall score (McClure, 2020). Internal consistency is used where instruments (or subscales) contain multiple items which measure the same construct (e.g. one subscale in the COMHON Index) and demonstrates how strongly the items are related (Enberg & Berben, 2012; Krabbe, 2017). Overall, this is based on the theory that as all items measure the same construct, they should be strongly related (Enberg & Berben, 2012). However, for some multi-dimensional constructs such as PI risk, subscales may all be important and relevant but do not need to be interrelated or co-dependant (Kottner & Streiner, 2010; Streiner & Kottner, 2014) as they may measure different aspects of risk (i.e. different risk factors).

Test/retest reliability relates to the consistency of the outcomes when a measurement is undertaken by the same rater and (if applicable) subject repeatedly over time (Enberg & Berben, 2012; Krabbe, 2017; LoBiondo-Wood & Haber, 2018c; McClure, 2020). For example, one nurse assessing one patient at two different time points. However, this approach is often limited in nursing research, as the constructs of interest (e.g. symptoms, clinical stability) change over time regardless of the instrument (Enberg & Berben, 2012). For example, a change in pressure injury risk measurement may be due to changes in the patient's clinical condition, rather than an unstable risk assessment scale.

Alternate-forms (or parallel forms) reliability is when two equivalent but slightly different forms used for measurement are compared, and then correlated (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020). This approach is used to prevent use of the first instrument influencing use of the second (Enberg & Berben, 2012), but such equivalent forms with identical components are often not available in health research (Enberg & Berben, 2012).

Interrater reliability and agreement refers to the consistency of measurement between two or more independent raters on one subject, such as two nurses assessing the pressure injury risk of one patient (Enberg & Berben, 2012). While similar, reliability and agreement are measured (de Vet, Terwee, Knol

& Bouter, 2006; Fulbrook & Anderson, 2016; Kottner & Dassen, 2010; Kottner *et al.*, 2014) and have been defined (Kottner & Dassen, 2010; Kottner *et al.*, 2014) separately. Kottner *et al.* (2014) defined reliability as the extent to which raters are able to differentiate between subjects versus agreement as the extent measurements are identical between raters; both being under similar assessment conditions. Interrater reliability and agreement are of particular importance in a clinical context where multiple health care professionals may assess a patient independently at multiple time points (Fulbrook & Anderson, 2016; Kottner *et al.*, 2014).

9.4.3.2 Validity

Validity refers to the accuracy of the measurement (LoBiondo-Wood & Haber, 2018c; Sullivan, 2011), or in other words, whether the instrument actually measures what it is intended to measure (Enberg & Berben, 2012; McClure, 2020). Types of validity include criterion validity (predictive and concurrent validity), content validity and construct validity (Enberg & Berben, 2012; McClure, 2020). It has been argued that all validity is now viewed as construct validity (as validity is a single entity) (Grimm & Widaman, 2012; Sireci & Sukin, 2013; Streiner & Kottner, 2014), and that different forms of validity have not been spoken of since the 1970s (Streiner & Kottner, 2014). However, some disagree as reported by Sireci and Sukin (2013). Furthermore, others describe and differentiate between these types of validation which are relevant to psychometric testing (e.g. Enberg & Berben, 2012; Krabbe, 2017; LoBiondo-Wood & Haber, 2018c; McClure, 2020 Pittman & Bakas, 2010), even if they are considered to all form part of construct validity by some (Grimm & Widaman, 2012).

Criterion validity examines how well an instrument correlates with another measure (or external standard [Enberg & Berben, 2012], criterion [McClure, 2020], 'gold standard' [Pittman & Bakas, 2010) of the same construct. Criterion validity comprises two validity sub-types; *predictive validity* and *concurrent validity* (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020). *Predictive validity* refers to the ability of the instrument to measure the construct by correlating it to another (different) future measurement of the construct (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020). In the context of PI risk assessment, the assessment is often correlated with the future PI incidence within the population assessed (Kottner & Balzer, 2010). In other words, how well the instrument differentiated between those who were at risk (as confirmed by development of a PI) and those who were not (as confirmed by no development of a PI), which is referred to respectively as sensitivity and specificity (Kottner & Balzer, 2010; Pancorbo-Hidalgo *et al.*, 2006). By contrast, *concurrent validity* correlates an instrument to another method/s or criterion (often a 'current' [Sireci & Sukin, 2013], present, [Enberg & Berben, 2012] more established [LoBiondo-Wood & Haber, 2018c) or 'gold standard' [Pittman & Bakas, 2010] criterion or instrument) for measuring the same construct at the same time (Enberg & Berben, 2012; McClure, 2020). For example, the correlation and level of agreement between two PI risk assessments undertaken at the same time point for the

same subject using different scales.

There are two other types of validity: *content validity* and *construct validity. Content validity* describes how well the instrument and its elements measure and cover aspects relevant to the *overall* domain of interest (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020; Pittman & Bakas, 2010), such as how adequately the COMHON Index and its subscales comprehensively measure PI risk overall. Unlike other types of validity which are examined analytically (Krabbe, 2017), as there is no objective measure of content validity, it is often explored based on judgement through focus groups, interview and expert panels (Enberg & Berben, 2012; Pittman & Bakas, 2010). Meanwhile, c*onstruct validity* describes how well the instrument and its structures measure the underlying attributes of the overall construct (Krabbe, 2017; LoBiondo-Wood & Haber, 2018c; McClure, 2020; Pittman & Bakas, 2010) intended, and how well the scores represent variability amongst subjects (Enberg & Berben, 2012). For example, whether the subscales of a PI risk assessment scale are actually representative of individual PI risk. *Construct validity* is complex and may comprise *convergent validity* (how well the instrument correlates to other measures of the same construct) and *discriminant or divergent validity* (the degree the instrument does *not* correlate with dissimilar measures) which may be determined with a multitrait-multimethod approach, known groups (two groups with varying construct levels assessed with an instrument) and statistical structure or hypothesis testing (Krabbe, 2017; LoBiondo-Wood & Haber, 2018c).

9.4.3.3 Phase Three considerations

In terms of reliability testing, *internal consistency* using Cronbach's alpha was not appropriate, given that PI risk is multidimensional and the subscales of the COMHON Index are all important but not reliant upon or related to each other. *Test/retest* and *alternate-forms reliability* were both inappropriate in this context given the noted limitations that clinical condition may change rapidly and obscure test/retest results, and equivalent forms with identical components were not being evaluated. *Interrater reliability and agreement* would be an appropriate measure, as individuals may be assessed for PI risk using the Mandarin COMHON Index by multiple differing clinicians on a regular basis within standard clinical practice (Fulbrook & Anderson, 2016; Kottner *et al.*, 2014). Thus, it is imperative that PI risk is measured consistently among clinicians to ensure accurate assessment and continuity of care. However, it was not feasible to perform interrater reliability and agreement testing in the context of Phase Three due to COVID-19 disruptions to cities, hospitals and research (including data collection). Further detail of the impacts of COVID-19 on this program of research, and Phase Three in particular, is provided in Chapter Twelve (section 12.6, pp. 232-233).

In terms of validity, content and construct validity of the COMHON Index was established in its initial development and testing (Cobos Vargas *et al.*, 2013); thus, these forms of validity were not necessary

for Phase Three of this program of research. Predictive validity is often used to test PI risk assessment scales (e.g. Adibelli & Korkmaz, 2019; Efteli & Güneş, 2020; García-Fernández *et al.*, 2014; Han *et al.*, 2018; Hyun *et al.*, 2013; Ninbanphot *et al.*, 2020; Ranzani *et al.*, 2016; Sanada *et al.*, 2008; Wei *et al.*, 2020), but as noted throughout the Introduction chapter (pp. 8-9, 28), PI risk assessment scales should not be used to predict PI (Lovegrove, Ven *et al.*, 2021). Rather, risk assessment scales should be used to prompt preventative intervention use and prevent PI, rendering predictive validity futile. However, for Phase Three, the concurrent validity of newly translated versions of the COMHON Index should be examined in comparison to other risk assessment scales in the same language. In this context, to examine the concurrent validity of the Mandarin version of the COMHON Index, there was no clear 'gold standard' PI risk assessment for comparison (Fulbrook & Anderson, 2016). Consequently, comparison was made with the Braden scale (Bergstrom *et al.*, 1987), the most widely studied risk assessment globally (Pancorbo-Hidalgo *et al.*, 2006; García-Fernández *et al.*, 2014) which has also been used within research in China previously (Chen *et al.*, 2017; Wei *et al.*, 2020; Zhou *et al.*, 2018), and was the standard care PI risk assessment scale used within the Phase Three study setting.

In testing of the English version of the COMHON Index, Fulbrook and Anderson (2016) examined *convergent validity* (a sub-type of construct validity; Krabbe, 2017) rather than *concurrent validity* (a sub-type of criterion validity; Enberg & Berben, 2012; McClure, 2020). Concurrent and convergent validity are sometimes used synonymously (LoBiondo-Wood & Haber, 2018c). Indeed, both are very similar and correlate an instrument to other measures of the same construct (e.g. a new PI risk assessment scale compared to an established PI risk assessment scale), but *convergent validity* is only associated with strong or positive correlations between the tested instruments (Krabbe, 2017; Sireci & Sukin, 2013). The strong correlations may also be referred to as *convergent relationships* (Sireci & Sukin, 2013). While strong correlations were evident in the comparison of the English version of the COMHON Index and Braden scale (Fulbrook & Anderson, 2016), it is not guaranteed for the Mandarin versions. Thus, Phase Three psychometric testing was focused on concurrent validity.

9.4.3.3 Sampling and sample size

The population to be sampled should reflect the research question (Haber, 2018; Kelley & Maxwell, 2012), so that the results are representative of, and may be generalised to, the intended population (Haber, 2018). Furthermore, a sample size calculation should be undertaken to ensure that the sample is of sufficient size and power to be representative of the population and is powered to detect an effect between the study groups which is of significance (Haber, 2018; Malone, Nicholl & Coyne, 2014). Factors which are taken into account when calculating sample size include design, sampling procedure, formulas used, precision required, heterogeneity of attributes being examined, frequency of the event of interest in the population and projected cost (Haber, 2018). For reliability and validity studies, recommended and previous sample sizes are variable (Streiner & Kottner, 2014). For PI risk assessment

in intensive care, some have tested interrater reliability within a preliminary smaller portion of a larger study (30 patients each rated by the same 2 nurses, Efteli & Günes, 2020; 50 patients each rated by two different nurses, Wåhlin *et al.*, 2020), but have not reported power for the reliability testing. Others who have examined interrater reliability and agreement (and some forms of validity) have based their sample sizes on reliability reported by others and expressed as ICC, resulting in smaller but still powered studies (26 patients each rated by five of the same nurses, Fulbrook & Anderson, 2016; 21-24 patients per unit each rated by three different nurses, Kottner & Dassen, 2010). The sample sizes for validity testing were much larger in two of these studies (*n* = 207 patients, Efteli & Günes, 2020; *n* = 300 patients, Wåhlin *et al.*, 2020), and were justified based on 'rules of thumb' for analyses of the number of items on the scale. However, the latter two (Fulbrook & Anderson, 2016; Kottner & Dassen, 2010) performed validity testing with the smaller sample size powered for reliability testing, and their approach to validity testing was most in line with that intended for Phase Three. Furthermore, the Phase Three concurrent validity study used previously collected, retrospective data. Thus, the sample size was one of convenience and already set (refer to sections 9.5.5 and 9.5.6, p. 190) but was larger than that of others (Fulbrook & Anderson, 2016; Kottner & Dassen, 2010).

9.4.3.4 Data analysis

9.4.3.4.1 Correlation coefficients

As described previously (section 9.4.3.2, pp. 183-184), concurrent validity correlates an instrument of interest to another established or gold standard instrument measuring the same construct (Enberg & Berben, 2012; LoBiondo-Wood & Haber, 2018c; McClure, 2020; Pittman & Bakas, 2010), such as the COMHON Index being correlated to the Braden scale. Thus, concurrent validity may be measured using correlation coefficients (Krabbe, 2017; LoBiondo-Wood & Haber, 2018c). When correlating PI risk assessment scales to one another, others have used Pearson product-moment correlation coefficient for sum scores (for convergent validity, Fulbrook & Anderson, 2016; referred to as construct validity, Kottner & Dassen, 2010), and Spearman's rho for subscales (Fulbrook & Anderson, 2016). Similarly, Pearson product-moment correlation coefficient has also been used for concurrent validity with other health assessments (e.g. Griswold *et al.*, 2015; Hall & Docherty, 2017). Therefore, these statistical approaches were used to examine the concurrent validity of the Mandarin COMHON Index, when correlated with the Braden scale.

Correlation coefficients can be positive or negative (i.e., range from -1.0 to +1.0; Sullivan-Bolyai & Bova, 2018b). The positive and negative values refer to the direction of the relationship, not the strength of the relationship; in other words, increasing scores on one instrument may be associated with increasing (positive) or decreasing (negative) scores on another (Sullivan-Bolyai & Bova, 2018b). The strength of the relationship is based upon the closeness of the correlation coefficient to 1, regardless

of whether it is negative or positive (Sullivan-Bolyai & Bova, 2018b). For Phase Three, correlation coefficients were interpreted according to Cohen (1977); *r* = 0.10 was considered a 'small' correlation, *r* = 0.30 was considered a 'medium' correlation, and *r* = 0.50 and above was considered a 'large' (or strong) correlation.

9.4.3.4.2 Kappa statistics

As interrater reliability and agreement were not examined, it was also of interest to measure the level of agreement between the two instruments in terms of PI risk categorisation in the context of instrument correlation. Level of agreement may suggest that one scale is inappropriate, or that one may lead to higher (or lower) risk categorisation and thus better preventative intervention use (Lovegrove, Ven *et al.*, 2021). For this purpose, as risk levels differ between instruments, the risk levels of the Braden scale were grouped to match the COMHON Index (Braden not at risk and mild risk = COMHON Index low risk; Braden moderate risk = COMHON Index moderate risk; Braden high and very high risk = COMHON Index high risk). While ICC have been recommended and are preferable for interrater reliability and agreement using continuous data and repeated scale measurements (Kottner & Dassen, 2010; Shrout & Lane, 2012; Streiner & Kottner, 2014), kappa statistics are appropriate for nominal and ordinal data (i.e. risk categories) (Kottner *et al.*, 2011; Krabbe, 2017).

Kappa statistics are measures of agreement beyond what would be expected by chance alone and are often used for measuring the level of agreement between different raters (Celentano & Szklo, 2019; McHugh, 2012; Tang *et al.*, 2015). Furthermore, kappa statistics may also be used to measure the level of agreement between different instruments (Pallant, 2020) and have been used previously to examine the level of agreement in terms of PI risk categorisation when assessing a patient using three different PI risk assessment scales (Charlier, 2001). There are different types of kappa statistics (Kottner *et al.*, 2011; McHugh, 2012; Tang *et al.*, 2015), including Cohen's kappa (Cohen, 1960) and Fleiss' kappa (1971). Cohen's kappa is appropriate for measuring agreement between two raters', while Fleiss Kappa is an adaption of Cohen's which is intended for more than two raters (McHugh, 2012). Therefore, in the context of Phase Three, Cohen's kappa was used to examine the level of agreement (beyond that of chance) between the Chinese Mandarin COMHON Index and Braden scale.

However, while still valid for Phase Three, Cohen's kappa was developed for nominal data (Cohen, 1960) and thus treats each category of nominal data equally (Kvålseth, 2018). Another kappa statistic is Cohen's weighted kappa (Cohen, 1968), an adaption of kappa which is weighted (linearly or quadratically) to account for the fact that data may be ordinal and that some disagreements are more serious than others (Kvålseth, 2018; Tang *et al.*, 2015). This is applicable to PI risk categories

which may be considered ordered (low, moderate, high), and where disagreements may be more serious (e.g. low risk versus high risk disagreement would be more serious than low risk versus moderate risk disagreement). Nonetheless, ordering is linear, and the difference between the categories is equal. Thus, level of agreement for Phase Three was also measured using linear weighted kappa.

The output of a kappa statistic ranges from 0 to 1, with 0 indicating potential agreement from random chance, and 1 indicating perfect agreement beyond chance (McHugh, 2012). Kappa values may also go below 0 which would represent disagreement (Kvålseth, 2018), but this is unlikely in practice (McHugh, 2012; Kvålseth, 2018). To interpret a kappa measurement of 0 to 1 for Phase Three, the levels of agreement proposed by Landis and Koch (1977) were applied: poor agreement (k < 0.00), slight agreement (k = 0.00-0.20), fair agreement (k = 0.21-0.40), moderate agreement (k = 0.41-0.60), substantial agreement (k =0.61-0.80) and almost perfect agreement (k = 0.81-1.00).

9.4.3.5 Reporting

There are four recommendation documents (American Educational Research Association *et al.*, 2014; Bossuyt *et al.*, 2003; Kottner *et al.*, 2011; Streiner & Kottner, 2014), which are potentially relevant to the reporting of reliability and agreement studies or instrument and tool development and testing studies. The Standards for Educational and Psychological Testing (first developed in 1966 and regularly updated; American Educational Research Association *et al.*, 2014) and the Standards for Reporting Diagnostic Accuracy (Bossuyt *et al.*, 2003) both contain comprehensive standards for reporting, particularly the former. However, as noted by Streiner and Kottner (2014), the first is aimed at high-level individual decision-making tests, such as educational tests and subsequent decisions, while the latter is medically and diagnostic testing focused. Of more relevance are the recommendations made by Kottner *et al.* (2011) and Streiner and Kottner (2014).

In 2011, a group of eight experts in reliability and agreement research developed the 'Guidelines for reporting reliability and agreement studies (GGRAS)' using a nominal group approach (Kottner *et al.*, 2011). The guidelines include 15 items which describe what should be reported for reliability and agreement studies, including recommendations for the reporting of the title and abstract, introduction, methods, results, discussion and auxiliary material in a paper (Kottner *et al.*, 2011). Later, Streiner and Kottner (2014) published recommendations for the reporting of instrument and tool development and testing. Similar to that of Kottner *et al.* (2011), the authors (Streiner & Kottner, 2014) provide recommendations for the reporting of the introduction, methods, results and discussion of a paper. Both publications (Kottner *et al.*, 2011; Streiner & Kottner, 2014) contain recommendations relevant to the reporting of Phase Three. Subsequently, to ensure quality, the reporting of the psychometric testing undertaken in Phase Three was guided by these recommendations (Kottner *et*

al., 2011; Streiner & Kottner, 2014).

9.5 Methods

The methods of the translation component of Phase Three are provided in full within the study report published in the *International Journal of Nursing Sciences* (Lovegrove, Fulbrook, Miles, Steele & Liu *et al.*, 2022), which is presented in Chapter Ten (pp. 193-204). The methods of the concurrent validity component of Phase Three, which followed translation, are presented below.

9.5.1 Research question

What is the concurrent validity of the Chinese Mandarin version of the COMHON Index when tested and correlated with the Braden scale within a Chinese intensive care setting?

9.5.2 Aims

To examine the concurrent validity of the Chinese Mandarin version of the COMHON Index against the Chinese Mandarin Braden scale.

9.5.3 Design

PI risk assessment data (Chinese Mandarin COMHON Index and Braden scale) were previously collected within a Chinese intensive care setting following the formal translation of the COMHON Index. The data were appropriate for examining the concurrent validity of the COMHON Index in comparison to the Braden scale. Thus, this component of Phase Three was a secondary analysis of observational non-identifiable PI risk assessment data.

9.5.4 Instruments

The formally translated Chinese Mandarin COMHON Index was the instrument of interest. As described previously (section 1.3, p. 33), the COMHON Index assesses five intensive care PI risk components; COnsciousness as per the Richmond Agitation Sedation Scale (Sessler *et al.*, 2002), Mobility, Haemodynamics, Oxygenation and Nutrition. Each of the five components may be scored from 1 to 4. Each component, or subscale, has clearly defined criteria to guide rating. The score of each component is then combined into a total sum score, which may range between 5 and 20. The sum score is correlated to a level of PI risk; the lower scores (5 to 9) are considered low risk, 10 to 13 is moderate risk, and 14 to 20 is high risk.

To examine the concurrent validity, comparisons were made with the Chinese Mandarin Braden scale (refer to section 9.4.3.2, pp. 183-184), which was already used in the setting from which data were collected. The Braden scale (Bergstrom *et al.*, 1987) measures six subscales; sensory perception, activity, mobility, moisture, nutrition and friction. The former five subscales may be scored from 1 up to 4, while the latter friction scale may be scored from 1 up to 3. Similar to the COMHON Index, each subscale has defined criteria to inform rating (Braden & Bergstrom, 1988); although, the Braden scale

is not targeted at intensive care. The total sum score, once subscales are combined, may range between 6 and 23. Lower scores indicate higher risk (Braden & Maklebust, 2005). However, 'cut off' scores for categorising patients as a level of PI risk, or as either at risk or not, vary in the literature (Lovegrove, Miles & Fulbrook, 2018). The following levels of risk based on total sum score have been recommended (Braden & Maklebust, 2005); 19-23 not at risk, 15-18 mild risk, 13-14 moderate risk, 10-12 high risk and $\leq$ 9 very high risk.

9.5.5 Data collection

Data were previously collected by a clinical nurse within the Tenth People's Hospital of Tongji University, Shanghai, China between October 2021 and January 2022. The hospital has five intensive care units (neurosurgery, surgical, cardiac and emergency) with more than 100 beds. Of these, data collection was undertaken in the surgical intensive care unit.

The clinical nurse worked with four nurses within the surgical intensive care unit to assess the PI risk of 80 adult patients (> 18 years of age) with no current PI. Each patient was assessed for PI risk using both the Chinese Mandarin COMHON Index and the Braden scale.

9.5.6 Dataset

The previously collected PI risk assessment data were de-identified with no participant (nurse and patient) information and collated into a non-identifiable dataset within Microsoft Excel™. The data were provided by the data owner from the Tenth People's Hospital of Tongji University and stored securely (refer to section 9.5.8, p. 191).

Specifically, the non-identifiable dataset included:

- An assessment number (1 to 80)
- COMHON Index assessment:
    - Documented score for each subscale
    - Documented overall sum score
    - Documented risk level
- Braden scale assessment:
    - Documented score for each subscale
    - Documented overall sum score
    - Documented risk level

9.5.7 Data analysis

Data were entered into Microsoft Excel™ and a statistical software package (IBM SPSS™) for analysis. Descriptive statistics were used to describe the completeness of assessments and the proportions of PI risk levels across the assessments. To examine concurrent validity, RAS sum scores were compared

using Pearson Product Moment Correlation (refer to section 9.4.3.4.1, pp. 186-187), with negative correlations anticipated due to the reverse scoring of the Braden scale (Fulbrook & Anderson, 2016). Similar subscale items between the two instruments (mobility, neurological and nutrition items) were also compared using Spearman's rho (Fulbrook & Anderson, 2016). Correlation coefficients were interpreted according to Cohen (1977); r = 0.10 was considered a 'small' correlation, r = 0.30 was considered a 'medium' correlation, and r = 0.50 and above was considered a 'large' (or strong) correlation.

Agreement between the two instruments in terms of PI risk categorisation were also measured using Cohen's kappa and weighted kappa statistics (refer to section 9.4.3.4.2, pp. 187-188). For this purpose, as risk levels differ between instruments, the risk levels of the Braden scale were grouped to match the COMHON Index (Braden not at risk and mild risk = COMHON Index low risk; Braden moderate risk = COMHON Index moderate risk; Braden high and very high risk = COMHON Index high risk). The levels of agreement proposed by Landis and Koch (1977) were applied: poor agreement (k < 0.00), slight agreement (k = 0.00-0.20), fair agreement (k = 0.21-0.40), moderate agreement (k = 0.41-0.60), substantial agreement (k =0.61-0.80) and almost perfect agreement (k = 0.81-1.00).

9.5.8 Ethical considerations

As this was a retrospective analysis of non-identifiable, already collected data, there were no foreseen risks to nurse or patient participants. As the analysis was undertaken as part of a Doctor of Philosophy degree, approval for access to and use of the non-identifiable data was sought from and granted by the Human Research Ethics Committee of Australian Catholic University (2022-2704N; Appendix K). Only aggregate data are reported. Data were stored on an electronic storage device, which was stored in a locked cupboard in a locked research office. Similarly, any printed data has been stored in the same manner. Electronic data were backed up within an Australian Catholic University CloudStor account. Data will be retained for at least five years from (NHMRC, Australian Research Council & Universities Australia, 2019) and will then be destroyed; paper copies will be shredded and electronic files erased.

9.6 Conclusion

This chapter has introduced Phase Three and has presented the research design and methodology of this phase.

Phase Three was justified as appropriate for addressing the relevant objective *to translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale*.

Phase Three comprises two components; the translation of the COMHON Index from English into Chinese Mandarin, followed by testing of the translated instrument in a Chinese intensive care setting. These components are reported separately. The translation is presented as a published paper in the next chapter (Ten), and the results of the instrument testing (a concurrent validity study) is provided in Chapter Eleven.

Chapter Ten: Translation of the COMHON Index (English to Chinese Mandarin)

10.1 Introduction

In Phase Three, instrument translation and testing were conducted to address the overall research objective *to translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale*. This was needed given that Chinese Mandarin is a widely spoken language (Eberhard *et al.*, 2022), and the minimum PI preventative intervention set developed in Phase Two requires international testing.

Phase Three comprised two parts; the instrument translation, and concurrent validity testing. This chapter presents the instrument translation, which was published in the *International Journal of Nursing Sciences* (Lovegrove, Fulbrook, Miles, Steele, Liu *et al.*, 2022). The translation of the COMHON Index initially led to some minor amendments being made to the original English and Spanish versions (Version 2.0, Appendix G), and the finalisation of Version 2.1 in Spanish, English and Chinese Mandarin (Version 2.1, Appendix H). The amendments to the original and Version 2.0 of the COMHON Index are described on pages 193 and 194 of this chapter. The translation, including pilot testing of the translated instrument, was approved as part of Phase Three by the Australian Catholic University Human Research Ethics Committee (2021-17H, Appendix I) and the Tenth People's Hospital of Tongji University Human Research Ethics Committee (SHSY-IEC-4.1/20-258/01, Appendix J).

The *International Journal of Nursing Sciences* was selected for publication of the Phase Three instrument translation as it is the English journal of the Chinese Nurses Association (Elsevier, 2022) and was thus ideal for dissemination of the Chinese Mandarin COMHON Index to Chinese intensive care nurses. It is a Q1 journal (Scimago, 2022b), and although it does not have an Impact Factor (Clarivate™, 2022b), it has a 2021 Scimago Journal Ranking (2022b) of 17/154 Nursing – Miscellaneous. The *International Journal of Nursing Sciences* is fully open access, and the publication is freely available (Elsevier, 2022). Confirmation that the published paper may be presented within the thesis in PDF form was provided in writing by the journal (email; Research Portfolio Appendix F). Furthermore, as with the Phase One systematic review publications (pp. 64, 95), presentation of the article within a thesis is allowed as per the Elsevier Permissions webpage (Elsevier, 2021b) and publisher Article Sharing policy (Elsevier, 2021a). Thus, the published paper is presented in this chapter in PDF form (pp. 194-203).

International Journal of Nursing Sciences 9 (2022) 169–178

Contents lists available at ScienceDirect

International Journal of Nursing Sciences

journal homepage: http://www.elsevier.com/journals/international-journal-of-nursing-sciences/2352-0132

Research Paper

Translation and piloting of the Chinese Mandarin version of an intensive care-specific pressure injury risk assessment tool (the COMHON Index)

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ARTICLE INFO

Article history:
Received 18 January 2022
Received in revised form
2 March 2022
Accepted 4 March 2022

Keywords:
Critical care
Intensive care units
Nursing care
Pressure injury
Pressure ulcer
Risk assessment
Translating

ABSTRACT

Objective: To translate an intensive care-specific pressure injury risk assessment tool (the COMHON Index) from English into Chinese Mandarin.
Methods: A four-step approach to instrument translation was utilised: 1) English-Mandarin forward-translation by three independent bilinguists; 2) Mandarin-English back-translation by two other independent bilinguists; 3) comparison of forward and back-translations, identification of discrepancies, with required amendments returned to step one; and 4) piloting of the translated instrument. The pilot study was undertaken in a Chinese surgical intensive care unit with a convenience sample of 20 nurses. A five-point ordinal scale (1 = very difficult; 5 = very easy) was used to assess ease-of-use and understanding. Translations were retained where medians $\geq$ 4 indicated use and understanding was easy to very easy.
Results: Five iterations of steps 1 to 3, and two sets of amendments to the original English instrument, were required to achieve translation consensus prior to pilot testing. Subscale scoring, sum scoring, and risk categorisation were documented in most pilot assessments ($\geq$ 80%), but three sum scores were incorrectly tallied. The overall tool and all subscales were easy to use and understand (medians $\geq$ 4), and most assessments (16/20, 80%) took $\leq$ 5 min to complete. Thus, translations were retained, with minor amendments made to instrument instructions for scoring and risk categorisation.
Conclusions: An easy-to-use Chinese Mandarin intensive care-specific pressure injury risk assessment tool has been introduced through cross-cultural translation. However, it requires further testing of interrater reliability and agreement. A rigorous translation and reporting exemplar is presented that provides guidance for future translations.

What is known?

- Intensive care patients are at high risk of pressure injury. Pressure injury prevention is an essential component of patient safety and begins with a risk assessment.
- Pressure injury risk assessment in intensive care should be setting-specific.
- The COMHON Index is an intensive care pressure injury risk assessment tool which has demonstrated promising psychometric properties.

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Peer review under responsibility of Chinese Nursing Association.

https://doi.org/10.1016/j.ijnss.2022.03.003

What is new?

- The COMHON Index has been translated into Chinese Mandarin using a rigorous approach.
- Most nurses who participated in the piloting process indicated it was relatively fast and easy to use and understand.
- It has widespread potential for use, but first requires further psychometric testing.
- Future translation work should employ appropriate methodology and reporting.

1. Introduction

1.1. Pressure injury in intensive care

Hospital-acquired pressure injury (PI) is considered an adverse event [1], with rates highest in intensive care units (ICUs) in comparison to wards [2]. An international PI point prevalence study across 1,117 ICUs in 90 countries found an overall prevalence of 26.6%, with an ICU-acquired prevalence of 16.2% [3]. This is of concern given the burdens associated with PI for individuals [4,5] and healthcare facilities [6]. A secondary analysis of Labeau et al.'s [3] international point prevalence data found an ICU-acquired prevalence of 4.3% across 198 Chinese ICUs [7]. Similarly, a study across 12 Chinese hospitals reported a hospital-acquired PI prevalence of 4.5% in an ICU sample of 1,094 [8]. Another Chinese study, across 25 hospitals from one province, reported a hospital-acquired PI prevalence of 1.4% in ICU ($n = 432$) [9]. While these rates of hospital-acquired PI in Chinese ICUs are lower than those reported globally [3], ICU-acquired PI nonetheless continues to be a challenge.

1.2. Risk assessment

Not all PIs are preventable [10], particularly in ICU [11], but most are avoidable using preventative interventions [12,13]. The first step of PI prevention is risk assessment [14]. Risk assessment may be aided with use of a PI risk assessment tool, but most do not include ICU-specific factors [15,16]. Risk factors associated with PI in ICU include immobility, hypotension or impaired perfusion, vasopressors and extended mechanical ventilation [15,17,18]. Recently, more ICU-specific tools have been developed and tested to some extent [e.g. 19–21]. Many tools are tested using predictive validity (i.e. whether a PI developed as predicted by assessed risk), but if preventative intervention use appropriately follows risk assessment and PI is thus prevented, predictive validity would be reflected as poor [22]. Therefore, other tool properties require consideration, such as interrater reliability.

The COMHON Index is an ICU-specific PI risk assessment tool which has displayed other promising properties. It was developed in Spain, with content established by the researcher group based on international PI risk assessment tools and evidence relevant to PI risk factors in ICU [19]. Following piloting, a tool with five subscales relevant to PI in ICU was finalised. Further testing was then undertaken in two Spanish hospitals, with the COMHON Index demonstrating positive interrater reliability (kappa 0.89–0.93), internal consistency (Cronbach's α 0.72–0.80) and concurrent validity with the Braden (kappa 0.74–0.81) and Norton scales (kappa 0.72–0.73) [19]. More recently in an Australian study, it was shown to have better interrater reliability (sum score intraclass correlation [ICC] 0.90, risk level category ICC 0.87) than three non-ICU-specific tools (Braden sum score ICC 0.66; risk level category ICC 0.65; Norton sum score ICC 0.77; risk level category ICC 0.45; Waterlow sum score ICC 0.47; risk level category ICC 0.43) and was more sensitive to small changes in patient condition [16]. An international Delphi study with a panel of ICU nurse experts has also matched the COMHON Index with a set of PI preventative interventions based on risk level [23]. This is significant, as it is not risk assessment which prevents PI, but the subsequent use of preventative interventions based on identified risk [14,16].

In addition to the Spanish and English versions of the COMHON Index, work has been undertaken to translate and test a Japanese version (Y. Ikematsu, personal communication). While English and Spanish are the first and fourth most spoken languages respectively (native and non-native speakers), Chinese Mandarin is the second most spoken language in this respect and the largest language when counting only native speakers [24]. There is a need for an ICU-specific PI risk assessment tool in this language, and although the development of setting-specific tools is relevant, it has been argued that indiscriminately creating new health assessment instruments within languages and cultures is unjustified where there are already existing instruments [25]. Indeed, the translation of instruments developed elsewhere is time- and resource-saving [25,26], and given the promising range of properties that the COMHON Index has demonstrated in Spanish and English, it is an appropriate tool to translate into Chinese Mandarin.

1.3. Translation approaches

Previous instrument translation has been reported poorly and methods have varied [27]. Nonetheless, translation approaches should be as rigorous as possible using appropriate methodology to ensure quality and accuracy [25–29]. Translation techniques may include: back-translation (source-target language translation [forward], then target-source translation [back]); committees (bilingual expert groups translate or review translation); a bilingual approach (original/translated instrument administered to bilingualists, comparison of responses); and pre-testing or piloting [26]. These techniques, among others, may be selected and combined based on research requirements [26,27]. However, consensus is lacking on a specific combination or 'gold standard' approach for cross-cultural translation and adaption of instruments [27] and self-report questionnaires [30].

Brislin's [31] approach has been widely adopted and recommends a procedure for English to other language translations with several steps, including back-translation iterations, multi-rater version examination and mono/bilingual testing. However, Jones et al. [32] argued that Brislin's approach was not efficient or accurate for languages with multiple dialects and suggested a revised approach with multiple translators from different regions, committees and bilingual testing. Meanwhile, Cha et al. [26] highlighted that both the models of Brislin [31] and Jones et al. [32] have the potential to require an unachievable number of bilingual translators and proposed a process including back-translation, a committee and monolingual pretesting. Numerous other variations of translation methodology have been reported for health, self-report and research instruments, with various additional techniques incorporated [e.g.25,28,29,33]. While there is evidently no standard methodology, there is some key overlap among approaches, with many including back-translation, at least two forward-translation bilinguists and pilot testing. Therefore, only translation methods that included these three techniques were considered for use in this translation study, of which the most suitable was that of Cha et al. [26].

1.4. Aim

This study aimed to translate an ICU-specific PI risk assessment tool, the COMHON Index, into Chinese Mandarin.

2. Methods

The COMHON Index [19] includes five subscales: level of **Co**nsciousness (Richmond Agitation Sedation Scale [34]), **M**obility, **H**aemodynamics, **O**xygenation and **N**utrition. Each subscale has defined criteria and is scored from 1 to 4. The score of each subscale is then summed to determine risk level (low 5–9; moderate 10–13; high 14–20). Permission was granted by the lead author (A. Cobos Vargas), on behalf of the authors of the original COMHON Index, to translate the tool into Chinese Mandarin and publish the Chinese Mandarin and English versions. Ethical approval was granted as part of a larger project by the Human Research Ethics Committees of the Tenth People's Hospital of Tongji University (SHSY-IEC-4.1/20–258/01) and Australian Catholic University (2021–17H).

2.1. Translation approach

Several modifications were made to the approach described by Cha et al. [26]. Cha et al. [26] described their translators, but specific requirements for the inclusion of translators such as background and knowledge were not detailed. Given the nature of the COMHON Index, bilingual ICU nurses were required for most of the translator roles. Forward-translators were required to be native speakers of the *target* language (Chinese Mandarin) with a good understanding of the *source* language (English). Ideally back-translators would have converse language requirements [25,29,33]. The following steps were employed (Appendix A).

2.1.1. Step 1 forward-translation

Three forward-translators independently translated the instrument from English into Chinese Mandarin. Forward-translators assessed each other's versions, and differences were discussed in a forward-translator committee meeting. This was repeated until all forward-translators agreed on a final forward-translation version.

2.1.2. Step 2 back-translation

Two back-translators, who differed from the forward-translators, independently translated the Mandarin version back into English. While Cha et al. [26] reported the use of one back-translator, we included two [28,29,32,33] to highlight discrepancies and facilitate a second committee approach. A monolingual investigator (English-speaking with over eight years' nursing/research experience) compared the two back-translations to identify discrepancies, and the back-translators were given the opportunity to review each other's versions. Any version discrepancies were discussed in a committee meeting of the back-translators and monolinguist investigator, and the two versions were synthesised into one back-translation version.

2.1.3. Step 3 comparison

The monolingual investigator, with assistance from two others (with extensive ICU nursing/research backgrounds), compared the synthesised back-translation version to the original English instrument. Detailed feedback of any identified discrepancies between the two was provided to the initial forward-translators. The lead COMHON Index developer answered queries where required. The forward-translators then amended the translation based on the feedback or provided justification for rejecting an amendment. Steps 1–3 were repeated for any identified discrepancies until the back-translation and original instrument were assessed to be equivalent in a 'pre-final' version.

Cha et al. [26] noted that their approach continued until the translation and original were identical with no errors in meaning. Given that the COMHON Index incorporates components which should not be adapted (e.g. prespecified scoring for haemodynamic criteria) an identical back-translation would, in part, be appropriate. However, consideration was also given to inherent differences between languages and interpretations. As the content of the COMHON Index was already established prior to translation and in line with the approach of Cha et al. [26], no further review of content was conducted outside of adaptions resulting from translation iterations. Content equivalence between original and translated phrases was considered in terms of Sechrest et al.'s [35] items of equivalence [26].

2.1.4. Step 4 pre-testing

The final step was to pilot the pre-final instrument in a sample representative of the intended population. While Cha et al. [26] pretested their translated instruments, the referenced 'feedback form' was not described with only internal consistency reported. However, measuring internal consistency with Cronbach's alpha may not be appropriate for the COMHON Index, given that each subscale is relevant to PI risk as a multi-dimensional construct, but not necessarily interrelated [36,37]. Overall, piloting a translated instrument should assess clarity and ensure appropriate understanding [27–29]. Thus, we developed a specific tool to pilot the COMHON Index translation to this end. If piloting indicated difficulties with subscale assessments or definitions, the relevant sections would be reviewed and amended with the translators. While further reliability and validity testing of the translated instrument would be required following finalisation and prior to clinical use, such testing should be separated from translation to ensure the adequate provision of detail in reporting [25].

2.2. Pilot study

The setting was a 1,860-bed Class A tertiary comprehensive hospital in Shanghai, China, with five ICUs. Recommended pilot sample sizes vary, including ranges from 5 [25] to 40 [29,33], thus, the sample size was selected based on these recommendations and feasibility. Piloting was undertaken in the surgical ICU with a convenience sample of 20 ICU nurses. While some nurses may have coincidently been bilingual, it was anticipated that most would be monolingual. Standard PI risk assessment in the pilot setting included use of the Braden scale. Participating nurses, who provided written informed consent, were asked to assess one patient they were looking after with the pre-final Chinese Mandarin COMHON Index and complete a short questionnaire about instrument ease-of-use and understanding. While written informed consent was obtained by a local researcher, no identifying details or demographic data were collected in written assessment and questionnaire responses, and data analysers were not aware of participant identities. No patient data (except for assessments) were collected. Written instructions were provided with the COMHON Index, directing nurses to circle subscale assessments and document the sum score and corresponding risk level. The pilot study questionnaire, which comprised questions for the instrument overall and each subscale (Table 1), was then completed.

2.3. Analysis

Translation iterations were reported narratively and summarised in a table. Pilot study data were entered into Microsoft Excel™ for cleaning and checking by two independent individuals, then exported into IBM SPSS™ (version 23) for analysis. Descriptive statistics were used to summarise instrument assessment completion and questionnaire responses. Translations for each subscale were retained where medians ≥ 4 indicated assessment and ease-of-use and understanding was 'easy' to 'very easy'.

Table 1
Pilot study questionnaire: overall instrument questions, subscale questions (presented for 'Level of conciousness' subscale).

OVERALL				
Overall, how easy was it to assess your patient using the COMHON Index?				
(1) Very difficult	(2) Difficult	(3) Medium	(4) Easy	(5) Very easy
How easy was it to calculate your patient's TOTAL score?				
(1) Very difficult	(2) Difficult	(3) Medium	(4) Easy	(5) Very easy
How easy was it to identify your patient's level of pressure injury risk (LOW, MODERATE or HIGH risk)?				
(1) Very difficult	(2) Difficult	(3) Medium	(4) Easy	(5) Very easy
How long did it take you to assess your patient using the COMHON Index?				
(1) 1 to 5 min	(2) 6 to 10 min	(3) 11 to 15 min	(4) Over 15 min	
LEVEL OF CONCIOUSNESS				
How easy was it to assess your patient using the **LEVEL OF CONCIOUSNESS** section?				
(1) Very difficult	(2) Difficult	(3) Medium	(4) Easy	(5) Very easy
How easy were the **LEVEL OF CONCIOUSNESS** definitions to understand?				
(1) Very difficult	(2) Difficult	(3) Medium	(4) Easy	(5) Very easy
Were there any areas of the **LEVEL OF CONCIOUSNESS** section that were difficult to understand?				
(1) No				
(2) Yes: please describe:				

3. Results

3.1. Translators

The three forward-translators were all native to China, with fluent English language skills. Two were ICU nurses (two- and nine-years' practice) currently working within a Chinese ICU, one of whom was an investigator. The third, also an investigator, coordinated the forward-translation and was an accomplished nursing and health researcher with a nursing doctorate.

Difficulty was experienced in identifying translators who were native English- and secondary Chinese Mandarin-speakers. Thus, the two back-translators were native to China but based in Australia. One was a nurse with over ten years' ICU experience in Australia, and previous experience as a theatre nurse within a Chinese hospital. The second had been residing in Australia for over six years and practicing as a perioperative nurse for over one year. Both completed undergraduate nursing qualifications in English.

3.2. Iterations

Three iterations between translation steps 1 to 3 achieved successful translation of the majority of tool items. The first iteration resulted in five phrases being fed back to the forward-translators for amendment, and the second resulted in two (Table 2; Appendix B). Over the first three iterations, three items requiring clarification or amendment by the tool developer were noted. Subsequently, two sets of amendments were made to the source instrument, and Version 2 of the COMHON Index was established. The amendments to the source instrument were followed by forward- and back-translation iterations (iterations four and five), in which there were no disagreements. Following the fifth iteration, the translation was deemed equivalent, and a 'pre-final' translation was established.

3.3. Items of equivalence [35]

Some English words or phrases did not have identically matched Chinese Mandarin characters (vocabulary equivalence), and some differences in linguistic and cultural translations (experiential equivalence) and different word or phrase meanings between languages (conceptual equivalence) were noted. This was evident in Iteration one, where there was disagreement between back-translators on the translation of two phrases (Table 2). Grammar and syntax are also vastly different between the languages (grammatical-syntactical equivalence). These challenges were overcome through identification and selection of the closest matching Mandarin characters (forward-translation), validation of the selection (back-translation) and subsequent consensus via iterations. No idioms (idiomatic equivalence) were identified.

3.4. Pilot results

Twenty nurses participated in the pilot study in September 2021. The results are presented in Table 3.

3.4.1. Scoring

The COMHON Index subscale scoring was documented in most cases (16/20, 80%), as was a sum score (19/20, 95%) and risk level (16/20, 80%). Of the 16 assessments with subscale scoring, sum score was totalled incorrectly in three cases. There were 16 assessments which had a sum score and a risk level documented, of

Table 2a
Iteration disagreements and instrument changes (iterations one and two).

Iteration	Source	Forward-translation	Back-translation
Iteration one	agitated, restless	烦躁，不安	烦躁 – agitated or restless [a] 不安 – restless or anxious [a]
	agitated/restless	烦躁/不安	烦躁 – agitated or restless [a] 不安 – restless or anxious [a]
	mechanical support	通气	mechanical ventilation
	cardiopulmonary mechanical support	机械通气支撑	mechanical ventilation support
	The patient is aware	意识	The patient is conscious
Iteration two	mechanical support	机械通气辅助	mechanical ventilation assistance/support
	cardiopulmonary mechanical support	机械通气辅助	mechanical ventilation assistance/support

Note: [a] Disagreement between back-translators.

Table 2b
Iteration disagreements and instrument changes (iterations three to five).

Iteration or instrument change	Original	Updated
Iteration three	Nil disagreement	
Changes to source *(English COMHON Index)*	*2. Agitated/restless/confused: RASS > 1* The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score **14.** *3. Sedated but responsive: RASS −1 to −3* **The patient is comatose with Glasgow Coma Score 9 to 13 or sedated** with RASS −1 to −3. Agitated, restless, confused (RASS > 1) (Glasgow **14**) Sedated but responsive (RASS −1 to −3) (Glasgow **9**–**13**) *1. No haemodynamic support* The patient does not require **vasoactive** drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).	*2. Agitated/restless/confused: RASS > 1* The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score **13 to 14.** *3. Sedated but responsive: RASS −1 to −3* **The patient has a Glasgow Coma Score of 9 to 12 or is** sedated with RASS −1 to −3. Agitated, restless, confused (RASS > 1) (Glasgow **13**–**14**) Sedated but responsive (RASS −1 to −3) (Glasgow **9**–**12**) *1. No haemodynamic support* The patient does not require **vasopressor** drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).
Iteration four	Nil disagreement	
Changes to source *(English COMHON Index, now Version 2)*	Awake and alert (RASS **0**–**1**) (Glasgow 15)	Awake and alert (RASS **0, + 1**) (Glasgow 15) Addition of 'Version 2, 2021' to footer of tool
Iteration five	Nil disagreement	

which all were correctly converted. However, two were based on incorrectly tallied sum scores, with one converting to a different risk level when the sum score was calculated correctly.

3.4.2. Ease-of-use and understanding

Nurses indicated that overall assessment, sum score calculation and risk level conversion were easy to very easy ($\geq$ 90% rating 4 and above). The majority (16/20, 80%) found the assessment took $\leq$ 5 min to complete.

All subscales had a median of $\geq$ 4 for both ease-of-use and ease-of-understanding. The level of consciousness subscale had the widest range for both (1–5), but the majority of ratings were $\geq$ 4 ($\geq$ 80%). Ease-of-understanding for the haemodynamic subscale was the only item which less than 80% of nurses rated as $\geq$ 4 (75%), but the median was 4.5. Only two nurses indicated a subscale aspect that was difficult to understand (haemodynamic, nutrition) (Table 3).

3.5. Final instrument

All subscales achieved medians of $\geq$ 4 in piloting, and the translation was finalised. While the COMHON Index did not previously contain directions to circle subscale assessments and document sum score and risk level, these were included on the pilot study assessment form. However, not all nurses documented these. The directions were retained, but enhanced (enlarged, coloured, centered), and added to Version 2.1 of the Spanish, English (Fig. 1), and Chinese Mandarin (Fig. 2) COMHON Index.

4. Discussion

4.1. Translation approach

A rigorous and replicable approach to instrument translation has been presented. While the lack of consensus on the best approach to instrument [27] and self-report questionnaire [30] translation and adaption remains, it was feasible and appropriate to select and adapt the best approach relative to the research requirements of this translation. For example, we adapted the approach of Cha et al. [26] based on the supporting literature to include two back-translators rather than one. This proved useful to identify errors and establish equivalence, such as where the back-translators disagreed on a translation in the first iteration. Moreover, it provided additional insight into equivalence; one back-translator provided more of a clinical interpretation, as opposed to the more literal translation of the other.

4.2. Reporting of instrument translation

There have been calls for more detailed reporting of translations [27] and for cultural adaptions and validation be reported separately to enable adequate and explicit detail [25]. Yet, it would seem that the uptake of these recommendations has been limited, with many reports providing only a very brief translation summary against larger psychometric testing or instrument use. Subsequently, translation equivalence and quality cannot be verified, and data obtained using the translated instrument may be inaccurate. Thus, it is imperative that further focus is put on the translation process and its reporting in future research. This report provides an exemplar of the level of detail required to adequately report an instrument translation, while also providing an audit trail. As such, it should be of benefit for future translation studies.

4.3. The Chinese Mandarin COMHON Index

In terms of the instrument itself, a Chinese Mandarin version of the COMHON Index equivalent to the source version has been produced. Of importance is that the pilot study results indicated that nurses found the instrument easy-to-use and understand, particularly given that pilot study participants were unfamiliar with the COMHON Index and received no prior education in its use or meanings. This is in contrast to some concerns voiced for other general PI risk assessment tools, such as ambiguity, and confusing or unclear definitions [38,39]. Furthermore, the majority of nurses indicated that COMHON Index assessment was relatively fast to complete ($\leq$ 5 min), although a few nurses did not fully document subscale assessments, sum scores or risk level. While instructions and sections for documenting these details were amended across

Table 3
Pilot study results ($n = 20$).

Overall ease-of-use			
Question		***Median* (range)**	**Ratings ≥ 4, *n***
Overall, how easy was it to assess your patient using the COMHON Index?		4 (3–5)	18
How easy was it to calculate your patient's TOTAL score?		5 (3–5)	18
How easy was it to identify your patient's level of pressure injury risk (LOW, MODERATE or HIGH risk)?		4 (3–5)	19
Time to complete			
Question		**Time in minutes**	***n***
How long did it take you to assess your patient using the COMHON Index?		1–5 min	16
		6–10 min	1
		11–15 min	1
		Over 15 min	2
Subscale ease-of-use			
Question	**Subscale**	***Median* (*range*)**	**Ratings ≥ 4, *n***
How easy was it to assess your patient using the [SUBSCALE] section?	Level of consciousness	4 (1–5)	18
	Mobility	4 (3–5)	19
	Haemodynamic	4.5 (3–5)	16
	Oxygenation	4.5 (3–5)	18
	Nutrition	4 (2–5)	18
How easy were the [SUBSCALE] definitions to understand?	Level of consciousness	4 (1–5)	16
	Mobility	4 (3–5)	19
	Haemodynamic	4.5 (2–5)	15
	Oxygenation	4.5 (3–5)	17
	Nutrition	4 (2–5)	19
Subscale difficulty			
Question	**Subscale**	**Answer**	***n*** **Comment**
Were there any areas of the [SUBSCALE] section that were difficult to understand?	Level of consciousness	No	20 –
	Mobility	No	20 –
	Haemodynamic	No	18
		Yes	1 intra-aortic balloon pump
		Missing	1
	Oxygenation	No	20 –
	Nutrition	No	19 For intensive care patients, we cannot estimate their body weight, and cannot assess their gastrointestinal function due to dysfunction of consciousness
		Yes	1

COMHON Index language versions (Version 2.1) following piloting, the provision of further education may be beneficial to improve COMHON Index completion and other PI risk assessment and documentation in general.

The cross-cultural generation of an easy-to-use, ICU-specific PI risk assessment tool in a widely used language is of significance. However, prior to use, the instrument requires further rigorous psychometric testing [26,33]. In particular, interrater reliability and agreement testing is warranted, given that individuals may be assessed for PI risk by multiple clinicians regularly within clinical practice, and there is a need for risk to be measured consistently among clinicians [16]. Subsequently, such testing is already underway. It is also important to note that PI risk assessment itself is not preventative, but that PI preventative interventions must be put in place relative to identified risk.

4.4. Limitations

It has been recommended that back-translators be blinded to the original instrument [29,32,33]. However, in this study, one back-translator identified the English instrument online, which may have influenced their translation. Criteria for retaining translations was also not defined until data analysis preparation, potentially introducing some bias. For future translations, implementing steps to address these limitations (i.e. ensuring blinding, *a priori* criteria specification) would enhance rigour.

Finally, piloting was undertaken in a convenience sample of nurses who were likely monolingual Chinese Mandarin speakers, although some may have been bilingual. Additional testing with bilinguists to compare the target and source language instruments may have provided further insight [27]. However, difficulties with the large resourcing requirements of such testing have been acknowledged [27,29] and the sampling undertaken was representative of the intended population and congruent with the intended approach [26]. While the pilot study sample size was small ($n = 20$ in one ICU) and generalizability is subsequently limited, it was appropriate for pre-testing an instrument in the context of translation. Beyond translation, any further psychometric testing should be adequately powered.

5. Conclusion

Overall, a Chinese Mandarin version of the COMHON Index has been produced following a rigorous and comprehensive translation approach. This paper provides an exemplar of the level of detail required to adequately report an instrument translation. The

The COMHON Index (RASS = Richmond Agitation Sedation Scale)

Please circle the most appropriate sections of the chart below:

Score	Level of consciousness	Mobility	Haemodynamic	Oxygenation	Nutrition
1	Awake and alert (RASS 0, + 1) (Glasgow 15)	Independent, walking with help	No haemodynamic support	Spontaneous breathing and $FiO_2 < 0.4$	Full oral diet
2	Agitated, restless, confused (RASS > 1) (Glasgow 13 – 14)	Limited, bed-chair activity	Volume expanders	Spontaneous breathing and $FiO_2 \geq 0.4$	Enteral or parenteral feeding
3	Sedated but responsive (RASS −1 to −3) (Glasgow 9 – 12)	Very limited but tolerates position change	Dopamine or norepinephrine or adrenaline. Mechanical support	Non-invasive mechanical ventilation	Oral fluids. Incomplete oral feeding
4	Coma, sedated and unresponsive (RASS < −3) (Glasgow < 9)	Unable to change position; lying prone	Needing two of the above	Invasive mechanical ventilation	No feeding

LOW RISK: 5 – 9, MODERATE RISK: 10 – 13, HIGH RISK: 14 – 20

TOTAL PATIENT SCORE = ☐ **RISK LEVEL =** ☐

SUBSCALE DEFINITIONS

Level of consciousness

1. ***Awake and alert: RASS 0 to + 1***
   The patient is conscious and orientated to time and space, obeys commands and recognises and responds to any stimulus in their environment. Glasgow Coma Score 15.
2. ***Agitated/restless/confused: RASS > 1***
   The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score 13 to 14.
3. ***Sedated but responsive: RASS −1 to −3***
   The patient has a Glasgow Coma Score of 9 to 12 or is sedated with RASS −1 to −3.
4. ***Coma, sedated and unresponsive: RASS −4 to −5***
   The patient is comatose with Glasgow Coma Score < 9 or sedated with RASS −4 to −5.

Mobility

1. ***Independent/walking with help***
   The patient walks alone or needs a support system to maintain balance.
2. ***Limited/bed-armchair activity***
   The patient is in bed and can move on their own. The patient has alternating periods of bed rest with periods of rest in a chair. The patient can stand up with or without assistance.
3. ***Very limited but tolerates change in position***
   The patient is in bed and cannot move without assistance but can be moved without affecting haemodynamic or respiratory status.
4. ***Unable to change position or lying prone***
   The patient is in bed and must not be moved due to haemodynamic or respiratory instability or the patient is lying in the prone position.

Haemodynamic

1. ***No haemodynamic support***
   The patient does not require vasopressor drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).
2. ***Volume expanders***
   The patient requires use of blood products, colloid or crystalloid to maintain haemodynamic status.
3. ***Dopamine or norepinephrine or adrenaline or cardiopulmonary mechanical support***
   The patient requires one or more of the above drugs by continuous infusion or cardiopulmonary mechanical assistance e.g. intra-aortic balloon pump, extra-corporeal membrane oxygenation, ventricular assist device, to maintain haemodynamic stability.
4. ***Needing two of the above***
   The patient requires two or more of the above supports to maintain haemodynamic stability.

Oxygenation

1. ***Spontaneous breathing and low FiO_2 (<0.4)***
   The patient is breathing by themself and requires no extra oxygen or less then 40%.
2. ***Spontaneous breathing and high FiO_2 (≥0.4)***
   The patient is breathing by themself and requires supplementary oxygen greater than 40%.
3. ***Non-invasive mechanical ventilation***
   The patient requires non-invasive mechanical ventilation.
4. ***Invasive mechanical ventilation***
   The patient requires invasive mechanical ventilation.

Nutrition

1. ***Full oral diet***
   The patient tolerates liquids and solids and is eating enough food to meet their needs.
2. ***Enteral nutrition / parenteral feeding***
   The patient is being fed with parenteral nutrition, enteral nutrition or both and may also be partially eating orally or not eating at all.
3. ***Oral fluids. Incomplete oral feeding***
   The patient has an inadequate or reduced diet that does not meet their needs and is not being enterally or parentally fed.
4. ***No feeding***
   The patient is not being fed at all.

Fig. 1. English COMHON Index Version 2.1.

translation approach used is replicable and recommended (with modifications based on research requirements) for future health-care instrument translation.

Given the global high prevalence of PI in ICU, the generation of a Chinese Mandarin ICU-specific PI risk assessment tool is a significant contribution to international PI prevention knowledge and practice. This study has indicated that the instrument is easy-to-use and understand in the population of interest. However, further psychometric testing, particularly interrater reliability and agreement testing, of the translated instrument is required to validate its use in clinical practice.

COMHON 指数 [RASS = Richmond 躁动镇静量表 (Richmond Agitation Sedation Scale)]

请在下面的图表中圈出最合适的部分：

分值	意识水平	活动能力	血流动力学	血氧	营养
1	清醒和警觉 (RASS 0, + 1) (格拉斯哥评分 15)	独立的，在帮助下行走	无血流动力学支持	自主呼吸和 FiO_2 < 0.4	完全经口饮食
2	烦躁, 不安, 意识混乱 (RASS > 1) (格拉斯哥评分 13~14)	受限制的, 床-椅活动	扩容制剂	自主呼吸和 FiO_2 ≥ 0.4	肠内或肠外喂养
3	镇静 但有反应 (RASS −1 ~ −3) (格拉斯哥评分 9~12)	非常受限但容许体位改变	多巴胺或去甲肾上腺素或肾上腺素。机械辅助	无创机械通气	经口流质，不完全经口喂养
4	昏迷，镇静和无反应 (RASS < −3) (格拉斯哥评分 < 9)	无法改变体位；俯卧	需要以上两种	有创机械通气	禁食

低风险: 5~9; 中风险: 10~13; 高风险: 14~20

患者总分 = ☐ 风险等级 = ☐

分量表定义

意识水平

1. **清醒和警觉: RASS 0 至 +1**
   患者有意识，有时间和空间方向感，服从命令，识别和响应环境中的任何刺激。格拉斯哥昏迷评分 15 分。
2. **烦躁/不安/意识混乱: RASS >1**
   患者清醒，但部分或间歇性地对时间和/或空间失去方向感，对刺激反应不充分。格拉斯哥昏迷评分 13 至 14 分。
3. **镇静但有反应: RASS −1 至−3**
   患者的格拉斯哥昏迷评分 9 至 12 分，或镇静 RASS −1 至 −3。
4. **昏迷，镇静和无反应: RASS −4 至−5**
   患者昏迷，格拉斯哥昏迷评分<9 分，或镇静 RASS −4 至 −5。

活动能力

1. **独立/在帮助下行走**
   患者独立行走或需要支持系统来保持平衡。
2. **受限制的/床-椅活动**
   患者在床上，可以自己移动。患者在椅子上休息的时间和在床上休息时间交替。患者在有协助和无协助下，均可站立。
3. **非常受限但容许体位改变**
   患者躺在床上，没有协助不能移动，但可以在不影响血流动力学或呼吸状态的情况下移动。
4. **无法改变体位或者俯卧**
   患者躺在床上，因血流动力学或呼吸不稳定而严禁移动，或患者俯卧位。

血流动力学

1. **无血流动力学支持**
   患者不需要血管升压药物或血浆扩容制剂或机械血流动力学支持（如主动脉内球囊泵）。
2. **扩容制剂**
   患者需要使用血液制品、胶体或晶体溶液来维持血流动力学状态。
3. **多巴胺或去甲肾上腺素或肾上腺素或心肺机械辅助**
   患者需要通过持续输注以上的一种或更多的药物或心肺机械辅助，如主动脉内球囊泵、体外膜氧合、心室辅助装置，来维持血流动力学稳定性。
4. **需要以上两种**
   患者需要两个或更多的上述支持，以维持血流动力学的稳定性。

血氧

1. **自主呼吸和低 FiO2 (<0.4)**
   患者自主呼吸，不需要额外的吸氧或少于 40%。
2. **自主呼吸和高 FiO_2 (≥0.4)**
   患者自主呼吸，需要大于 40%的额外吸氧。
3. **无创机械通气**
   患者需要无创机械通气。
4. **有创机械通气**
   患者需要有创机械通气。

营养

1. **完全经口饮食**
   患者能进食液体和固体食物，并且吃了足够的食物来满足他们的需要。
2. **肠内营养/肠外喂养**
   患者正在接受肠外营养、肠内营养或两者兼有，也可能部分经口进食或完全不经口进食。
3. **经口流质，不完全经口喂养**
   患者不足或减少饮食且未满足他们的需要，以及没有进行肠内或肠内喂养。
4. **禁食**
   患者被禁食。

版本 2.1, 2021

Fig. 2. Chinese Mandarin COMHON Index Version 2.1.

CRediT authorship contribution statement

Josephine Lovegrove: Conceptualization, Methodology, Validation, Formal analysis, Resources, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualisation, Project administration, Funding acquisition. **Paul Fulbrook:** Conceptualization, Methodology, Validation, Investigation, Resources, Writing – review & editing, Supervision, Funding

acquisition. **Sandra Miles:** Conceptualization, Methodology, Validation, Investigation, Writing – review & editing, Supervision. **Michael Steele:** Conceptualization, Methodology, Validation, Investigation, Writing – review & editing, Supervision. **Xian-Liang Liu:** Validation, Investigation, Resources, Writing – review & editing, Project administration. **Lin Zhang:** Investigation, Resources, Writing – review & editing, Project administration. **Angel Cobos Vargas:** Conceptualization, Resources, Writing – review & editing.

Declaration of competing interest

The authors have declared no conflict of interest.

Funding

This work was supported in part by a PhD scholarship awarded to the first author by The Prince Charles Hospital Foundation [grant number PhD2019-01]. The funding source had no role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

Data availability statement

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Acknowledgments

We acknowledge and sincerely thank the following contributors: Associate Professor Frances Lin for her assistance with identifying back-translators; Li Zeng for her efforts in forward-translation and data collection; Ying (Maggie) Gao and Yichen (Annie) Wang for their efforts in back-translation; and the pilot study hospital, intensive care unit and the participating nurses for their contribution.

Appendices. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnss.2022.03.003.

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10.2 Conclusion

This chapter has presented the instrument translation undertaken in Phase Three. In this chapter, a Chinese Mandarin version of the COMHON Index has been produced, to in part address the research objective *to translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale*. To fully address this research objective, the next chapter (Eleven) presents the concurrent validity testing of the translated instrument.

Chapter Eleven: Concurrent validity of the Chinese Mandarin COMHON Index

11.1 Introduction

In Phase Three, instrument translation and testing were conducted to address the research objective *to translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale*. This was needed given that Chinese Mandarin is a widely spoken language (Eberhard *et al.*, 2022), and the minimum PI preventative intervention set developed in Phase Two requires international testing.

Phase Three comprised two parts; the instrument translation, and concurrent validity testing. The previous chapter (Ten) presented the formal translation of the instrument. This chapter details the results of the concurrent validity testing of the Chinese Mandarin COMHON Index (Version 2.1, Appendix H) against the Chinese Mandarin Braden scale (Appendix L), and a brief discussion of the results. The methodology and methods of the concurrent validity testing were described in full in Chapter Nine. Access to and use of non-identifiable retrospective data for concurrent validity testing was approved by the Australian Catholic University Human Research Ethics Committee (2022-2704N, Appendix K).

11.2 Results

11.2.1 Sample

A total of 80 paired patient assessments (*n* = 1 COMHON Index assessment and *n* = 1 Braden scale risk assessment for each of *n* = 80 patients), conducted by four nurses, were included in the concurrent validity testing dataset for analysis.

11.2.2 Assessment completion

Of the COMHON Index assessments, one (1.25%) was missing the majority of subscale assessments, a documented sum score and a documented risk category, with only the nutrition subscale assessment assessed. Thus, only 79 assessments were available in the concurrent validity and agreement analyses. The documented sum scores of four other assessments (5%), based on documented subscale assessments, were incorrect, with one of those subsequently resulting in an incorrectly documented risk category.

Of the Braden scale assessments, five (6.25%) had an incorrect sum score documented, from which four (5%) also had an incorrect risk category documented. One further assessment (1.25%) did not have a sum score while two risk categories were documented, but subscale assessments were fully documented.

During analysis, it was noted that the Chinese Mandarin Braden scale (Appendix L) contained an error. One subscale assessment was incorrectly numbered for scoring. While the subscale should comprise (1) very poor, (2) probably inadequate, (3) adequate, and (4) excellent, the third option was listed as (2) adequate. However, the option was placed in the correct column, which indicates all subscale options in said column are scored as 3. A visual example is provided in Table 11.1.

Table 11.1: Braden scale error

	1 point	**2 point**	**3 point**	**4 point**
Subscale	1 Subscale rating criteria:	2 Subscale rating criteria:	3 Subscale rating criteria:	4 Subscale rating criteria:
Subscale	1 Subscale rating criteria:	2 Subscale rating criteria:	3 Subscale rating criteria:	4 Subscale rating criteria:
Subscale	1 Subscale rating criteria:	2 Subscale rating criteria:	2* Subscale rating criteria:	4 Subscale rating criteria:
*Incorrect score within scale				

Six assessments (7.5%) comprised an assessment using this subscale subcategory, but four of six (66.67%) had correctly documented sum scores and risk levels, nonetheless.

For the purposes of concurrent validity testing, corrected sum scores and risk levels (based on the

documented subscale assessments) were used in the analysis henceforth.

11.2.3 Level of risk

Based on the COMHON Index assessments, the mean sum score was 12.15 (SD 2.64), which corresponds to a risk category of moderate risk. The median sum score was 12 (range 6 to 16).

The mean sum score of the Braden scale assessments was 12.25 (SD 1.69), which is equal to a risk category of high risk. The median sum score was 12 (range 8 to 15).

The proportions of patients assessed to be at each level of risk for both instruments are presented in Table 11.2. More patients were assessed to be at high and very high risk using the Braden scale (60%, respectively), compared to the COMHON Index (high risk 38%). Conversely, more patients were assessed to be at low and moderate risk of PI using the COMHON Index (62%), than the Braden scale (40.1%).

Table 11.2: Risk category proportions

Instrument	**Risk category**	***n* (%)**
COMHON Index*	Low risk	15 (19%)
	Moderate risk	34 (43%)
	High risk	30 (38%)
Braden scale	Not at risk	0 (0%)
	Mild risk	7 (8.8%)
	Moderate risk	25 (31.3%)
	High risk	46 (57.5%)
	Very high risk	2 (2.5%)
*Missing value *n* = 1		

11.2.4 Concurrent validity

11.2.4.1 Sum score correlation

Pearson Product Moment Correlation was used to investigate the relationship between the sum scores of the COMHON Index and Braden scale assessments of each patient. Preliminary analyses were conducted to ensure no violation of the assumption of normality and linearity (Pallant, 2020); with a scatterplot (Figure 11.1) indicating a linear, although widely spread, relationship between the data. The case with missing data (i.e. the one COMHON Index assessment with missing subscale assessments, sum score and risk level) was excluded pairwise. There was a strong (large correlation $r > 0.5$; Cohen, 1977; see sections 9.4.3.4.1 and 9.5.7, pp. 186-187, 190-191), significant negative relationship between the two variables, $r = -0.67$, $n = 79$, $p = <0.001$, with higher COMHON Index sum

scores associated with lower Braden scale sum scores. A negative relationship was anticipated due to the reverse scoring of the Braden scale (see section 9.5.7, pp. 190-191; Fulbrook & Anderson, 2016), with higher COMHON Index sum scores and lower Braden scale sum scores indicating higher risk.

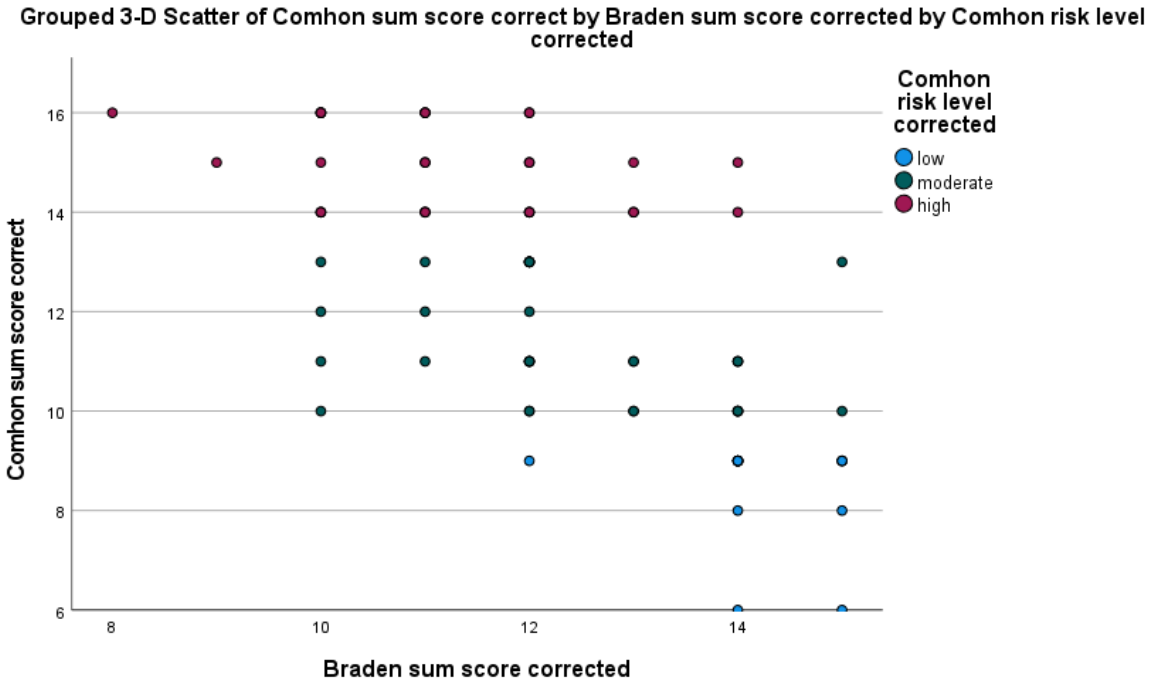

Figure 11.1: Sum score correlation scatterplot

11.2.4.2 Subscale correlations

Relationships between instrument subscales which were similar (COMHON and Braden mobility subscales, COMHON level of consciousness and Braden sensory perception subscales, COMHON and Braden nutrition subscales) were investigated using Spearman's rho.

There was a strong, significant negative correlation between the COMHON Index level of consciousness subscale and the Braden scale sensory perception subscale (r = -0.64, n = 79, p < 0.001).

The correlation between the COMHON Index and Braden scale mobility subscales was significant, but small (r < 0.30; Cohen, 1977; see sections 9.4.3.4.1 and 9.5.7, 178-179, 181-182) in a negative direction (r = -0.28, n = 79, p = 0.014).

The correlation between the instrument nutrition subscales was insignificant, lower than the definition of a 'small' correlation (r < 0.30; Cohen, 1977; see sections 9.4.3.4.1 and 9.5.7, pp. 186-187, 190-191) and in a positive direction (r = 0.07, n = 80, p = 0.517).

11.2.5 Level of agreement

11.2.5.1 Overall level of agreement

To measure the level of agreement between the two instruments in terms of risk categorisation, the risk levels of the Braden scale were grouped to match the COMHON Index (see sections 9.4.3.4.2 and 9.5.7, pp. 187-188, 190-191; Braden not at risk and mild risk = COMHON Index low risk; Braden moderate risk = COMHON Index moderate risk; Braden high and very high risk = COMHON Index high risk). Level of agreement for risk categorisation overall was measured using Cohen's kappa, which indicated there was a fair level of agreement (k = 0.23; Landis & Koch, 1977; see sections 9.4.3.4.2 and 9.5.7, pp. 187-188, 190-191), which was significant (p = 0.005).

11.2.5.2 Level of agreement for ordered risk categories

The proportions of cross-categorisation of patient risk by instrument is detailed in Table 11.3. The largest proportion of agreement was for categorisation of patients at high risk (83.3%). One patient was assessed as being at low risk of PI using the COMHON Index, but at high risk of PI using the Braden scale.

Table 11.3: Cross-categorisation of pressure injury risk between instruments

		COMHON Index			Total
		Low risk	**Moderate risk**	**High risk**	
Braden scale	**Low risk**	5 (33.3%)	2 (5.9%)	0 (0%)	7 (8.9%)
	Moderate risk	9 (60.0%)	11 (32.4%)	5 (16.7%)	25 (31.6%)
	High risk	1 (6.7%)	21 (61.8%)	25 (83.3%)	47 (59.5%)
Total		15 (100%)	34 (100%)	30 (100%)	79 (100%)

Cohen's weighted kappa was used to measure level of agreement between the two instruments in the context of risk levels being 'ordered' (refer to section 9.4.3.4.2, pp. 187-188). The level of agreement was fair (k = 0.36; Landis & Koch, 1977; see sections 9.4.3.4.2 and 9.5.7, pp. 187-188, 190-191) and was significant ($p < 0.001$).

11.3 Discussion

11.3.1 Concurrent validity

Overall, there was a strong correlation between the sum scores of the Chinese Mandarin COMHON Index and the Braden scale (r = -0.67, $p < 0.001$); thus, the relationship was convergent. The results are similar to those of Fulbrook and Anderson (2016), who tested the interrater reliability of the original English COMHON Index and its convergent validity with the Braden, Norton and Waterlow scales in an Australian intensive care unit. The English COMHON Index was strongly correlated with

the Braden (r = -0.70, p < 0.001) and Norton (r = -0.66, p < 0.001) scales but not the Waterlow (r = 0.10, p = 0.25). While the study of Fulbrook and Anderson (2016) differed in that five nurses conducted PI risk assessments on each patient using four different scales, both sets of results suggest that the Chinese Mandarin and English COMHON Index versions measure the same construct as the Braden scale (i.e. PI risk). This is significant given that the Braden scale is an established measure of this construct which is widely used and tested globally.

Of interest, however, were the different correlations observed for compared subscales. Only one subscale demonstrated a strong and significant correlation between the two instruments: the COMHON Index level of consciousness and Braden sensory perception subscales (r = -0.64, p < 0.001), which was congruent with Fulbrook and Anderson's (2016) comparison of the same subscales (r = -0.80, p < 0.001). This may be unsurprising given the anecdotal similarities between the two subscales and their strong relevance to intensive care patients. However, the remaining two subscales compared between the instruments (mobility and nutrition) were found to have small correlations (mobility r = -0.28, p = 0.014; nutrition r = 0.07, p = 0.517), one of which (nutrition) was not significant. Furthermore, the correlation between the COMHON Index and Braden nutrition subscales was in a positive direction, which may suggest disagreement given that the respective scales scoring systems are reversed (refer to section 9.5.7, 181-182). Conversely, Fulbrook and Anderson found that both of these subscales were significantly correlated between the COMHON Index and the Braden, although the correlation coefficient was less (mobility r = -0.63, p < 0.001; mobility r = -0.63, p < 0.001; nutrition r = -0.46, p < 0.001).

While the subscales are theoretically measuring the same domains within a larger overall scale, the lower correlations between the mobility and nutrition subscales may be symptomatic of the population for which the instruments are intended for use. In other words, the mobility and nutrition subscales of the COMHON Index may be more closely aligned with intensive care specific factors within these domains, as opposed to the more general focus of the Braden. Alternatively, it may be contended that perhaps nurses did not fully understand or correctly assess these subscales in one of the instruments, and in this case, the COMHON Index is the new, experimental instrument, while the Braden scale was routinely used in the study setting. However, the pilot testing of the COMHON Index would suggest otherwise, with nurses indicating both subscales were easy to use and understand (Lovegrove, Fulbrook, Miles, Steele, Liu *et al.*, 2022; Chapter Ten). Thus, it would seem more likely that the lower correlations are attributable to the intensive care-specification of the COMHON Index, and in line with one of the resounding themes highlighted in this thesis, supports the use of setting-specific risk assessment scales in the intensive care setting.

11.3.2 Risk categorisation and level of agreement

The categorisation of risk by the two compared instruments and level of agreement provides further

support to the assertion that PI risk assessment should be setting specific. The initial testing of the original Spanish COMHON Index suggested that agreement with the Braden scale was substantial (k = 0.74-0.81; Cobos Vargas *et al.*, 2013). However, it was unclear how the differing risk categories of the two instruments were matched to measure agreement in the Spanish testing. In this analysis, when the Braden risk categories were converted to match those of the COMHON, agreement was found to be 'fair' (k = 0.23, p = 0.005) which is at the lower end of the spectrum in terms of level of agreement. More patients were assessed to be at high and very high risk using the Braden scale (60%), compared to the COMHON Index (high risk 38%), while more patients were assessed to be at low and moderate risk of PI using the COMHON (62%) than the Braden (40.1%). While the Braden scale was the 'established' instrument in this study, that does not necessarily mean that its assessments are correct, or more accurate than that of the COMHON Index. Indeed, *all* intensive care patients may be at some level of PI risk (Lovegrove, Fulbrook, Miles & Steele, 2022), particularly higher risk (Fulbrook & Anderson, 2016), and it has been contended that is far better to over- rather than under-estimate risk (Lovegrove, Ven *et al.*, 2021). However, Richardson and Barrow (2015a) noted that most critically ill individuals have low Braden scale scores (which corresponds to higher PI risk), and conjected that this indicates that the Braden scale is not able to detect varying levels of PI risk within these vulnerable individuals. Furthermore, Fulbrook and Anderson (2016) found that, through calculation of measures of importance (minimally important change and minimally detectable change), the COMHON Index and Norton scale may be more sensitive to small changes in patient condition (and thus PI risk level) than the Braden and Waterlow. Overall, it would seem likely that the trend in which the Braden categorised patients at higher PI risk than the COMHON may again be symptomatic of the intensive care-specification of the COMHON Index, in that it is able to better able to measure varying levels of PI risk within this highly vulnerable population.

11.3.3 Instrument completion

The proportions of COMHON Index and Braden scale assessments which contained missing or incorrect data (subscale assessments and/or documented sum scores/risk levels) was comparable. In the context of the Braden scale, this was despite it being in routine use in the study setting and nurses thus having familiarity with the instrument. However, a minor error in the Braden scale (detailed in section 11.2.2, p. 206) was noted during analysis that had the potential to influence scoring. Nonetheless, the majority of assessments which may have been influenced by the error were summed correctly. A representative for the study setting has since been notified of the error to enable correction, meaning this analysis has already had a positive impact on practice.

The completion rates of the COMHON Index assessments were not only comparable to that of the Braden, but also to that of the pilot testing conducted for the formal translation of the instrument (Lovegrove, Fulbrook, Miles, Steele, Liu *et al.*, 2022; Chapter Ten). This suggests that the

enhancements of directions prompting sum scoring and risk level categorisation on Version 2.1 of the Chinese Mandarin COMHON Index do not ensure full completion alone. A recommendation following pilot testing and finalisation of the translation was for the provision of further education to improve COMHON Index and other PI risk assessment and documentation completion, which is certainly warranted given the completion rates of assessments in this analysis.

11.3.4 Other psychometric testing

This analysis has established the concurrent validity of the COMHON Index against the widely used Braden scale. However, reliability testing should in fact come before validity because reliability represents the consistency of a measurement, or conversely, the level of error which may be present in a measurement (Pittman & Bakas, 2010). Alternatively, validity demonstrates whether an instrument is measuring the intended concept (Pittman & Bakas, 2010). This is to say that an instrument may be reliable while not valid, but overall validity cannot be established without reliability (Pittman & Bakas, 2010).

In terms of Phase Three and the Mandarin COMHON Index, interrater reliability and agreement would be the most important measure, as individuals may be assessed for PI risk using the Mandarin COMHON Index by multiple differing clinicians on a regular basis within standard clinical practice (Fulbrook & Anderson, 2016; Kottner *et al.*, 2014). Thus, it is imperative that PI risk is measured consistently among clinicians to ensure accurate assessment and continuity of care. ***Subsequently, it is important to note that the testing performed in Phase Three, following formal translation, was initially intended to be interrater reliability and agreement and concurrent validity testing.*** In fact, ethical approval for a full interrater reliability study, in combination with the instrument translation and pilot testing, was sought and granted from the Human Research Ethics Committee of Australian Catholic University (2021-17H; Appendix I) and the relevant hospital Human Research Ethics Committee of the Tenth People's Hospital of Tongji University (SHSY-IEC-4.1/20-258/01; Appendix J). Study set up had progressed, and data collection was ready to commence. Unfortunately, data collection was then interrupted, and as previously noted (section 9.4.3.3, page 180), it was no longer feasible to perform the required data collection due to COVID-19 disruptions to cities, hospitals and research within China. Further detail of the impacts of COVID-19 on this program of research, and Phase Three in particular, is provided in Chapter Twelve (section 12.6, pp. 232-233). Therefore, the psychometric testing component of Phase Three evolved into focusing on concurrent validity alone using retrospective data; and has nonetheless provided valuable insight into the properties of the Chinese Mandarin COMHON Index. When once again feasible, there is an intention to conduct the initially planned and approved interrater reliability and agreement component as a postdoctoral study.

11.4 Conclusion

This chapter has presented the Phase Three concurrent validity analysis of the Chinese Mandarin COMHON Index against the widely used Braden scale. While this component of the program of research was initially intended to also include interrater reliability and agreement testing, this was prevented by the impacts of COVID-19 (as detailed in Chapter Twelve, section 12.6, pp. 232-233). Nonetheless, the concurrent validity analysis has demonstrated that the Chinese Mandarin COMHON Index was strongly correlated to the Braden scale, suggesting they measure the same construct, which is significant. Furthermore, the results of this analysis have suggested that there are variations in the two instruments, which is likely due to the intensive care-specification of the COMHON Index, and supports the use of setting-specific risk assessment scales in intensive care. This analysis has laid a foundation for further psychometric testing of the Chinese Mandarin COMHON Index, namely interrater reliability testing, which is required prior to implementation into practice and is now intended to be undertaken as a postdoctoral study.

The combined completion of the formal translation of the instrument (Chapter Ten) and the concurrent validity testing (Chapter Eleven) has addressed the research objective *to translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale* and brings Part Three of this thesis to a close.

The next part of this thesis (Part Four) presents a synthesised discussion of the results from the overall program of research, relates these results to the wider evidence-base, highlights the strengths and limitations of the program of research, and concludes with recommendations for future practice.

PART FOUR: DISCUSSION AND CONCLUSION

Chapter Twelve: Discussion and Conclusion

12.1 Introduction

This thesis has presented a rigorous program of research which has answered the overarching research question "*What interventions should be applied relative to the level of PI risk for critically ill patients, as determined by an intensive care-specific risk assessment scale (the COMHON Index), and as part of a minimum set of PI preventative interventions for international use within intensive care units?*". The program of research comprised three phases, with each phase having its own associated overarching objective. Phase One was a systematic review and meta-analysis undertaken to determine which PI preventative have demonstrated effectiveness in acute hospital and intensive care settings in randomised controlled trials. Phase Two was a modified Delphi study conducted to establish which of those effective PI preventative interventions identified in Phase One should be implemented for each COMHON Index level of risk in intensive care patients (thus establishing a minimum set of preventative interventions for application relative to risk level). Finally, in Phase Three, the COMHON Index was translated into Chinese Mandarin and tested for concurrent validity, to enable international testing of the minimum intervention set developed in Phase Two. This chapter now presents a discussion of the overall program of research and the recommendations and conclusion drawn from the results.

12.2 Discussion

In addition to the individual discussions presented for each phase of this program of research, this discussion relates the overall program of research and its three phases to the current, wider evidence-base in the context of the overarching research question. Specifically, it discusses the higher-level evidence underpinning the minimum PI preventative intervention set, the inclusion of interventions, evidence supporting the use of PI preventative intervention sets, and most importantly, the risk-stratification of the intervention set developed by this research and its significance. The strengths and limitations of the overall program of research, in addition to those identified previously in each separate phase, are also detailed, along with recommendations for future practice and research.

12.2.1 High-level evidence underpinning the minimum pressure injury preventative intervention set

The systematic review and meta-analysis undertaken in Phase One was separated into two separate syntheses; an acute hospital setting synthesis (Lovegrove *et al.*, 2021) and an intensive care setting synthesis (Lovegrove, Fulbrook, Miles & Steele, 2022). While this program of research was aimed at establishing a minimum intervention set for use in intensive care, it was necessary to also include an acute hospital setting synthesis. This was due to the results of previous reviews indicating that the high-level evidence demonstrating the effectiveness of individual PI preventative interventions was limited (Alshahrani *et al.*, 2021; Tayyib & Coyer, 2016). It was also appropriate as the underlying mechanism of action of an intervention may be the same across populations. Indeed, the current international guideline specifies that most of their recommendations "are relevant to all individuals with or at risk of pressure injuries", although some individuals have specific PI prevention needs "due to their clinical condition, age or care setting" (EPUAP *et al.*, 2019, p. 28). Nonetheless, it was also necessary to separate the systematic review syntheses by setting given the inherent differences between the two populations (Coyer *et al.*, 2017); thus, allowing for close examination of intervention effectiveness within the populations of interest and better guidance for future setting-specific intervention use.

The syntheses were further broken down by analysis type; specifically, intention-to-treat versus per-protocol analysis. An intention-to-treat analysis involves analysing participants in the study group (control or intervention) to which they were allocated, regardless of lack of protocol adherence, follow up losses, or other reasons for attrition (Abraha *et al.*, 2017; Elkins & Moseley, 2015; Gewandter *et al.*, 2014; McCoy, 2017; Ranganathan *et al.*, 2016). This is more representative of real-world practice and non-concordance with correct intervention use (Elkins & Moseley, 2015; McCoy, 2017; Ranganathan *et al.*, 2016). If a per-protocol analysis is performed and following protocol violations the control participants who received the intervention were switched to the intervention group, and conversely

the intervention group participants who did not receive the intervention were switched to the control group, bias would be introduced and the results would not be pragmatically representative, but instead would reflect 'true efficacy' (Elkins & Moseley, 2015; McCoy, 2017; Ranganathan *et al.*, 2016). Thus, the two are not interchangeable; however, many systematic reviews and meta-analyses, including Cochrane reviews, combine the two. The Phase One systematic review and meta-analysis provides a novel approach which makes a clear separation between pragmatic effects and true efficacy. This is congruent with the recommended use of intention-to-treat analysis (Abraha *et al.*, 2017; Elkins & Mosely, 2015; Gewandter *et al.*, 2014; Higgins, Savović, *et al.*, 2022; McCoy, 2017; Ranganathan *et al.*, 2016) and is recommended for future syntheses.

Notably, both acute and intensive care syntheses revealed a significant lack in high-level empirical evidence supporting the use of many PI preventative interventions (Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022), while evidently more interventions were tested in acute hospitals than intensive care where the occurrence of PI is greater (Coyer *et al.*, 2017; Lahmann *et al.*, 2012; VanGilder *et al.*, 2021). Only one intervention (use of Australian medical sheepskin surfaces compared to standard care) demonstrated effectiveness in the acute hospital setting intention-to-treat meta-analysis. Likewise, the intensive care-specific intention-to-treat meta-analysis found that only sacral and heel prophylactic dressings (plus standard care) were effective in preventing PI when compared to standard care alone.

12.2.2 Inclusion of interventions in the pressure injury preventative minimum intervention set

The Phase Two modified Delphi expert panel also demonstrated strong support for the use of prophylactic dressings, with the inclusion of sacral, heel and trochanteric dressings for use for intensive care patients assessed as being at high risk of PI in the minimum intervention set (Lovegrove *et al.*, 2020). Alternatively, the use of Australian medical sheepskin did not receive support and was rejected from the intervention set, despite it being the only intervention to demonstrate effectiveness in the acute hospital intention-to-treat meta-analysis. As the interventions which demonstrated significant effectiveness in intention-to-treat meta-analysis, all three had certainty of evidence ratings applied retrospectively using the GRADE approach (Schünemann *et al.*, 2013). The bodies of evidence for both sacral and heel dressings were rated as being of low certainty, while the evidence body supporting Australian medical sheepskin use was rated as being very low certainty. However, it must be acknowledged that the meta-analyses and GRADE ratings were not available at the time of the Delphi study, which may have influenced this result; although, the panel was provided with a list of the trials supporting each intervention.

Nevertheless, it is of interest that, as the interventions with the strongest support statistically speaking (even though the quality of evidence was low), two were retained but one was rejected from the minimum intervention set. This may reflect the robustness of the expert panel; reasons for the

exclusion of sheepskin were evident in the panel comments, including limited availability and use in some countries, and concerns with sheepskin maintenance and infection control (Lovegrove *et al.*, 2020). The exclusion of the Australian medical sheepskin intervention may indeed then be appropriate, given the intended global applicability of the minimum preventative intervention set. It may also better reflect the improvement and uptake of contemporary support surfaces (active and reactive); the function of which could be impaired by the addition of a sheepskin layer (EPUAP *et al.*, 2019). Meanwhile, the expert panel included the prophylactic dressing interventions, along with the rest of the interventions included in the bundle, despite the limited evidence. This speaks to the methodology of the consensus method used in this program of research; there were few intervention types for which meta-analysis could be undertaken and even fewer meta-analyses which demonstrated a significant effect, but the pooled studies with a significant effect were also limited. Thus, while it may be contended that interventions for practice and bundles should have a strong supporting evidence-base of moderate or high certainty, this would not be realistic. Where the evidence is limited, particularly across interventions, guidance for clinical practice and guidelines must be drawn from the limited evidence available and expert consensus.

As such, given the lack of interventions supported by meta-analyses and GRADE ratings, interventions were selected for presentation to the Delphi panel and potential inclusion in the minimum preventative intervention set based on effectiveness demonstrated in individual trials, as defined by a p value of < 0.05. It was also clear from the review of interventions and subsequent identification of a low-quality supporting evidence base that further high-level research across PI preventative interventions in acute hospital and intensive care settings is required. Indeed, given the potential PI prophylactic benefit of Australian medical sheepskins, further research into their effectiveness and comparisons to contemporary support surfaces would be of value, particularly in high-risk settings such as intensive care. Notably, the updated systematic review searches (covering the years 2020 and 2021; Chapter Five, pp. 117-124) undertaken to identify any further trials published since the initial completion yielded no further interventions which would have been included for consideration by the expert panel. Thus, the interventions selected for potential inclusion would remain the same in the years since Phase Two was conducted. However, while the updated systematic review searches found no further evidence examining sheepskin interventions, several more recent trials further supporting the use of prophylactic dressings in both settings were found (Beeckman *et al.*, 2021; Eberhardt *et al.*, 2021; Hahnel *et al.*, 2020; Oe *et al.*, 2020). Subsequently, the GRADE rating for the prophylactic dressing interventions may now be higher, and the inclusion of the prophylactic dressing interventions in the minimum intervention set may reflect the benefit of expert consensus in recognising clinically appropriate interventions which have a growing evidence base.

The limited high-level evidence for PI prevention identified in this program of research has also been

found elsewhere, with a systematic review of PI guidelines finding that recommendations were largely based on lower levels of evidence and expert consensus or opinion (Gillespie, Latimer *et al.*, 2021). Similarly, a meta-synthesis of PI prevention and treatment Cochrane reviews confirmed the low certainty of relevant trials (Walker *et al.*, 2020). As previously noted in this section, one must look to such lower levels of evidence, and the opinion of subject matter experts, where such evidence is lacking at higher levels. Indeed, the inclusion of risk assessment frequency and repositioning as potential interventions for the minimum intervention set was based on support from international guidelines and recommendations (EPUAP *et al.*, 2019; NPUAP *et al.*, 2014). Repositioning, for example, has a strong theoretical justification (Avsar *et al.*, 2020; Gillespie, Walker *et al.*, 2021), but the evidence supporting important clinical decisions like frequency and position is lacking (Gillespie, Walker *et al.*, 2021). The expert Delphi panel retained four-hourly and two-hourly repositioning for patients assessed to be at low and moderate to high risk of PI respectively. A more recent systematic review of the effects of varying repositioning regimes for those at risk of PI suggested that repositioning every two to three hours as opposed to longer frequencies (four- to six-hourly) resulted in less PIs developing (Avsar *et al.*, 2020). It would thus seem appropriate that higher risk patients be repositioned more frequently, in line with the final minimum preventative intervention set repositioning schedule.

It is important to note that repositioning is not negated by the use of support surfaces (Kim, Kim *et al.*, 2022). In this context, the expert Delphi panel also included the use of reactive mattresses for patients at moderate to high risk of PI and active mattresses and seating support surfaces for patients at high risk of PI. This may reflect an underlying preconception in practice that active support surfaces are superior to reactive support surfaces. While it is appropriate for support surfaces to be upgraded as risk level increases, any superiority in active over reactive surfaces remains unclear. Indeed, a more recent systematic review of support surface use for PI prevention within intensive care found that no one support surface was superior, although some studies found that alternating pressure mattresses and viscoelastic foam mattresses decreased PI incidence (Bambi *et al.*, 2022). However, no meta-analyses were undertaken and the majority of the studies included were also included in the Phase One systematic review and meta-analyses. The results of the Phase One systematic review and meta-analyses supported use of active and/or reactive surfaces over standard surfaces (Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022), which is congruent with the results of others (Shi *et al.*, 2018; Shi *et al.*, 2021b). Interestingly, the updated systematic review searches did yield one study which provided further insight into repositioning and support surface use within intensive care (Jiang *et al.*, 2020). Jiang *et al.* (2020) compared four-hourly repositioning with a viscoelastic foam mattress to a control of two-hourly repositioning with a powered air mattress in 13 intensive care units (7 Chinese hospitals) with significantly fewer PIs developed in the intervention group. However, in contrast to the statistical significance of the results, the authors argued that the incidence was low in

both groups, and that both regimes were thus safe for use. Regardless, repositioning and support surface interventions are intertwined in this study, and the results cannot therefore be extrapolated into separate interventions as required by the minimum intervention set.

There was one key area of PI prevention which was not included in the final minimum intervention set: interventions relating to the prevention of device-related PI. This is of particular relevance to intensive care, where multiple devices are often used for the monitoring and treatment of those who are critically ill, and the associated risk of device-related PI development (Coyer, Cook, Doubrovsky, Vann & McNamara, 2022; Dalli *et al.*, 2022; Dang *et al.*, 2022; Fulbrook, Lovegrove, Miles & Isaqi, 2022). More focus has been placed on these injuries in recent times, and it would seem that a clinically significant proportion of PI within intensive care are associated with device use (Coyer, Cook, Doubrovsky, Campbell *et al.*, 2022; Fulbrook, Lovegrove, Miles & Isaqi, 2022; Mehta *et al.*, 2019; Shimura *et al.*, 2022). Overall, a systematic review of medical device-related PI in intensive care found a pooled incidence and prevalence of 3.9% (range 0.7% to 8.3%) and 5.0% (range 1.3% to 15.4%) respectively, and a hospital-acquired pooled incidence and prevalence of 3.4% and 33.7% (range 5.0% to 55.9%) respectively (Barakat-Johnson *et al.*, 2019). Elsewhere, a systematic review focused on mucous membrane PI found an intensive care incidence and prevalence of 0.8% to 30.4% and 1.7% to 3.7%, respectively, across four studies from which incidence and prevalence were able to be calculated (Fulbrook, Lovegrove, Miles & Isaqi, 2022).

More recent studies have found a hospital-acquired device-related PI point prevalence of 11.3% in one Australian intensive care unit (Coyer, Cook, Doubrovsky, Vann & McNamara, 2022); an average device-related prevalence of 13.1% (range 0% to 33.3%) across intensive care units in 30 Chinese hospitals (Dang *et al.*, 2022); a medical device-related PI incidence of 48.8% in a Turkish intensive care unit (Dalli *et al.*, 2022) and a prevalence of 38.1% across intensive care units in 10 Jordanian hospitals (Najjar *et al.*, 2022) and 5.0% across 28 intensive care units in 3 Jordanian hospitals (Saleh & Ibrahim, 2022); a device-related nasal mucosal PI incidence 10.9% in the intensive care of a Chinese tertiary hospital (Nan *et al.*, 2022); and a medical device-related PI cumulative incidence of 3.3% compared to a 'self-load-related' PI cumulative incidence of 4.2% in a Japanese critical care medical centre and a cardiac care unit (Shimura *et al.*, 2022). However, only one of these studies specified the rate of device-related PI which were hospital-acquired (Coyer, Cook, Doubrovsky, Vann & McNamara, 2022), as opposed to rates overall. One more recent study has reported the incidence of hospital-acquired mucosal membrane PI, rather than device-related PI overall, for acute and intensive care sub-settings in one Australian hospital (Fulbrook, Lovegrove & Butterworth, 2022). Over five years, the incidence was 0.1% and 2.4% in these sub-settings respectively. Incidence was evidently low in both, but it was still clinically significant and around 70 times greater in intensive care compared to acute care. While the study was focused on mucosal injuries alone, all were medical device-related, except for one (*n* =

1/374), with the most common associated devices being urinary catheters in acute care, and oral endotracheal tube-related devices in intensive care (Fulbrook, Lovegrove & Butterworth, 2022).

Risk factors for device-related PI in intensive care include total number of devices, length of intensive care stay, vasopressor use, and increasing severity of illness (Coyer, Cook, Doubrovsky, Vann & McNamara, 2022; Dalli *et al.*, 2022; Dang *et al.*, 2022; Weber *et al.*, 2022). Furthermore, adding to already present risk factors, follow-up observations of patients who developed a medical device-related PI (*n* = 15 of the overall sample *n* = 299; prevalence 5.01%) in a prospective study across 28 intensive care units in three Jordanian hospitals indicated that prevention and treatment interventions were inadequate (Saleh & Ibrahim, 2022). Another contributor to the clinically significant rates of device-related PI may be the insufficient perception and/or knowledge of device-related PI in intensive care nurses reported by some (Dalli & Girgin, 2022; Sönmez & Bahar, 2022); although knowledge has been deemed sufficient elsewhere (Zhang, He *et al.*, 2021). Indeed, a qualitative study which interviewed 17 participants from acute care, academia and industry across 11 countries to examine barriers and facilitators to reporting of medical device-related PI identified numerous such barriers (knowledge, attitudes, workload, time, staffing, and perception of consequences) (Crunden *et al.*, 2022). This is of concern given that rates of medical device-related PI are already of clinical significance, but may be in fact far greater than recorded, emphasising the need for better PI prevention in this area.

While implementation of the minimum PI preventative intervention set into practice may increase focus on PI prevention and subsequently lead to a decrease in device-related PI, an additional focus on interventions targeted at device-related prevention is warranted and requires incorporation into the intervention set through further research. Indeed, one prospective study found that medical device-related PI incidence significantly decreased in three Saudi Arabian critical care units after the implementation of a medical device-related PI prevention bundle/mnemonic (Tayyib *et al.*, 2021). Similarly, evidence implementation in a Chinese intensive care unit using a framework for guideline implementation into practice significantly improved nurses' knowledge and PI prevention (Cao *et al.*, 2022). An international consensus document on device-related PI, which also outlines a structured approach to prevention, is now available (Gefen *et al.*, 2020; Gefen, Alves *et al.*, 2022), and could be considered for incorporation into, or use in conjunction with, the minimum PI preventative intervention and other PI prevention bundles.

12.2.3 Pressure injury prevention bundles within intensive care

This program of research has developed a minimum PI preventative intervention set, underpinned by high-level evidence, using a rigorous process. While research (year 2000 to May 2018) included in a systematic review examining the use of PI prevention programs within intensive care was largely of lower levels (e.g. quality improvement projects), the included studies did indicate that the programs

were effective in reducing PI and, significantly, increasing PI prevention concordance (Lin *et al.*, 2020). A more recent, although lower quality, systematic review of the effects and interventions of PI preventative care bundles for critically ill patients had similar findings (Trisnaningtyas *et al.*, 2021). The review identified 17 studies published between the years 2009 and 2020, of which 14 demonstrated a decrease in PI incidence based on bundle implementation. In developed countries, the decrease in PI incidence ranged from 4.3% to 36.2%, while PI incidence decreased by a range of 4.2% to 25.7% in developing countries. The bundles which significantly reduced PI incidence comprised seven interventions: risk assessment, skin care, repositioning, nutrition, support surfaces, education and medical device maintenance. Interestingly, Trisnaningtyas *et al.* (2021) acknowledged that the most commonly used PI risk assessment scale was the Braden scale, as was found in the systematic reviews undertaken for this program of research (Lovegrove *et al.*, 2021; Lovegrove, Fulbrook, Miles & Steele, 2022), but the authors noted that the Cubbin Jackson is more comprehensive in terms of risk assessment for the critically ill.

The findings of these systematic reviews in terms of PI prevention bundle effectiveness continue to be supported by more recent research, in addition to those targeted at device-related PI. A pre- (retrospective data collection) and post- (prospective data collection) intervention cohort study implemented a quality improvement bundle in one United States intensive care unit (McLaughlin *et al.*, 2022). The bundle incorporated a PI protocol for patients at risk of PI (Braden score ≤ 18) including prophylactic dressings, risk assessment, education, support surfaces, skin care, nutrition, repositioning, and multidisciplinary assistance. A significant decrease in PI was found post-intervention (McLaughlin *et al.*, 2022). Similarly, an Egyptian quasi-experimental study found that use of a PI prevention bundle, comprising body surface support, skin examination, mobility and repositioning, incontinence care, nutrition and hydration and prophylactic skin care, significantly decreased PI incidence in a trauma intensive care unit, in comparison to standard care (Sayed & Sliman, 2021). In an Australian tertiary intensive care unit, a prospective study found that phased implementation of defined PI prevention strategies for staff (e.g. skin integrity rounds, education) and patients (e.g. prophylactic dressings, skin assessment and cleansing, support surface use, medical device securement and repositioning) also significantly decreased PI prevalence in the final phase where all interventions were implemented (Coyer, Cook, Doubrovsky, Campbell *et al.*, 2022). Meanwhile, a quasi-experimental study which included 49 registered nurses' with ≥ 1 year intensive care practice across 12 hospitals found that use of an online clinical decision support system with machine learning for PI prevention care significantly improved PI prevention attitudes, PI prevention nursing performance and visual staging assessment ability for skin and oral mucosal PI. The clinical decision support system was targeted at risk prediction, stage discrimination and education for skin and oral mucosal PI (Kim, Ryu *et al.*, 2022).

In Turkey, another PI prevention bundle trialled in a neurosurgical intensive care unit, which incorporated eight interventions (nurse education, risk assessment, skin assessment, skin care, nutrition management, activity management, moisture management, support surface management), was found to decrease PI incidence, although not significantly (Yilmazer & Tuzer, 2022a). Notably, the study indicated that nurses' knowledge improved with bundle implementation and education, and that nurses concordance with the bundle was 78.9% (Yilmazer & Tuzer, 2022a). The authors also tested a PI prevention bundle with six interventions (education, risk assessment, skin assessment, skin care, nutrition management, activity management, wetness/incontinence management, support surface management) in an anaesthesia and reanimation intensive care unit (Yilmazer & Tuzer, 2022b). Similar to the former study, PI incidence did decrease after bundle implementation, but the difference was not significant. However, the authors also examined the effect of the bundle on nursing workload and costs. Daily nursing workload in terms of mobilisation and skin care was significantly lower after implementation of the bundle, while education workload was significantly higher and there was no significant difference for other interventions. Importantly though, PI prevention workload costs were found to be significantly lower after implementation of the bundle (Yilmazer & Tuzer, 2022b).

Evidently, PI prevention bundles have a positive impact on PI incidence and also potentially improve nurses' PI prevention knowledge and attitudes. Furthermore, the study by Yilmazer and Tuzer (2022b) suggests that PI prevention bundles may also decrease nursing workload and health care costs. However, all these bundles once again are either targeted at all patients, or at patients at risk of PI in general, which is often based on a PI risk assessment which was not intensive care specific. No consideration has been given to variations in level of PI risk, the inclusion of key PI risk factors for the critically ill in risk assessment scales, and subsequent preventative requirements.

12.2.4 The risk-stratified minimum pressure injury preventative intervention set

The key difference, and underlying concept, of the bundle developed in this program of research is the intensive care-specific risk stratification of PI preventative interventions. It has three significant functions:

1. The selection and implementation of interventions is guided by an intensive care-specific risk assessment. Risk assessment is the first step of PI prevention, and its purpose is to estimate PI risk and guide intervention use. Crucially, in the context of intensive care, risk assessment should be setting specific. Otherwise, important intensive care PI risk factors such as mechanical ventilation and vasopressor use are not taken into account (Cox, 2020; Cox *et al.*, 2020) which may have negative implications for the outcomes of risk assessment (risk level, preventative interventions; Lovegrove, Ven *et al.*, 2021). The developed minimum PI preventative intervention set is underpinned by risk assessment using the COMHON Index, an intensive care PI risk assessment scale which has displayed promising psychometric properties. However, the assessment of risk is

redundant if intervention use does not follow or increase relative to risk level. Thus, to reiterate, the intervention set comprises interventions stratified to assessed risk.

2. It ensures that PI prevention strategies, which can be costly and resource-intensive, are appropriately applied relative to assessed individual level of risk, rather than being under-utilised and endangering patients, or conversely over-utilised and wasteful. This is particularly relevant to developing countries, where such resources may be in short supply. While it may somewhat 'stretch' resources in these countries, it would also assist to target their use and future funding, ensure the implementation of evidence-based care, and potentially minimise PI development thus enabling PI treatment resources to be directed to PI prevention.
3. More importantly, it ensures that all critically ill individuals admitted to an intensive care unit have a set of PI preventative interventions applied relative to their assessed level of risk *at the absolute minimum*. This is crucial for patient safety and the prevention of PI. Notably, as it is a *minimum* intervention set, variations can be made to the implemented interventions based on individual requirements.

It may be argued that if interventions in such a set can be 'tweaked' based on individual requirements, that there is no need for such an intervention set, and interventions should be selected based on individual assessment anyway. Ideally speaking, this is a solid argument. However, research has demonstrated the effectiveness of PI prevention bundles within intensive care using a 'catch all' approach, but stratification by risk is more congruent with the need for PI prevention to be individualised, as recommended by the international guideline (EPUAP *et al.*, 2019). Furthermore, from a pragmatic perspective, there are significant gaps in practice which impede such individualised assessment and intervention prescription and implementation. A number of studies have indicated that the PI knowledge of nurses within intensive care is suboptimal (Araújo *et al.*, 2022; Azhar *et al.*, 2022; Hu, Sae-Sia & Kitrungrote, 2021a; Khojastehfar *et al.*, 2020; Tayyib *et al.*, 2016), and therefore it cannot be expected that PI preventative interventions are always appropriately prescribed and implemented relative to assessed risk.

Indeed, a systematic review of PI prevention knowledge, attitudes and practice in Iranian nurses found that knowledge and practice was insufficient, while nurses' attitudes were contradictory across studies (Zeydi *et al.*, 2022). In singular studies, a Jordanian correlational study conducted across 11 hospitals revealed that only 74.5% of nurses had 'satisfactory' PI prevention knowledge based on positive answers to a knowledge and implementation questionnaire and, of concern, only 49.2% of nurses were observed actually implementing PI preventative interventions in practice (Saleh *et al.*, 2019). The authors called for training programs and systems, regular updates on best practice and for specific training and practice translation activities within specialty areas. A cross-sectional study in an Ethiopian hospital which included 240 nurses found that over half (53.3%) of nurses had 'poor' knowledge of PI

prevention based on a questionnaire, while only 37.9% of nurses had 'good' PI prevention practices (Awoke *et al.*, 2022). A large proportion of nurses (> 70% for each factor impacting PI prevention) reported that there were shortages of pressure relieving devices, a lack of guidelines for risk assessment and PI prevention practice, a lack of formal education, staff shortages, a work environment that did not facilitate patient safety and a lack of job satisfaction. Factors which were statistically positively associated with nurses' PI prevention practices included education (bachelor's degree or higher) and experience (> 10 years), while poor knowledge and greater age (> 40 years) were negatively associated with PI prevention practices. Similarly, a study examining nurses' PI prevention knowledge in five Turkish hospitals found that nurses with a postgraduate degree and nurses with more than 10 years of service scored significantly better on the PI prevention knowledge assessment (Dirgar *et al.*, 2022). Of concern though, almost all (91.6%) of the 406 nurses were deemed to have insufficient knowledge.

A cross-sectional study of nurses and nursing students from a clinical Croatian hospital had similar results, with less than 50% of PI prevention knowledge questions from a survey being answered correctly (Cukljek *et al.*, 2022). In Swedish hospitals, a recent nation-wide study found that PI preventative care improved over a 10-year period, but in the final year (2020) only 70.2% of patients had a PI risk and skin assessment within 24 hours of hospital admission (Källman *et al.*, 2022). As well, while 96.2% of patients had a pressure-reducing mattress, of those at risk of PI only 58.4% had a repositioning schedule. In the United States, a retrospective analysis of a cross-sectional database which included data from over 290 000 patients and 1801 acute care facilities demonstrated that concordance with PI prevention strategies was variable across patients at risk of PI (Braden scale ≤ 18) (Edsberg *et al.*, 2022). Of those without a hospital-acquired PI, 86.0% had a daily skin assessment, 74.6% had pressure redistribution surfaces implemented, 67.0% had concordance with routine repositioning, 71.6% had moisture management 55.9% had nutritional support and 23.9% had heel elevation, while intervention frequencies increased for those with a Stage I or II PI and more severe PI stages. These particular studies were not intensive care focused, but they highlight the stark deficiencies in PI prevention knowledge and practice and the need for strategies to address this.

In critical care alone, a recent Malaysian study in three hospitals indicated that not only was nurses' (*n* = 275) knowledge suboptimal (Azhar *et al.*, 2022), but attitudes were also unsatisfactory and there was a moderately high level of perceived barriers towards PI prevention. Perceived barriers to PI prevention included lack of resources (manpower, linen) and 'overcrowding'. Even where nurses' knowledge has been assessed as sufficient, this is not necessarily translated into practice (Ghazanfari *et al.*, 2022; Saleh *et al.*, 2019) and other barriers to PI prevention remain (Coyer *et al.*, 2019; Johansen *et al.*, 2022). An Iranian study found that critical care nurses' knowledge, attitude and practice related to PI across four hospitals were desirable, positive and relatively desirable, respectively (Ghazanfari *et*

al., 2022). However, the authors acknowledged that in practice, nurses were unable to properly implement PI prevention guidelines due to other factors including heavy workload, inadequate staffing and lack of local guidelines, and concluded that nurse managers and policymakers should focus on addressing such factors. Similarly, Coyer *et al.* (2019) found that, in an Australian intensive care unit, nurses' attitudes were positive and knowledge was sound. While the nurses reported a moderate to high ability to overcome other barriers, a major barrier to care was still high patient acuity.

Elsewhere, Adibelli and Korkmaz (2022) interviewed nine intensive care nurses in Turkey and found that the PI risk assessment of nurses lacked structure, comprehensiveness and replicability as they deviated from use of scales, the PI preventative practices were not congruent with evidence-based recommendations, and intervention implementation was suboptimal (Adibelli & Korkmaz, 2022). Elsewhere, a Japanese study across six intensive care units even found that personality traits can both positively and negatively affect nursing compentence (Okumura *et al.*, 2022). In Jordan, a cross-sectional study of medical device-related PI in intensive care units across 10 hospitals found that only 17% of patients assessed to be at risk of PI using the Braden scale has adequate PI preventative measures in place (Najjar *et al.*, 2022). More recently, a qualitative study with six focus groups across three hospitals in Norway and Iceland found that intensive care nurses acknowledged that all intensive care patients were at risk of PI and were subsequently diligent with PI preventative care (Johansen *et al.*, 2022). However, the nurses indicated that they felt insecure with PI treatment, and that there were often other clinical priorities before skin care. Furthermore, nurses noted that sometimes patients were too critically ill to reposition and, in some of the institutions, reported limited access to resources including appropriate beds and mattresses.

Clearly, further efforts to improve PI knowledge and capability in intensive care nurses are required, such as the implementation of training programs (Araújo *et al.*, 2022; Baykara *et al.*, 2021; Gaeun *et al.*, 2020). Additionally, other barriers to care such as workload, staffing, local guidelines and resourcing require addressing. The developed minimum PI preventative intervention set assists to address some of these gaps and barriers in practice (e.g. providing guidance where knowledge is lacking, potential local guidance for intervention use, better resource allocation), and provides a structured approach to the application of PI preventative interventions relative to assessed PI risk. Subsequently, the structured intervention set can be implemented by the bedside nurse, allied health or other health care workers early on in the intensive care admission, regardless of knowledge level, clinical acuity, workloads or other barriers to care. Thus, a minimum set of PI preventative interventions is *in situ* in a timely manner to protect the patient until the barriers to more individualised care can be overcome (e.g. more knowledgeable nurses are available, acuity or other time-demands settle, workload improves), and the interventions can be adjusted based on individual need.

However, the minimum intervention set still requires testing on an international scale. This is enabled

by the availability of the COMHON Index in Spanish and English, and its rigorous translation into Chinese Mandarin. The benefits of the minimum intervention set, its clinical applicability and potential ability to overcome practice deficits and barriers are also of relevance to China. Similar to elsewhere, there are variations in nurses' knowledge within intensive care (Hu, Sae-Sia & Kitrungrote, 2021a; Hu, Sae-Sia & Kitrungrote, 2021b; Li, Zhu *et al.*, 2022; Zhang, He *et al.*, 2021), and PI prevention practices can indeed be nuanced across one country (Levido *et al.*, 2021). A web-based survey of nurses from intensive care units in over 50 hospitals in one Chinese province found that PI prevention knowledge was inadequate, although interestingly, attitudes were generally positive and self-reported PI prevention practice was acceptable (Hu, Sae-Sia & Kitrungrote, 2021a). The same study reported elsewhere on the predictors of PI prevention practices, highlighting that a healthy work environment, organisational support for PI prevention, and positive attitudes were predictors of good PI prevention practice, while knowledge was not (Hu, Sae-Sia & Kitrungrote, 2021b). Another study focused on device-related PI found that nurses' knowledge, attitude and practice in intensive care units across 37 hospitals in a different province were generally acceptable, but the authors concluded further education would be beneficial (Zhang, He *et al.*, 2021).

A more recent observational study, however, has suggested that PI prevention practices may be lacking in other Chinese intensive care units. A survey including 950 intensive care nurses from 15 hospitals across six Chinese provinces found that, while nurses' attitudes towards PI prevention were positive and 99% of nurses strongly or somewhat agreed PI prevention was very important, knowledge was poor and PI prevention practices were suboptimal (Li, Zhu *et al.*, 2022). Subsequently, the authors concluded there is a notable gap between the available evidence and practice implementation. Similar results have been reported in other areas of the broader hospital setting, with practices and concordance with PI prevention guideline recommendations in medical and surgical nurses in a Chinese tertiary hospital also found to be inadequate (Li *et al.*, 2021). Alternatively, interviews conducted with 27 nurses in a separate qualitative study in the same hospital suggested that nurses had a strong and active role in leading and delivering PI prevention, conducted PI risk assessments for all patients using a PI risk assessment scale with clinical judgement and provided individualised care, stressed the importance of collaboration to ensure appropriate PI prevention care for high-risk patients and strived to deliver PI preventative care (Li, Marshall *et al.*, 2022). However, the nurses also identified a number of obstacles to PI preventative care, including lack of assistance, heavy workloads, patient and carer compliance, and some reported limited access to PI preventative equipment.

Pressure injury occurrence also continues within Chinese intensive care units. In Mainland China, Lin *et al.* (2022) found an intensive care-acquired prevalence of 4.3% (range across regions 1.6-7.6%) in 198 intensive care units. In an older prevalence study in a Chinese teaching hospital, hospital-acquired PI prevalence was 1.5% (Zhao *et al.*, 2010); however, prevalence was much higher in intensive care

(45.5%), but the sample size was very small (*n* = 11) and it was unclear whether these were hospital-acquired. A larger study across 12 Chinese hospitals (Jiang, Li, Qu *et al.*, 2014) reported an overall hospital-acquired PI prevalence of 0.6%, with intensive care hospital-acquired prevalence higher (4.5%) but comparable to that of Lin *et al.* (2022). Similarly, another prevalence study including 25 hospitals in one Chinese province found that overall prevalence ranged from 0-3.5% (Zhou *et al.*, 2018). Within intensive care alone, prevalence was 9.7%, and of the 42 intensive care patients that had a PI, six were hospital-acquired (Zhou *et al.*, 2018). These more recent rates of hospital-acquired PI in intensive care may be lower than found elsewhere internationally (Labeau *et al.*, 2020), but are nonetheless clinically significant.

Against the background of ongoing PI prevalence in China, another intensive care PI prevention bundle, which was targeted at all patients and included risk assessment (Braden scale), skin assessment and care, repositioning, pressure reducing devices and nutrition care, significantly reduced PI incidence in critical care units across 26 hospitals in a Chinese province (Zhang, Wu *et al.*, 2021). Thus, the minimum PI preventative intervention set developed in this program of research may further improve PI incidence and prevention practices through its risk-stratified approach and use of a setting-specific risk assessment scale. Additionally, outside of the intervention set, this program of research has delivered a Chinese Mandarin version of the COMHON Index where there previously was not an intensive care-specific PI risk assessment scale available. A concurrent validity analysis has confirmed the translated instrument is strongly correlated with the established measure of PI risk, while variations identified between the two suggest that the COMHON Index as an intensive care-specific scale may be superior in terms of measuring varying levels of PI risk in the highly vulnerable intensive care population. While interrater reliability and agreement testing of the Chinese Mandarin COMHON Index is still required prior to implementation into practice and there is an intention to conduct such a postdoctoral study, the formal development of the instrument through translation is a significant contribution to Chinese intensive care nursing.

12.3 Strengths

Overall, a rigorous program of research has been conducted to address the stated research aim and objectives. The objectives were addressed in the following ways.

12.3.1 Research objective 1

To identify which PI preventative interventions are effective in preventing PI in adult inpatients admitted to acute hospital and intensive care settings.

- A systematic review and meta-analysis of randomised controlled trials, comprising an acute hospital setting synthesis and an intensive care setting synthesis, was conducted in Phase One (Thesis Part One, Chapters Two to Five) to identify PI preventative interventions which are

effective in preventing PI.

- Systematic reviews of randomised controlled trials are classified as the highest form of research evidence for effectiveness (Level 1.a, The Joanna Briggs Institute, 2014; Level I, NHMRC, 2000).
- The systematic review and meta-analysis was conducted to the highest standard, in line with relevant guidelines and recommendations, in particular the Cochrane Handbook for systematic reviews of interventions (Higgins, Thomas *et al.*, 2019; 2022). Additionally, the review and meta-analysis went beyond recommendations to separate intention-to-treat (primary) and per-protocol (secondary) data and syntheses. This is a novel approach which provides a better picture of pragmatic effect versus true efficacy.
- A total of 69 relevant studies were identified and included across the two syntheses. From these, intention-to-treat meta-analyses revealed that one intervention in the acute hospital setting synthesis (Australian medical sheepskin) and one in the intensive care setting synthesis (two by location: sacral and heel prophylactic dressings) demonstrated effectiveness in preventing PI. Updated searches yielded a further 12 studies.
- From the systematic review syntheses, 10 interventions which had demonstrated effectiveness in an individual randomised controlled trial were identified for use in Phase Two.

12.3.2 Research objective 2

To develop international consensus about a minimum PI preventative intervention set that should be implemented relative to intensive care patients' level of PI risk, as determined by the COMHON Index.

- A modified Delphi study was undertaken in Phase Two (Thesis Part Two, Chapters Six to Eight) to develop a minimum PI preventative intervention set based on those interventions identified in Phase One.
- Given that evidence surrounding the use of interventions relative to assessed level of PI risk in intensive care patients was lacking, it was appropriate to obtain consensus representative of international expertise to establish an applicable minimum PI preventative intervention set, using a recognised consensus method. While expert consensus is low level evidence according to The Joanna Briggs Institute (Level 5.b, 2014), and is not classified within the evidence levels by NHMRC (2000), use of a consensus method was appropriate to address the second research objective.
- The modified Delphi design was appropriate to facilitate international collaboration and integration of expert consensus with the evidence-based interventions identified in the first phase of this research.
- Through a rigorous process using the modified Delphi design, which involved three iterations, consensus was achieved and indicated that all patients should receive: risk assessment within

two hours of admission, eight hourly risk reassessment, and use of disposable incontinence pads. Additionally, moderate and high-risk patients should receive: a reactive mattress support surface and a heel offloading device. High-risk patients should also receive: nutritional supplements if eating orally, prophylactic dressings (sacral, heel and trochanteric), an active mattress support surface, and a pressure redistributing cushion for sitting. Repositioning should be performed at least four hourly for patients at low risk of PI, and at least two hourly for patients a moderate and high risk of PI.

12.3.3 Research objective 3

To translate the COMHON Index into a very commonly used language (Chinese Mandarin) and test the concurrent validity of the translated version against the widely used Braden scale.

- In Phase Three (Thesis Part Three, Chapters Nine to Eleven), instrument translation was performed using rigorous methods, which was followed by concurrent validity testing of the translated version in the population of interest.
- An observational design was used. While observational research without a control group is Level 3.e evidence as per The Joanna Briggs Institute (2014) and Level IV NHMRC (2000) evidence, it was an appropriate means of addressing the third research objective.
- Instrument translation methodology and methods were based on the relevant surrounding literature, resulting in the application of a rigorous and replicable approach which may be used for future research.
- The instrument translation was reported separately to the subsequent concurrent validity testing, which is recommended but not widely done. This allowed for comprehensive and adequate reporting, and the resulting paper is an exemplar for future instrument translation reporting.
- Concurrent validity testing was also performed using data from a representative population, which was appropriate to compare and correlate the translated instrument to the scale used in standard practice.

12.3.4 Overall program of research

Overall, by addressing the objectives derived from the overall research aim, the aim *to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care units* was itself addressed following a high-quality program of research.

12.4 International impact

This rigorous program of research and its outcomes carry significant impacts for intensive care PI

prevention internationally. Firstly, an internationally relevant minimum PI preventative intervention set has been developed specifically for intensive care which has the potential to improve PI preventative care and outcomes for critically ill individuals, although the set requires testing. Secondly, an intensive care-specific PI risk assessment scale is now available in three of the most commonly spoken languages in the world (largest three when counting native speakers; first, second and fourth largest when counting native and non-native speakers; Eberhard *et al.*, 2022). Specifically, this program of research has formally translated the COMHON Index into Chinese Mandarin. In addition to the promising psychometric properties demonstrated for the English and Spanish COMHON Index (Cobos Vargas *et al.*, 2016; Fulbrook & Anderson, 2016), pilot testing of the Chinese Mandarin COMHON Index in Phase Three indicated the instrument is easy to use and understand, and its completion is relatively fast (Lovegrove, Fulbrook, Miles, Steele, Liu *et al.*, 2022). The translation process also resulted in amendments being made to the Spanish and English versions of the instrument to improve language translations and clinical understanding.

This program of research directly resulted in Version 2.1 of the COMHON Index in the Spanish, English and Chinese Mandarin languages, all of which have since been published on the World Federation of Critical Care Nurses website for free download and use (World Federation of Critical Care Nurses, 2022). Moreover, psychometric testing to support the use of the Chinese Mandarin COMHON Index in practice was also undertaken and provides valuable insight for clinicians and supports the use of setting-specific PI risk assessment within intensive care internationally. The psychometric testing analysis also resulted in the identification of an error in a PI risk assessment scale used in practice in a Chinese hospital, and its correction has a direct positive impact on practice.

12.5 Limitations

While appropriate and rigorous, there were several limitations to the program of research. First, trials testing interventions identified in Phase One (a systematic review and meta-analysis of randomised controlled trials) which were used to inform Phase Two (a modified Delphi study) were limited to the English language. This may have resulted in some relevant interventions being missed. Indeed, international guidelines and recommendations had to be used to justify the inclusion of some interventions (risk assessment frequency, repositioning and repositioning frequency). Similarly, as noted in this chapter, other relevant interventions (specifically, those relating to medical device-related PI prevention) were not included. Additionally, Phase Two was completed prior to Phase One. This meant that, while relevant trials and effective interventions had been identified, the Phase One meta-analyses and subsequent GRADE ratings were not completed for provision to the Phase Two expert panel. The results of the meta-analyses and GRADE ratings, had they been available, may have influenced the selection of PI preventative interventions for the minimum intervention set. GRADE ratings were also undertaken retrospectively and may have otherwise provided further insight in the

systematic review publications had they been performed in tandem with the meta-analyses.

For the Phase Two Delphi study, the evidence supporting the interventions presented to the expert panel were limited, with pooled trials demonstrating an intervention effect being of low certainty. However, this supported use of the chosen consensus methodology with an international expert pane. In terms of the expert Delphi panel, the inclusion of panel members was limited to countries from which panel members were identified. However, the included panel members were from a wide range of countries (*n* = 35). Nonetheless, lower wealth countries may have had less representation due to issues with communication and internet access. Additionally, some panel members may not have been familiar will all interventions or have access to such interventions. Thus, while the panel was globally representative, resourcing and education issues may require addressing in some settings prior to implementation of the minimum PI preventative intervention set.

In Phase Three, the sample size for the pilot study undertaken as part of the instrument translation was small, limiting generalisability. However, it was appropriate as part of the translation approach. Similarly, the Phase Three concurrent validity analysis was limited to retrospective data and subsequently a pre-specified sample size. Future psychometric testing, in particular interrater reliability testing, should be adequately powered. Furthermore, the psychometric testing conducted in Phase Three was limited to concurrent validity. This will now be discussed further in the context of the impacts of COVID-19 on the program of research presented in this thesis.

12.6 Impacts of COVID-19

Following planning of the program of research presented in this thesis and commencement of candidature, the COVID-19 pandemic began to have significant impacts on hospitals, research and the community. Globally, COVID-19 has affected the feasibility of research, impeded or suspended study progression and data collection (Bratan *et al.*, 2021; Harper *et al.*, 2020; Weiner *et al.*, 2020), and has displaced non-pandemic related research through reallocation of research efforts to COVID-19 (Bratan *et al.*, 2021; Harper *et al.*, 2020; Riccaboni & Verginer, 2022; Weiner *et al.*, 2020). Indeed, an analysis of biomedical publications within PubMed narrowed by use of Medical Subject Headings (MeSH) terminology demonstrated that, between January 2019 and December 2020, there was a dramatic increase in COVID-19 publications, with displacement of research in unrelated biomedical fields (Riccaboni & Verginer, 2022). In the context of PI, this is despite research suggesting that PI prevalence is higher in those admitted to intensive care with COVID-19, than in those admitted without the virus (Pokorná *et al.*, 2022). Furthermore, an online survey and workshop with investigators in Germany found that health research had been severely impacted by the COVID-19 pandemic; projects were impeded or suspended, publications were delayed or not feasible, and there had also been negative impacts on continuation of PhD and Masters theses in some cases (Bratan *et al.*, 2021). Nonetheless, Phases One (Thesis Part One, Chapters Two to Five) and Two (Thesis Part Two, Chapters Six to Eight)

were able to proceed as planned and were completed.

However, Phase Three (Thesis Part Three, Chapters Nine to Eleven) in its intended form was no longer feasible even with a six-month extension of candidature sought and granted in response to the COVID-19 pandemic. Previously, Phase Three was planned to comprise a formal translation of the COMHON Index to Chinese Mandarin and psychometric testing with an interrater reliability and agreement and concurrent validity study. Following ethical approval for all intended components (2021-17H, Appendix I; SHSY-IEC-4.1/20-258/01, Appendix J), formal translation and pilot testing of the Chinese Mandarin COMHON Index were completed (Chapter Ten), and study set up and data collection for psychometric testing within an intensive care unit in Shanghai, China began. Unfortunately, the 2022 COVID-19 outbreak in Shanghai then occurred, and its impacts on the city, study hospital, intensive care unit and nurses prevented any continuation of data collection.

Subsequently, the psychometric testing component of Phase Three was replanned. Some data had already been collected using the Chinese Mandarin COMHON Index and Braden scale within the study intensive care unit. The data were sufficient for performing a concurrent validity analysis and were available in a non-identifiable dataset. Therefore, the psychometric testing component of Phase Three evolved into a concurrent validity analysis (Chapter Eleven); a protocol was developed, permission to access the data was received, and ethical approval for use of the non-identifiable data was sought from and granted by the Australian Catholic University Human Research Ethics Committee (2022-2704N; Appendix K). This approach still addressed a research and clinical need, furthered the reach of the developed minimum preventative intervention set and provided a Chinese Mandarin version of the COMHON Index with established concurrent validity for future international testing. However, interrater reliability and agreement testing of the Chinese Mandarin COMHON Index is still required, as well as international testing of the developed intervention set, and there is an intention for such studies to be conducted as part of postdoctoral research.

12.7 Recommendations

12.7.1 For future practice

From this program of research and the points discussed in this chapter, and in addition to the recommendations made in the published research papers for each individual research phase (Chapters Three, Four, Eight, Ten), the following key recommendations are made for future practice:

- PI risk assessment in intensive care should be setting specific, thus taking into account important intensive care PI risk factors.
- The primary outcome of PI risk assessment in this context (i.e. risk status/level) must then be used to guide the prescription and implementation of PI preventative interventions.
- PI risk assessment and risk assessment scales should be evaluated for effectiveness in terms

of these outcomes (risk status identification and preventative intervention use), rather than PI occurrence or PI 'prediction'.

- Where possible, the use of PI preventative interventions should be supported by the highest available levels of evidence. Where high levels of evidence are not available, lower levels of evidence should be considered. PI prevention and treatment guidelines are also available to inform practice.
- A risk-stratified approach to PI preventative intervention prescription and implementation should be considered.
- The minimum PI preventative intervention set developed in this program of research has international clinical applicability, and the potential to overcome barriers to PI prevention practice. However, it requires international testing to establish its effectiveness within the intensive care setting.

12.7.2 For future research

The overarching recommendation for future research stemming from this program of research and the discussion points of this chapter, is:

- The effectiveness of the minimum PI preventative intervention set applied relative to COMHON Index level of risk requires testing on a primary outcome of PI incidence within international intensive care units.

The following key recommendations are also put forth:

- Further high-level research on the effectiveness of all singular PI preventative interventions within intensive care is required to inform practice, with certainty of evidence assessments recommended for future systematic reviews.
- Further research examining the psychometric properties of the Chinese Mandarin COMHON Index is required and should be adequately powered. In particular, the interrater reliability and agreement of the instrument needs to be established prior to clinical implementation.
- Further research which considers incorporation of device-related PI prevention interventions into the developed minimum intervention set is needed.
- Research examining nurses' perceptions of the minimum intervention set and its ease of use in practice is also warranted.

12.8 Conclusion

In conclusion, the overall aim of this program of research was to develop a minimum set of evidence-based PI preventative interventions relative to PI level of risk, as determined by the COMHON Index, for international use within intensive care units. The aim was achieved through a three-phase approach, which included a systematic review and meta-analysis, a modified Delphi study, and instrument translation and psychometric testing. From this, the results and recommendations add to the body of knowledge related to PI prevention and have the potential to inform future practice and further research.

Specifically, this program of research has developed an intensive care-specific minimum PI preventative intervention set, which is a significant contribution to intensive care practice internationally. It has promising global clinical applicability, and the potential to assist with overcoming poor PI preventative care stemming from poor PI prevention nursing knowledge and barriers to practice. However, the minimum PI preventative intervention set requires testing on an international scale, along with an examination of intensive care nurses' perception of the set and its use in practice.

Following on from the identified recommendations for future research, a program of post-doctoral research is planned to undertake interrater reliability and agreement testing of the Chinese Mandarin COMHON Index and international testing of the developed minimum PI preventative intervention set and its impact on PI incidence, as well as nurses' perceptions of the clinical utility of the set. An international cluster randomised crossover trial across countries which speak the languages in which the COMHON Index is officially available (Spanish, English, Chinese Mandarin) would be well placed in the context of testing the intervention set internationally.

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Research Portfolio Appendices

Research Portfolio Appendix A: List of publications

Phase One: Chapter Three

Lovegrove, J., Fulbrook, P., Miles, S. & Steele, M. (2021). Effectiveness of interventions to prevent pressure injury in adults admitted to acute hospital settings: A systematic review and meta-analysis of randomised controlled trials. *International Journal of Nursing Studies, 122*, 104027. https://doi.org/10.1016/j.ijnurstu.2021.104027

Josephine Lovegrove *I acknowledge that my contribution to the above paper is 65%.*

Paul Fulbrook *I acknowledge that my contribution to the above paper is 20%.*

Sandra J. Miles *I acknowledge that my contribution to the above paper is 10%.*

Michael Steele *I acknowledge that my contribution to the above paper is 5%.*

Phase One: Chapter Four

Lovegrove, J., Fulbrook, P., Miles, S. & Steele, M. (2022). Effectiveness of interventions to prevent pressure injury in adults admitted to intensive care settings: A systematic review and meta-analysis of randomised controlled trials. *Australian Critical Care, 35*(2), 186-203. https://doi.org/10.1016/j.aucc.2021.04.007

Josephine Lovegrove *I acknowledge that my contribution to the above paper is 65%.*

Paul Fulbrook *I acknowledge that my contribution to the above paper is 20%.*

Sandra J. Miles *I acknowledge that my contribution to the above paper is 10%.*

Michael Steele *I acknowledge that my contribution to the above paper is 5%.*

Phase Two: Chapter Eight

Lovegrove, J., Fulbrook, P. & Miles, S. (2020). International consensus on pressure injury preventative interventions by risk level for critically ill patients: A modified Delphi study. *International Wound Journal, 17*(5), 1112-1127. https://doi.org/10.1111/iwj.13461

Josephine Lovegrove *I acknowledge that my contribution to the above paper is 65%.*

Paul Fulbrook *I acknowledge that my contribution to the above paper is 25%.*

Sandra J. Miles *I acknowledge that my contribution to the above paper is 5%.*

Phase Three: Chapter Eleven

Lovegrove, J., Fulbrook, P., Miles, S., Steele, M., Liu, X., Zhang, L. & Cobos Vargas, A. (2022). Translation and piloting of the Chinese Mandarin version of an intensive care-specific pressure injury risk assessment tool (the COMHON Index). *International Journal of Nursing Sciences, 9*(2), 169-178. https://doi.org/10.1016/j.ijnss.2022.03.003

Josephine Lovegrove *I acknowledge that my contribution to the above paper is 55%.*

Paul Fulbrook *I acknowledge that my contribution to the above paper is 10%.*

Sandra J. Miles *I acknowledge that my contribution to the above paper is 7.5%.*

Michael Steele *I acknowledge that my contribution to the above paper is 7.5%.*

Xian-Liang Liu *I acknowledge that my contribution to the above paper is 7.5%.*

Lin Zhang *I acknowledge that my contribution to the above paper is 7.5%.*

Angel Cobos Vargas *I acknowledge that my contribution to the above paper is 5%.*

Research Portfolio Appendix B: List of presentations

Conference presentations

Fulbrook, P., **Lovegrove, J.**, Miles, S., Steele, M. & Cobos Vargas, A. (2021). Preventative interventions to prevent pressure injury in ICU: Delphi study. *17th Emirates Critical Care Conference and 16th WFCCN World Congress.* Dubai, United Arab Emirates. 18-19 June 2021.

Higher Degree Research Seminar presentations

Lovegrove, J. (2022). Development of an international risk-stratified pressure injury prevention bundle for intensive care. *Australian Catholic University Final Year Review.* Chermside, Australia. 26 April 2022.

Lovegrove, J. (2021). Development of an international risk-stratified pressure injury prevention bundle for intensive care. *Australian Catholic University Mid-Candidature Review.* Chermside, Australia. 29 June 2021.

Lovegrove, J. (2019). Matching preventative interventions to risk level to reduce pressure injury in critically ill patients: an international Delphi study and cluster randomised crossover trial. *Australian Catholic University Confirmation of Candidature.* Banyo, Australia. 25 June 2019.

Research Portfolio Appendix C: Journal permissions - International Journal of Nursing Studies

Journal email advice

RE: Approval request

Waller, Stephanie <stephanie.waller@kcl.ac.uk>
on behalf of
kcl - ijns <ijns@kcl.ac.uk>
Tue 2/11/2021 2:30 AM
To: Josephine Lovegrove <Josephine.Lovegrove@health.qld.gov.au>

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Managing Editor, *Aging Cell*
Senior Editorial Assistant, *International Journal of Nursing Studies*

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LONDON
SE1 8WA
Tel: 020 7848 3365
Fax: 020 7848 3069
Email: agingcell@kcl.ac.uk
ijns@kcl.ac.uk

From: Josephine Lovegrove <Josephine.Lovegrove@health.qld.gov.au>
Sent: 01 November 2021 05:50
To: kcl - ijns <ijns@kcl.ac.uk>
Subject: Approval request

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Research Portfolio Appendix D: Journal permissions – Australian Critical Care

Journal email advice

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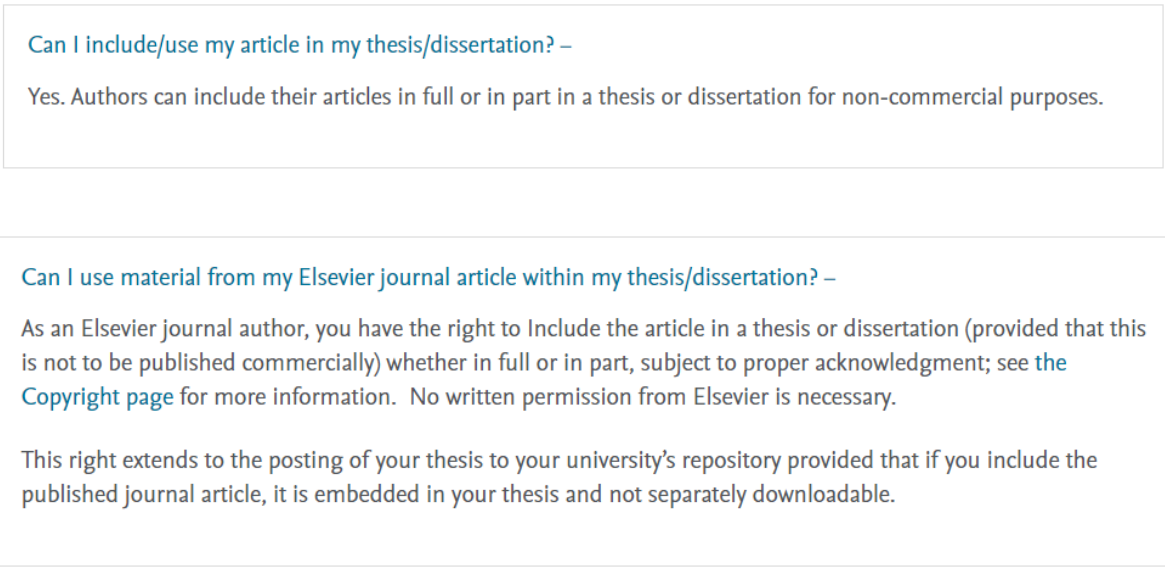

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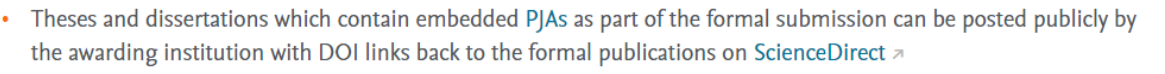

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Research Portfolio Appendix E: Journal permissions – International Wound Journal

Journal email permission

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Dear Josephine Lovegrove

Permission granted provided proper acknowledgement is given.

Best regards
Thomas Trier-Mork

Thomas Trier-Mork
Senior Journals Publishing Manager
Health Sciences

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From: Josephine Lovegrove <Josephine.Lovegrove@health.qld.gov.au>
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Appendices

Appendix A: The COMHON Index (Original version; Spanish and English versions)

Índice COMHON

Versión en español

Puntuación	NIVEL DE CONCIENCIA	MOVILIDAD	HEMODINAMICA	OXIGENACION	NUTRICION
1	Despierto y alerta (RASS 0 - 1) (Glasgow 15)	Independiente. Deambula con ayuda	Sin soporte hemodinámico	Respiración espontánea y $FiO_2 < 0.4$	Dieta oral completa
2	Agitado. Inquieto. Confuso (RASS > +1) (Glasgow 14)	Limitada. Actividad cama-sillón	Con expansores plasmáticos	Respiración espontánea y $FiO_2 \geq 0.4$	Nutrición enteral Nutrición parenteral
3	Sedado con respuesta a estímulos. (RASS -1 a -3) (Glasgow 9 - 13)	Muy limitada, pero tolera cambios posturales	Perfusión de dopamina, adrenalina o noradrenalina. O uso de dispositivos de apoyo cardiopulmonares	Ventilación Mecánica no invasiva	Dieta oral líquida. Ingesta incompleta de alimentos
4	Coma. Sedado sin respuesta a estímulos. (RASS -4,-5) (Glasgow < 9)	No tolera cambios posturales. Decúbito prono	Con más de dos apoyos hemodinámicos de los anteriores	Ventilación mecánica invasiva	Dieta absoluta

BAJO RIESGO: 5-9, RIESGO MODERADO: 10-13, ALTO RIESGO: 14-20

DEFINICIONES DE LAS SUBESCALAS

Nivel de conciencia_____

1. ***Despierto y alerta: RASS: 0, +1***
   Paciente consciente y orientado en tiempo y espacio, obedece órdenes, responde y reconoce cualquier estimulo de su entorno. Glasgow 15

2. ***Agitado. Inquieto. Confuso: RASS: > +1***
   Consciente, desorientado parcialmente o intermitentemente en tiempo y/o espacio. Respuesta inadecuada a estímulos. Glasgow 14

3. ***Sedado con respuesta a estímulos: RASS -1 a -3***
   Paciente comatoso con Glasgow 9 a 13, o sedado con RASS -1 a -3.

4. ***Coma, sedado sin respuesta a estímulos: RASS -4 a -5***
   Paciente comatoso con Glasgow < 9, o sedado con RASS -4 a -5.

Movilidad_____

1. ***Independiente/Deambula con Ayuda***
   Paciente que camina solo o precisa algún sistema de apoyo para mantener el equilibrio

2. ***Limitada. Actividad Cama-Sillón***
   Paciente encamado que se moviliza el solo. Alterna periodos de reposo en cama con periodos de reposo en sillón. Puede mantenerse en pie con o sin ayuda.

3. ***Muy limitada, pero tolera cambios posturales***
   Paciente encamado que no se moviliza por sí sólo, pero al que se le pueden realizar cambios posturales sin repercusión hemodinámica ni respiratoria.

4. ***No tolera cambios posturales/Decúbito Prono***
   Paciente encamado que no se moviliza el solo ni existe posibilidad de cambios posturales. No debe movilizarse por inestabilidad hemodinámica o respiratoria.
   Paciente en decúbito prono.

Hemodinámica_____

1. ***Sin soporte hemodinámico***
   Paciente sin drogas vasoactivas, ni expansores plasmáticos ni dispositivos mecánicos de apoyo hemodinámico (ej: balón de contrapulsación intraaórtico).

2. ***Con expansores plasmáticos***
   Paciente que precisa de administración de hemoderivados, coloides o cristaloides para el mantenimiento de su hemodinámica.

3. ***Dopamina, adrenalina, noradrenalina o algún dispositivo de apoyo cardiopulmonar***
   El paciente requiere una de estas drogas en perfusión continua o de algún dispositivo de apoyo mecánico, ej: balón de contrapulsación intraaórtico, oxigenación por membrana extracorpórea, dispositivos de apoyo ventricular, para el mantenimiento de la hemodinámica

4. ***Con más de dos apoyos de los anteriormente descritos***
   El paciente requiere de más de dos apoyos de los anteriormente descritos para el mantenimiento de la hemodinámica.

Oxigenación_____

1. ***Respiración espontánea y baja FiO_2 (< 0.4)***
   Paciente que respira por si solo y que precisa aporte extra de oxígeno inferior al 40%.

2. ***Respiración espontánea y alta FiO_2 ($\geq$ 0.4)***
   Paciente que respira por si solo y que precisa aporte extra de oxígeno superior al 40%.

3. ***Ventilación mecánica no invasiva***
   El paciente requiere de ventilación mecánica no invasiva.

4. ***Ventilación mecánica invasiva***
   El paciente requiere de ventilación mecánica invasiva.

Nutrición_____

1. ***Dieta oral completa***
   Tolera líquidos y sólidos, manteniendo ingesta de alimentos que satisfacen sus necesidades

2. ***Nutrición Enteral / parenteral***
   Paciente con nutrición parenteral, enteral o ambas. El paciente puede estar simultáneamente ingiriendo algún alimento vía oral.

3. ***Dieta oral líquida/ ingesta incompleta de alimentos***
   Paciente con dieta inadecuada o incompleta para satisfacer su aporte calórico, componiéndose esta de ingesta exclusiva de líquidos.

4. ***Dieta absoluta***
   Paciente sin ningún tipo de aporte nutricional.

The COMHON Index (RASS = Richmond Agitation Sedation Scale)

Score	Level of consciousness	Mobility	Haemodynamic	Oxygenation	Nutrition
1	Awake and alert (RASS 0 - 1) (Glasgow 15)	Independent, walking with help	No haemodynamic support	Spontaneous breathing and $FiO_2 < 0.4$	Full oral diet
2	Agitated, restless, confused (RASS > 1) (Glasgow 14)	Limited, bed-chair activity	Volume expanders	Spontaneous breathing and $FiO_2 \geq 0.4$	Enteral or parenteral feeding
3	Sedated but responsive (RASS -1 to -3) (Glasgow 9-13)	Very limited but tolerates position change	Dopamine or norepinephrine or adrenaline. Mechanical support	Non-invasive mechanical ventilation	Oral fluids. Incomplete oral feeding
4	Coma, sedated and unresponsive (RASS < -3) (Glasgow < 9)	Unable to change position; lying prone	Needing two of the above	Invasive mechanical ventilation	No feeding

LOWER RISK: 5-9, MODERATE RISK 10-13, HIGH RISK 14-20

SUBSCALE DEFINITIONS

Level of consciousness

1. ***Awake and alert: RASS 0 to +1***
   The patient is conscious and orientated to time and space, obeys commands and recognises and responds to any stimulus in their environment. Glasgow Coma Score 15.
2. ***Agitated/restless/confused: RASS > 1***
   The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score 14.
3. ***Sedated but responsive: RASS -1 to -3***
   The patient is comatose with Glasgow Coma Score 9 to 13 or sedated with RASS -1 to -3.
4. ***Coma, sedated and unresponsive: RASS -4 to -5***
   The patient is comatose with Glasgow Coma Score < 9 or sedated with RASS -4 to -5.

Mobility

1. ***Independent/walking with help***
   The patient walks alone or needs a support system to maintain balance.
2. ***Limited/bed-armchair activity***
   The patient is in bed and can move on their own. The patient has alternating periods of bed rest with periods of rest in a chair. The patient can stand up with or without assistance.
3. ***Very limited but tolerates change in position***
   The patient is in bed and cannot move without assistance but can be moved without affecting haemodynamic or respiratory status.
4. ***Unable to change position or lying prone***
   The patient is in bed and must not be moved due to haemodynamic or respiratory instability or the patient is lying in the prone position.

Haemodynamic

1. ***No haemodynamic support***
   The patient does not require vasoactive drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).
2. ***Volume expanders***
   The patient requires use of blood products, colloid or crystalloid to maintain haemodynamic status.
3. ***Dopamine or norepinephrine or adrenaline or cardiopulmonary mechanical support***
   The patient requires one or more of the above drugs by continuous infusion or cardiopulmonary mechanical assistance e.g. intra-aortic balloon pump, extra-corporeal membrane oxygenation, ventricular assist device, to maintain haemodynamic stability.
4. ***Needing two of the above***
   The patient requires two or more of the above supports to maintain haemodynamic stability.

Oxygenation

1. ***Spontaneous breathing and low FiO_2 (< .4)***
   The patient is breathing by themself and requires no extra oxygen or less then 40%.
2. ***Spontaneous breathing and high FiO_2 ($\geq$ .4)***
   The patient is breathing by themself and requires supplementary oxygen greater than 40%.
3. ***Non-invasive mechanical ventilation***
   The patient requires non-invasive mechanical ventilation.
4. ***Invasive mechanical ventilation***
   The patient requires invasive mechanical ventilation.

Nutrition

1. ***Full oral diet***
   The patient tolerates liquids and solids and is eating enough food to meet their needs.
2. ***Enteral nutrition / parenteral feeding***
   The patient is being fed with parenteral nutrition, enteral nutrition or both and may also be partially eating orally or not eating at all.
3. ***Oral fluids. Incomplete oral feeding***
   The patient has an inadequate or reduced diet that does not meet their needs and is not being enterally or parentally fed.
4. ***No feeding***
   The patient is not being fed at all.

Appendix B: Phase Two modified Delphi study Round 1 questionnaire

INTRODUCTION

RESEARCH TEAM

Josephine Lovegrove, Paul Fulbrook, Sandra Miles, Michael Steele, Angel Cobos Vargas

INVITATION

You were nominated to take part in the panel because you have been identified as an expert in the fields of critical care nursing and pressure injury prevention. You are now invited to participate in the above Delphi study.

Confidentiality

Although the research team will know your identity, only aggregate data will be reported. Your individual responses will not be reported.

Consent

Your consent to participate in this Delphi study will be implied by your completion and submission of each survey.

ABOUT THE DELPHI STUDY

This study has been approved by the World Federation of Critical Care Nurses and has received ethical approval via the Australian Catholic University (2019-25E).

Through professional consensus (agreement), the aim of this study is to identify a standardised set of pressure injury preventative interventions that can be applied to critically ill intensive care patients relative to their level of risk of developing a pressure injury.

In this study, pressure injury risk level is categorised using the COMHON Index risk assessment tool, which was emailed to you previously.

It identifies three levels of risk: LOW, MODERATE or HIGH.

The Delphi study will entail a series of survey rounds. In each round, you will be sent a weblink with a questionnaire to complete online.

The questionnaire will comprise a series of evidence-based pressure injury preventative interventions that have been sourced by the research team. Where evidence-based sources are inconclusive, recommendations from international guidelines are used. The level of evidence of the interventions is indicated for each intervention.

In each round, you will be asked to indicate your strength of agreement for each intervention to be implemented for three levels:

- **All patients (Low, Moderate and High risk)**
- **Moderate and High risk patients only**

- **High risk patients only.**

It is anticipated that up to three rounds will be necessary to achieve consensus between the expert panel members about which pressure injury preventative interventions should be applied for each risk level.

Each survey questionnaire should be submitted online within two weeks of receipt.

All rounds will be undertaken online; no face-to-face time is required. You can complete the survey at any time that is convenient to you within the two-week time-frame.

Each intervention is rated on a scale of 1 (strongly disagree) to 9 (strongly agree). A median score of 7 will be used as the cut-off to indicate professional consensus. All questions must be answered before the survey can be submitted.

ALL QUESTIONS APPLY TO CRITICALLY ILL PATIENTS IN INTENSIVE CARE.

Round 1
The first round of the survey is provided on the following pages. It contains 16 preventative interventions. You will be asked to rate each intervention according to the pressure injury risk level of the patients that it should be used for.

Round 2
Based on the results of the first survey, a second round will be distributed online. In this round, only the preventative interventions that did not achieve expert panel consensus (agreement) in Round 1 will be presented in the questionnaire.

Round 3
If there are any remaining interventions that did not achieve professional consensus in Round 2, a third round will be distributed.

THANK YOU

On behalf of the research team, thank you for participating.

Please click the 'NEXT' button to continue.

RATING INTERVENTIONS

You will be asked to indicate your strength of agreement for interventions to be implemented for three levels:

· All patients (Low, Moderate AND High risk)
· Moderate and High risk patients ONLY
· High risk patients ONLY.

Each intervention will be rated on a scale of 1 (strongly disagree) to 9 (strongly agree).

For example, you may strongly agree that an intervention should be applied for ALL patients (Low, Moderate AND High risk), and rate the intervention as a 9 for this level of risk. In this case, your level of agreement for the intervention to be applied to the other risk levels (Moderate and/or High risk patients ONLY) would be lower as this does not include all patients.

In another example, you may agree that the most appropriate level of risk for an intervention to be applied to is High risk patients ONLY, and rate your agreement as an 8. As you feel this intervention is most appropriate for High risk patients ONLY, your level of agreement that the intervention should be applied to other risk levels (ALL patients, or patients at Moderate AND High risk only), would be rated lower than an 8.

You may also disagree that an intervention should be applied to any level of risk.

RISK ASSESSMENT

Evidence level: international guidelines.

* 1. **Following admission to intensive care, pressure injury risk assessment should be completed:**

- ◯ Within 2 hours
- ◯ Within 4 hours
- ◯ Within 6 hours
- ◯ Within 8 hours
- ◯ Other (please specify):

* 2. **Intensive care patients should be reassessed for pressure injury risk:**

- ◯ Once every 8 hours
- ◯ Once every 12 hours
- ◯ Once every 24 hours
- ◯ Only when there is a significant change in the patient's condition
- ◯ Other (please specify):

CONTINENCE

Evidence level: randomised controlled trials.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following interventions for each risk level.

* 3. **Indwelling urinary catheter entry points should be washed with soap and water, and the catheter should be repositioned to the opposite thigh and secured, three times daily for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 4. **For intensive care patients who are incontinent of urine and/or faeces, disposable adult incontinence pads (e.g. adult incontinence underpads, briefs, diapers) should be used for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

HEEL OFFLOADING

Evidence level: randomised controlled trials.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following interventions for each risk level.

* 5. **Pressure should be offloaded from the heels using a heel offloading device for:**

A <u>HEEL OFFLOADING DEVICE</u> will remove or relieve pressure from the heels by elevating (suspending, lifting or floating) the heels off the bed or other lying surface. For example, a heel elevation boot may be applied to each heel for an intensive care patient to remove heel pressure while the patient is lying in bed.

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

NUTRITION

Evidence level: randomised controlled trials.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following interventions for each risk level.

* 6. **For intensive care patients who <u>ARE ABLE TO EAT FOOD ORALLY</u>, oral nutritional supplements should be provided in addition to standard nutrition for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

PREVENTATIVE DRESSINGS

Evidence level: randomised controlled trials.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following interventions for each risk level.

* 7. **A preventative sacral dressing should be applied for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 8. **Preventative heel dressings should be applied for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 9. **Preventative trochanteric (hip) dressings should be applied for:**

For example, applying preventative dressings to the bony point of both hips.

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 1 Version 1.2 17 July 2019

REPOSITIONING

Evidence level: international guidelines.

PLEASE NOTE: THE FOLLOWING QUESTIONS APPLY TO PATIENTS IN STANDARD BEDS, NOT AUTOMATED BEDS.

* 10. **LOW RISK patients should be repositioned:**

- ◯ At least 2 hourly
- ◯ At least 3 hourly
- ◯ At least 4 hourly

If you wish, please make a comment about your decision:

* 11. **MODERATE RISK patients should be repositioned:**

- ◯ At least 2 hourly
- ◯ At least 3 hourly
- ◯ At least 4 hourly

If you wish, please make a comment about your decision:

* 12. **HIGH RISK patients should be repositioned:**

- ◯ At least 2 hourly
- ◯ At least 3 hourly
- ◯ At least 4 hourly

If you wish, please make a comment about your decision:

SUPPORT SURFACES - BED/MATTRESS

Evidence level: randomised controlled trials.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following interventions for each risk level.

* 13. **Medical grade sheepskin mattress overlays should be used for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 14. **Reactive mattress support surfaces should be used for:**

A <u>REACTIVE support surface</u> is pressure reducing. *It changes load distribution in response to an applied load (such as the patient's body). The mattress conforms to and surrounds the body. A reactive support surface may be foam, air or fluid, and may be powered or unpowered.*

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 15. **Active mattress support surfaces should be used for:**

An <u>ACTIVE support surface</u> is pressure relieving. *It changes pressure mechanically by alternating pressure. Alternating pressure usually occurs as the mattress automatically inflates and deflates different parts of the mattress. There is no load required on the mattress for it to alternate pressure. Active support surfaces are powered.*

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

SUPPORT SURFACES - SEATING

Evidence level: international guidelines.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following interventions for each risk level.

* 16. **When an intensive care patient is sat out of bed, a pressure redistributing seat cushion should be used for:**

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
All patients (Low, Moderate and High risk)	○	○	○	○	○	○	○	○	○
Moderate and High risk patients only	○	○	○	○	○	○	○	○	○
High risk patients only	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Appendix C: Phase Two modified Delphi study Round 2 questionnaire

INTRODUCTION

RESEARCH TEAM

Josephine Lovegrove, Paul Fulbrook, Sandra Miles, Michael Steele, Angel Cobos Vargas

ROUND 2

Round 1 of this study has been closed and the results have been analysed. You are now invited to participate in the Round 2 survey. The Round 2 survey contains interventions which did not meet the criteria for consensus in Round 1.

In this round, you will be asked to indicate your strength of agreement for each intervention for use at a particular risk level. This will be the risk level which received the highest median score and the most agreement between panel members in the previous round.

CONFIDENTIALITY

Although the research team will know your identity, only aggregate data will be reported. Your individual responses will not be reported.

CONSENT

Your consent to participate in this Delphi study will be implied by your completion and submission of each survey.

SUBMISSION

This questionnaire should be submitted online within two weeks of receipt.

You can complete the survey at any time that is convenient to you within the two-week time-frame.

All questions must be answered before the survey can be submitted.

ALL QUESTIONS APPLY TO CRITICALLY ILL PATIENTS IN INTENSIVE CARE.

THANK YOU

On behalf of the research team, thank you for participating.

Delphi Survey 2 Version 1 9 October 2019

RISK ASSESSMENT

Evidence level: international guidelines.

* 1. **In Round 1, the largest group (44%) of panel members agreed that risk assessment should be completed within 2 hours of admission to intensive care.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Following admission to intensive care, pressure injury <u>risk assessment should be completed within 2 hours.</u>

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 2. **In Round 1, the largest groups of panel members agreed that intensive care patients should be reassessed for pressure injury risk once every 8 hours (32%) or once every 24 hours (24%).**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statements:

Intensive care patients should be reassessed for pressure injury risk:

	1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
Once every 8 hours	○	○	○	○	○	○	○	○	○
Once every 24 hours	○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

CONTINENCE

Evidence level: randomised controlled trials.

* 3. **In Round 1, the highest median score (6.5) between risk levels indicated that indwelling urinary catheter entry points should be washed with soap and water, and the catheter should be repositioned to the opposite thigh and secured, three times daily only for patients at HIGH RISK of pressure injury.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Indwelling urinary catheter entry points should be washed with soap and water, and the catheter should be repositioned to the opposite thigh and secured, three times daily only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 4. **In Round 1, the highest median score (8) between risk levels indicated that for intensive care patients who are incontinent of urine and/or faeces, disposable adult incontinence pads should be used for all patients (LOW, MODERATE and HIGH RISK of pressure injury).**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

For intensive care patients who are incontinent of urine and/or faeces, disposable adult incontinence pads (e.g. adult incontinence underpads, briefs, diapers) should be used for all patients (LOW, MODERATE and HIGH RISK of pressure injury).

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

HEEL OFFLOADING

Evidence level: randomised controlled trials.

* 5. **In Round 1, the highest median score (9) between risk levels indicated that pressure should be offloaded from the heels using a heel offloading device only for patients at MODERATE and HIGH RISK of pressure injury.**

A HEEL OFFLOADING DEVICE will remove or relieve pressure from the heels by elevating (suspending, lifting or floating) the heels off the bed or other lying surface. For example, a heel elevation boot may be applied to each heel for an intensive care patient to remove heel pressure while the patient is lying in bed.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Pressure should be offloaded from the heels using a heel offloading device only for patients at MODERATE and HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 2 Version 1 9 October 2019

NUTRITION

Evidence level: randomised controlled trials.

* 6. **In Round 1, the highest median score (8) between risk levels indicated that for intensive care patients who ARE ABLE TO EAT FOOD ORALLY, oral nutritional supplements should be provided in addition to standard nutrition only for patients at HIGH RISK of pressure injury.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

For intensive care patients who ARE ABLE TO EAT FOOD ORALLY, oral nutritional supplements should be provided in addition to standard nutrition only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

PREVENTATIVE DRESSINGS

Evidence level: randomised controlled trials.

* 7. **In Round 1, the highest median score (8) between risk levels indicated that a preventative sacral dressing should be applied only for patients at HIGH RISK of pressure injury.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

A preventative sacral dressing should be applied only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 8. **In Round 1, the highest median score (8) between risk levels indicated that preventative heel dressings should be applied only for patients at HIGH RISK of pressure injury.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Preventative heel dressings should be applied only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 9. **In Round 1, the highest median score (8) between risk levels indicated that preventative trochanteric (hip) dressings should be applied only for patients at HIGH RISK of pressure injury.**

For example, applying preventative dressings to the bony point of both hips.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Preventative trochanteric (hip) dressings should be applied only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 2 Version 1 9 October 2019

REPOSITIONING

Evidence level: international guidelines.

* 10. **PLEASE NOTE: The following question APPLIES TO PATIENTS IN STANDARD BEDS ONLY, NOT AUTOMATED BEDS.**

In Round 1, the largest group (66%) of panel members agreed that patients at LOW RISK of pressure injury should be repositioned at least 4 hourly.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Patients at LOW RISK of pressure injury should be repositioned at least 4 hourly.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 11. **PLEASE NOTE: The following question APPLIES TO PATIENTS IN STANDARD BEDS ONLY, NOT AUTOMATED BEDS.**

In Round 1, the largest group (52%) of panel members agreed that patients at MODERATE RISK of pressure injury should be repositioned at least 2 hourly.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Patients at MODERATE RISK of pressure injury should be repositioned at least 2 hourly.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 12. **PLEASE NOTE: The following question APPLIES TO PATIENTS IN STANDARD BEDS ONLY, NOT AUTOMATED BEDS.**

In Round 1, the largest group (78%) of panel members agreed that patients at HIGH RISK of pressure injury should be repositioned at least 2 hourly.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Patients at HIGH RISK of pressure injury should be repositioned at least 2 hourly.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 2 Version 1 9 October 2019

SUPPORT SURFACES - BED/MATTRESS

Evidence level: randomised controlled trials.

* 13. **In Round 1, the highest median score (5) with the most panel member agreement between risk levels indicated that medical grade sheepskin mattress overlays should be used only for patients at MODERATE and HIGH RISK of pressure injury.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Medical grade sheepskin mattress overlays should be used only for patients at MODERATE and HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 14. **In Round 1, the highest median score (7) with the most panel member agreement between risk levels indicated that reactive mattress support surfaces should be used only for patients at MODERATE and HIGH RISK of pressure injury.**

A REACTIVE support surface is PRESSURE REDUCING. It changes load distribution in response to an applied load (such as the patient's body). The mattress conforms to and surrounds the body. A reactive support surface may be foam, air or fluid, and may be powered or unpowered.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

REACTIVE mattress support surfaces should be used only for patients at MODERATE and HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

* 15. **In Round 1, the highest median score (9) with the most panel member agreement between risk levels indicated that active mattress support surfaces should be used only for patients at HIGH RISK of pressure injury.**

An ACTIVE support surface is PRESSURE RELIEVING. It changes pressure mechanically by alternating pressure. Alternating pressure usually occurs as the mattress automatically inflates and deflates different parts of the mattress. There is no load required on the mattress for it to alternate pressure. Active support surfaces are powered.

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

ACTIVE mattress support surfaces should be used only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 2 Version 1 9 October 2019

SUPPORT SURFACES - SEATING

Evidence level: international guidelines.

* 16. **In Round 1, the highest median score (9) between risk levels indicated that when an intensive care patient is sat out of bed, a pressure redistributing seat cushion should be used only for patients at HIGH RISK of pressure injury.**

Please rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

When an intensive care patient is sat out of bed, a pressure redistributing seat cushion should be used only for patients at HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 2 Version 1 9 October 2019

Appendix D: Phase Two modified Delphi study Round 3 questionnaire

INTRODUCTION

RESEARCH TEAM

Josephine Lovegrove, Paul Fulbrook, Sandra Miles, Michael Steele, Angel Cobos Vargas

ROUND 3

Round 2 of this study has now closed and the results have been analysed. You are now invited to participate in the Round 3 survey. Round 3 is the final round.

This Round 3 survey only contains three interventions that did not meet the criteria for consensus in Round 2.

In this round, you will be asked to again rate your strength of agreement for each intervention for use at a particular risk level.

CONFIDENTIALITY

Although the research team will know your identity, only aggregate data will be reported. Your individual responses will not be reported.

CONSENT

Your consent to participate in this Delphi study will be implied by your completion and submission of each survey.

SUBMISSION

This questionnaire should be submitted online within two weeks of receipt.

You can complete the survey at any time that is convenient to you within the two-week time-frame.

All questions must be answered before the survey can be submitted.

ALL QUESTIONS APPLY TO CRITICALLY ILL PATIENTS IN INTENSIVE CARE.

THANK YOU

On behalf of the research team, thank you for participating.

Delphi Survey 3 Version 1 31 October 2019

RISK ASSESSMENT

Evidence level: international guidelines.

* 1. In Round 2, the highest median score (8) indicated that intensive care patients should be **reassessed for pressure injury risk once every 8 hours**, rather than every 24 hours (median score 5). However, the range of scores was quite wide.

So that we can be certain of the consensus level of agreement of the expert panel, please would you again rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Intensive care patients should be reassessed for pressure injury risk once every 8 hours.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 3 Version 1 23 November 2019

CONTINENCE

Evidence level: randomised controlled trials.

* 2. In Round 2, the expert panel **did not reach consensus** (median score 6) that indwelling urinary catheter entry points should be washed with soap and water, and the catheter should be repositioned to the opposite thigh and secured, three times daily **only for patients at HIGH RISK of pressure injury**. However, there was a wide range of scores.

(In Round 1, there was consensus agreement that the above intervention should not be used for LOW and MODERATE risk patients.)

So that we can be certain of the consensus level of agreement of the expert panel, please would you again rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Indwelling urinary catheter entry points should be washed with soap and water, and the catheter should be repositioned to the opposite thigh and secured, three times daily for patients at HIGH RISK of pressure injury ONLY.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 3 Version 1 23 November 2019

SUPPORT SURFACES

Evidence level: randomised controlled trials.

* 3. In Round 2, the expert panel **did not reach consensus** (median score 6) that medical grade sheepskin mattress overlays should be used **only for patients at MODERATE and HIGH RISK of pressure injury.** However, the range of scores was quite wide.

(In Round 1, there was consensus agreement that the above intervention should not be used for LOW risk patients; or that they should be used for HIGH risk patients ONLY.)

So that we can be certain of the consensus level of agreement of the expert panel, please would you again rate your strength of agreement from 1 (strongly disagree) to 9 (strongly agree) for the following statement:

Medical grade sheepskin mattress overlays should be used only for patients at MODERATE and HIGH RISK of pressure injury.

1 Strongly Disagree	2	3	4	5	6	7	8	9 Strongly Agree
○	○	○	○	○	○	○	○	○

If you wish, please make a comment about your decision:

Delphi Survey 3 Version 1 23 November 2019

Appendix E: Phase Two Modified Delphi study ethics approval

2019-25E Ethics application approved!

Nina Robinson <Nina.Robinson@acu.edu.au>
on behalf of
Res Ethics <Res.Ethics@acu.edu.au>
Fri 14/06/2019 11:23 AM

To: Paul Fulbrook <Paul.Fulbrook@acu.edu.au>
Cc: Sandra Miles <Sandra.Miles@acu.edu.au>; Michael Steele <Michael.Steele@acu.edu.au>; josephine.lovegrove@myacu.edu.au <josephine.lovegrove@myacu.edu.au>; Res Ethics <Res.Ethics@acu.edu.au>

Dear Professor Fulbrook,

Chief Investigator: Professor Paul Fulbrook
Co-Investigators: Sandra Miles, Dr Mike Steele and Angel Cobos Vargas
Student Researcher: Josephine Grace Lovegrove
Ethics Register Number: 2019-25E
Project Title: International consensus on pressure injury preventative interventions by risk level for critically ill patients: a modified Delphi study
Date Approved: 14/06/2019
End Date: 30/06/2020

This is to certify that the above application has been reviewed by the Australian Catholic University Human Research Ethics Committee (ACU HREC). The application has been approved for the period given above.

Continued approval of this research project is contingent upon the submission of an annual progress report which is due on/before each anniversary of the project approval. A final report is due upon completion of the project. A report proforma can be downloaded from the ACU Research Ethics website.

Researchers are responsible for ensuring that all conditions of approval are adhered to and that any modifications to the protocol, including changes to personnel, are approved prior to implementation. In addition, the ACU HREC must be notified of any reportable matters including, but not limited to, incidents, complaints and unexpected issues.

Researchers are also responsible for ensuring that they adhere to the requirements of the National Statement on Ethical Conduct in Human Research, the Australian Code for the Responsible Conduct of Research and the University's Research Code of Conduct.

Any queries relating to this application should be directed to the Ethics Secretariat (res.ethics@acu.edu.au). Please quote your ethics approval number in all communications with us.

If you require a formal approval certificate in addition to this email, please respond via reply email and one will be issued.

We wish you every success with your research.

Kind regards,

Nina Robinson
on behalf of ACU HREC Chair, Assoc Prof. Michael Baker

Research Ethics and Integrity Officer | Office of the Deputy Vice Chancellor (Research) Australian Catholic University
T: +61 2 9739 2646 E: res.ethics@acu.edu.au

Appendix F: Formal COMHON Index translation (English to Mandarin) pilot questionnaire (Chinese Mandarin and English versions)

请使用下面的 COMHON 指数评估 1 名患者

请在下面的图表中圈出最合适的部分:

COMHON 指数 (RASS = Richmond 躁动镇静量表 【Richmond Agitation Sedation Scale】)

分值	意识水平	活动能力	血流动力学	血氧	营养
1	清醒和警觉 (RASS 0, + 1) (格拉斯哥评分 15)	独立的，在帮助下行走	无血流动力学支持	自主呼吸和 FiO_2 < 0.4	完全经口饮食
2	烦躁, 不安, 意识混乱 (RASS > 1) (格拉斯哥评分 13 - 14)	受限制的, 床-椅活动	扩容制剂	自主呼吸和 $FiO_2 \geq 0.4$	肠内或肠外喂养
3	镇静 但有反应 (RASS -1 - -3) (格拉斯哥评分 9 - 12)	非常受限但容许体位改变	多巴胺或去甲肾上腺素或肾上腺素。机械辅助	无创机械通气	经口流质，不完全经口喂养
4	昏迷，镇静和无反应 (RASS < -3) (格拉斯哥评分 < 9)	无法改变体位；俯卧	需要以上两种	有创机械通气	禁食

低风险: 5-9, 中风险: 10-13, 高风险: 14-20

患者总分 = ☐ **风险等级 =** ☐

分量表定义

意识水平

1. ***清醒和警觉: RASS 0 到 +1***
   患者有意识，有时间和空间方向感，服从命令，识别和响应环境中的任何刺激。格拉斯哥昏迷评分 15 分。
2. ***烦躁/不安/意识混乱: RASS > 1***
   患者清醒，但部分或间歇性地对时间和/或空间失去方向感，对刺激反应不充分。格拉斯哥昏迷评分 13 到 14 分。
3. ***镇静但有反应: RASS -1 到 -3***
   患者的格拉斯哥昏迷评分 9 到 12 分，或镇静 RASS-1 到-3。
4. ***昏迷，镇静和无反应: RASS -4 to -5***
   患者昏迷，格拉斯哥昏迷评分<9，或镇静 RASS-4 至-5。

活动能力

1. ***独立/在帮助下行走***
   患者独立行走或需要支持系统来保持平衡。
2. ***受限制的/床-椅活动***
   患者在床上，可以自己移动。患者在椅子上休息的时间和在床上休息时间交替。患者在有协助和无协助下，均可站立。
3. ***非常受限但容许体位改变***
   患者躺在床上，没有协助不能移动，但可以在不影响血流动力学或呼吸状态的情况下移动。
4. ***无法改变体位或者俯卧***
   患者躺在床上，因血流动力学或呼吸不稳定而严禁移动，或患者俯卧位。

血流动力学

1. ***无血流动力学支持***
   患者不需要血管升压药物或血浆扩容制剂或机械血流动力学支持（如主动脉内球囊泵）。
2. ***扩容制剂***
   患者需要使用血液制品、胶体或晶体溶液来维持血流动力学状态。
3. ***多巴胺或去甲肾上腺素或肾上腺素或心肺机械辅助***
   患者需要通过持续输注以上的一种或更多的药物或心肺机械辅助，如主动脉内球囊泵、体外膜氧合、心室辅助装置，来维持血流动力学稳定性。
4. ***需要以上两种***
   患者需要两个或更多的上述支持，以维持血流动力学的稳定性。

血氧

1. ***自主呼吸和低 FiO_2 (< .4)***
   患者自主呼吸，不需要额外的吸氧或少于 40%。
2. ***自主呼吸和高 FiO_2 ($\geq$ .4)***
   患者自主呼吸，需要大于 40%的额外吸氧。
3. ***无创机械通气***
   患者需要无创机械通气。
4. ***有创机械通气***
   患者需要有创机械通气。

营养

1. ***完全经口饮食***
   患者能吃液体和固体食物，并且吃了足够的食物来满足他们的需要。
2. ***肠内营养/肠外喂养***
   患者正在接受肠外营养、肠内营养或两者兼有，也可能部分经口进食或完全不经口进食。
3. ***经口流质，不完全经口喂养***
   患者不足或减少饮食且未满足他们的需要，以及没有进行肠内或肠内喂养。
4. ***禁食***
   患者被禁食。

COMHON 指数评估患者后，请回答以下问题：

每个问题请提供一个答案.

总体
总的来说，使用 COMHON 指数评估您的患者有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
计算患者的**总分**多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
确定患者的压力损伤风险水平（**低、中或高风险**）有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
您用 COMHON 指数评估您的病人花了多长时间？ (1) 1 至 5 分钟 (2) 6 至 10 分钟 (3) 11 至 15 分钟 (4) 超过 15 分钟
意识水平
使用**意识水平**部分评估您的患者有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
意识水平部分的定义有多容易理解？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
意识水平部分有什么地方难以理解吗？ (1) 没有 (2) 有：请描述：
活动能力
使用**活动能力**部分评估您的患者有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
活动能力部分的定义有多容易理解？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
活动能力部分有什么地方难以理解吗？ (1) 没有 (2) 有：请描述：

血流动力学
使用**血流动力学**部分评估您的患者有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
血流动力学部分的定义有多容易理解？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
血流动力学部分有什么地方难以理解吗？ (1) 没有 (2) 有：请描述：
血氧
使用**血氧**部分评估您的患者有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
血氧部分的定义有多容易理解？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
血氧部分有什么地方难以理解吗？ (1) 没有 (2) 有：请描述：
营养
使用**营养**部分评估您的患者有多容易？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
营养部分的定义有多容易理解？ (1) 非常困难 (2) 困难 (3) 中等 (4) 容易 (5) 非常容易
营养部分有什么地方难以理解吗？ (1) 没有 (2) 有：请描述：

PLEASE ASSESS ONE PATIENT USING THE COMHON INDEX BELOW

Please circle the most appropriate sections of the chart below:

The COMHON Index (RASS = Richmond Agitation Sedation Scale)

Score	Level of consciousness	Mobility	Haemodynamic	Oxygenation	Nutrition
1	Awake and alert (RASS 0, + 1) (Glasgow 15)	Independent, walking with help	No haemodynamic support	Spontaneous breathing and $FiO_2 < 0.4$	Full oral diet
2	Agitated, restless, confused (RASS > 1) (Glasgow 13 - 14)	Limited, bed-chair activity	Volume expanders	Spontaneous breathing and $FiO_2 \geq 0.4$	Enteral or parenteral feeding
3	Sedated but responsive (RASS -1 to -3) (Glasgow 9 - 12)	Very limited but tolerates position change	Dopamine or norepinephrine or adrenaline. Mechanical support	Non-invasive mechanical ventilation	Oral fluids. Incomplete oral feeding
4	Coma, sedated and unresponsive (RASS < -3) (Glasgow < 9)	Unable to change position; lying prone	Needing two of the above	Invasive mechanical ventilation	No feeding

LOW RISK: 5-9, MODERATE RISK: 10-13, HIGH RISK: 14-20

TOTAL PATIENT SCORE = ☐ **RISK LEVEL =** ☐

SUBSCALE DEFINITIONS

Level of consciousness

1. ***Awake and alert: RASS 0 to + 1***
   The patient is conscious and orientated to time and space, obeys commands and recognises and responds to any stimulus in their environment. Glasgow Coma Score 15.
2. ***Agitated/restless/confused: RASS > 1***
   The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score 13 to 14.
3. ***Sedated but responsive: RASS -1 to -3***
   The patient has a Glasgow Coma Score of 9 to 12 or is sedated with RASS -1 to -3.
4. ***Coma, sedated and unresponsive: RASS -4 to -5***
   The patient is comatose with Glasgow Coma Score < 9 or sedated with RASS -4 to -5.

Mobility

1. ***Independent/walking with help***
   The patient walks alone or needs a support system to maintain balance.
2. ***Limited/bed-armchair activity***
   The patient is in bed and can move on their own. The patient has alternating periods of bed rest with periods of rest in a chair. The patient can stand up with or without assistance.
3. ***Very limited but tolerates change in position***
   The patient is in bed and cannot move without assistance but can be moved without affecting haemodynamic or respiratory status.
4. ***Unable to change position or lying prone***
   The patient is in bed and must not be moved due to haemodynamic or respiratory instability or the patient is lying in the prone position.

Haemodynamic

1. ***No haemodynamic support***
   The patient does not require vasopressor drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).
2. ***Volume expanders***
   The patient requires use of blood products, colloid or crystalloid to maintain haemodynamic status.
3. ***Dopamine or norepinephrine or adrenaline or cardiopulmonary mechanical support***
   The patient requires one or more of the above drugs by continuous infusion or cardiopulmonary mechanical assistance e.g. intra-aortic balloon pump, extra-corporeal membrane oxygenation, ventricular assist device, to maintain haemodynamic stability.
4. ***Needing two of the above***
   The patient requires two or more of the above supports to maintain haemodynamic stability.

Oxygenation

1. ***Spontaneous breathing and low FiO_2 (< .4)***
   The patient is breathing by themself and requires no extra oxygen or less then 40%.
2. ***Spontaneous breathing and high FiO_2 ($\geq$ .4)***
   The patient is breathing by themself and requires supplementary oxygen greater than 40%.
3. ***Non-invasive mechanical ventilation***
   The patient requires non-invasive mechanical ventilation.
4. ***Invasive mechanical ventilation***
   The patient requires invasive mechanical ventilation.

Nutrition

1. ***Full oral diet***
   The patient tolerates liquids and solids and is eating enough food to meet their needs.
2. ***Enteral nutrition / parenteral feeding***
   The patient is being fed with parenteral nutrition, enteral nutrition or both and may also be partially eating orally or not eating at all.
3. ***Oral fluids. Incomplete oral feeding***
   The patient has an inadequate or reduced diet that does not meet their needs and is not being enterally or parentally fed.
4. ***No feeding***
   The patient is not being fed at all.

AFTER USING THE COMHON INDEX TO ASSESS YOUR PATIENT, PLEASE ANSWER THE FOLLOWING QUESTIONS.

PLEASE PROVIDE ONLY ONE RESPONSE TO EACH QUESTION.

OVERALL
Overall, how easy was it to assess your patient using the COMHON Index? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy was it calculate your patient's TOTAL score? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy was it to identify your patient's level of pressure injury risk (LOW, MODERATE or HIGH risk)? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How long did it take you to assess your patient using the COMHON Index? (1) 1 to 5 minutes (2) 6 to 10 minutes (3) 11 to 15 minutes (4) Over 15 minutes
LEVEL OF CONCIOUSNESS
How easy was it to assess your patient using the **LEVEL OF CONCIOUSNESS** section? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy were the **LEVEL OF CONCIOUSNESS** definitions to understand? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
Were there any areas of the **LEVEL OF CONCIOUSNESS** section that were difficult to understand? (1) No (2) Yes: please describe:
MOBILITY
How easy was it to assess your patient using the **MOBILITY** section? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy were the **MOBILITY** definitions to understand? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
Were there any areas of the **MOBILITY** section that were difficult to understand? (1) No (2) Yes: please describe:

HAEMODYNAMIC
How easy was it to assess your patient using the **HAEMODYNAMIC** section? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy were the **HAEMODYNAMIC** definitions to understand? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
Were there any areas of the **HAEMODYNAMIC** section that were difficult to understand? (1) No (2) Yes: please describe:
OXYGENATION
How easy was it to assess your patient using the **OXYGENATION** section? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy were the **OXYGENATION** definitions to understand? Please circle an answer: (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
Were there any areas of the **OXYGENATION** section that were difficult to understand? (1) No (2) Yes: please describe:
NUTRITION
How easy was it to assess your patient using the **NUTRITION** section? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
How easy were the **NUTRITION** definitions to understand? (1) Very difficult (2) Difficult (3) Medium (4) Easy (5) Very easy
Were there any areas of the **NUTRITION** section that were difficult to understand? (1) No (2) Yes: please describe:

Appendix G: COMHON Index Version 2.0 (Spanish and English versions)

Índice COMHON

Versión en español

Puntuación	NIVEL DE CONCIENCIA	MOVILIDAD	HEMODINAMICA	OXIGENACION	NUTRICION
1	Despierto y alerta (RASS 0 , + 1) (Glasgow 15)	Independiente. Deambula con ayuda	Sin soporte hemodinámico	Respiración espontánea y $FiO_2 < 0.4$	Dieta oral completa
2	Agitado. Inquieto. Confuso (RASS > +1) (Glasgow 13 - 14)	Limitada. Actividad cama-sillón	Con expansores plasmáticos	Respiración espontánea y $FiO_2 \geq 0.4$	Nutrición enteral Nutrición parenteral
3	Sedado con respuesta a estímulos. (RASS -1 a -3) (Glasgow 9 - 12)	Muy limitada, pero tolera cambios posturales	Perfusión de dopamina, adrenalina o noradrenalina. O uso de dispositivos de apoyo cardiopulmonares	Ventilación Mecánica no invasiva	Dieta oral líquida. Ingesta incompleta de alimentos
4	Coma. Sedado sin respuesta a estímulos. (RASS -4,-5) (Glasgow < 9)	No tolera cambios posturales. Decúbito prono	Con más de dos apoyos hemodinámicos de los anteriores	Ventilación mecánica invasiva	Dieta absoluta

BAJO RIESGO: 5-9, RIESGO MODERADO: 10-13, ALTO RIESGO: 14-20

DEFINICIONES DE LAS SUBESCALAS

Nivel de conciencia_____

1. ***Despierto y alerta: RASS: 0, +1***
   Paciente consciente y orientado en tiempo y espacio, obedece órdenes, responde y reconoce cualquier estimulo de su entorno. Paciente con Glasgow 15

2. ***Agitado. Inquieto. Confuso: RASS: > +1***
   Consciente, desorientado parcialmente o intermitentemente en tiempo y/o espacio. Respuesta inadecuada a estímulos. Paciente con Glasgow 13 a 14

3. ***Sedado con respuesta a estímulos: RASS -1 a -3***
   Paciente con Glasgow 9 a 12, o sedado con RASS -1 a -3.

4. ***Coma, sedado sin respuesta a estímulos: RASS -4 a -5***
   Paciente comatoso con Glasgow < 9, o sedado con RASS -4 a -5.

Movilidad_____

1. ***Independiente/Deambula con Ayuda***
   Paciente que camina solo o precisa algún sistema de apoyo para mantener el equilibrio

2. ***Limitada. Actividad Cama-Sillón***
   Paciente encamado que se moviliza el solo. Alterna periodos de reposo en cama con periodos de reposo en sillón. Puede mantenerse en pie con o sin ayuda.

3. ***Muy limitada, pero tolera cambios posturales***
   Paciente encamado que no se moviliza por sí sólo, pero al que se le pueden realizar cambios posturales sin repercusión hemodinámica ni respiratoria.

4. ***No tolera cambios posturales/Decúbito Prono***
   Paciente encamado que no se moviliza el solo ni existe posibilidad de cambios posturales. No debe movilizarse por inestabilidad hemodinámica o respiratoria.
   Paciente en decúbito prono.

Hemodinámica_____

1. ***Sin soporte hemodinámico***
   Paciente sin fármacos vasopresores, ni expansores plasmáticos ni dispositivos mecánicos de apoyo hemodinámico (ej: balón de contrapulsación intraaórtico).

2. ***Con expansores plasmáticos***
   Paciente que precisa de administración de hemoderivados, coloides o cristaloides para el mantenimiento de su hemodinámica.

3. ***Dopamina, adrenalina, noradrenalina o algún dispositivo de apoyo cardiopulmonar***
   El paciente requiere una de estas drogas en perfusión continua o de algún dispositivo de apoyo mecánico, ej: balón de contrapulsación intraaórtico, oxigenación por membrana extracorpórea, dispositivos de apoyo ventricular, para el mantenimiento de la hemodinámica

4. ***Con más de dos apoyos de los anteriormente descritos***
   El paciente requiere de más de dos apoyos de los anteriormente descritos para el mantenimiento de la hemodinámica.

Oxigenación_____

1. ***Respiración espontánea y baja FiO_2 (< 0.4)***
   Paciente que respira por si solo y que precisa aporte extra de oxígeno inferior al 40%.

2. ***Respiración espontánea y alta FiO_2 (≥ 0.4)***
   Paciente que respira por si solo y que precisa aporte extra de oxígeno superior al 40%.

3. ***Ventilación mecánica no invasiva***
   El paciente requiere de ventilación mecánica no invasiva.

4. ***Ventilación mecánica invasiva***
   El paciente requiere de ventilación mecánica invasiva.

Nutrición_____

1. ***Dieta oral completa***
   Tolera líquidos y sólidos, manteniendo ingesta de alimentos que satisfacen sus necesidades

2. ***Nutrición Enteral / parenteral***
   Paciente con nutrición parenteral, enteral o ambas. El paciente puede estar simultáneamente ingiriendo algún alimento vía oral.

3. ***Dieta oral líquida/ ingesta incompleta de alimentos***
   Paciente con dieta inadecuada o incompleta para satisfacer sus necesidades y no estás siendo alimentado por vía enteral o parenteral

4. ***Dieta absoluta***
   Paciente sin ningún tipo de aporte nutricional.

The COMHON Index (RASS = Richmond Agitation Sedation Scale)

Score	Level of consciousness	Mobility	Haemodynamic	Oxygenation	Nutrition
1	Awake and alert (RASS 0, + 1) (Glasgow 15)	Independent, walking with help	No haemodynamic support	Spontaneous breathing and $FiO_2 < 0.4$	Full oral diet
2	Agitated, restless, confused (RASS > 1) (Glasgow 13 - 14)	Limited, bed-chair activity	Volume expanders	Spontaneous breathing and $FiO_2 \geq 0.4$	Enteral or parenteral feeding
3	Sedated but responsive (RASS -1 to -3) (Glasgow 9 - 12)	Very limited but tolerates position change	Dopamine or norepinephrine or adrenaline. Mechanical support	Non-invasive mechanical ventilation	Oral fluids. Incomplete oral feeding
4	Coma, sedated and unresponsive (RASS < -3) (Glasgow < 9)	Unable to change position; lying prone	Needing two of the above	Invasive mechanical ventilation	No feeding

LOW RISK: 5-9, MODERATE RISK: 10-13, HIGH RISK: 14-20

SUBSCALE DEFINITIONS

Level of consciousness

1. ***Awake and alert: RASS 0 to + 1***
   The patient is conscious and orientated to time and space, obeys commands and recognises and responds to any stimulus in their environment. Glasgow Coma Score 15.
2. ***Agitated/restless/confused: RASS > 1***
   The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score 13 to 14.
3. ***Sedated but responsive: RASS -1 to -3***
   The patient has a Glasgow Coma Score of 9 to 12 or is sedated with RASS -1 to -3.
4. ***Coma, sedated and unresponsive: RASS -4 to -5***
   The patient is comatose with Glasgow Coma Score < 9 or sedated with RASS -4 to -5.

Mobility

1. ***Independent/walking with help***
   The patient walks alone or needs a support system to maintain balance.
2. ***Limited/bed-armchair activity***
   The patient is in bed and can move on their own. The patient has alternating periods of bed rest with periods of rest in a chair. The patient can stand up with or without assistance.
3. ***Very limited but tolerates change in position***
   The patient is in bed and cannot move without assistance but can be moved without affecting haemodynamic or respiratory status.
4. ***Unable to change position or lying prone***
   The patient is in bed and must not be moved due to haemodynamic or respiratory instability or the patient is lying in the prone position.

Haemodynamic

1. ***No haemodynamic support***
   The patient does not require vasopressor drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).
2. ***Volume expanders***
   The patient requires use of blood products, colloid or crystalloid to maintain haemodynamic status.
3. ***Dopamine or norepinephrine or adrenaline or cardiopulmonary mechanical support***
   The patient requires one or more of the above drugs by continuous infusion or cardiopulmonary mechanical assistance e.g. intra-aortic balloon pump, extra-corporeal membrane oxygenation, ventricular assist device, to maintain haemodynamic stability.
4. ***Needing two of the above***
   The patient requires two or more of the above supports to maintain haemodynamic stability.

Oxygenation

1. ***Spontaneous breathing and low FiO_2 (< .4)***
   The patient is breathing by themself and requires no extra oxygen or less then 40%.
2. ***Spontaneous breathing and high FiO_2 ($\geq$ .4)***
   The patient is breathing by themself and requires supplementary oxygen greater than 40%.
3. ***Non-invasive mechanical ventilation***
   The patient requires non-invasive mechanical ventilation.
4. ***Invasive mechanical ventilation***
   The patient requires invasive mechanical ventilation.

Nutrition

1. ***Full oral diet***
   The patient tolerates liquids and solids and is eating enough food to meet their needs.
2. ***Enteral nutrition / parenteral feeding***
   The patient is being fed with parenteral nutrition, enteral nutrition or both and may also be partially eating orally or not eating at all.
3. ***Oral fluids. Incomplete oral feeding***
   The patient has an inadequate or reduced diet that does not meet their needs and is not being enterally or parentally fed.
4. ***No feeding***
   The patient is not being fed at all.

Version 2, 2021

Appendix H: COMHON Index Version 2.1 (Spanish, English and Chinese Mandarin versions)

Índice COMHON

Por favor, marque con un círculo las secciones más apropiadas de la siguiente tabla:

Puntuación	NIVEL DE CONCIENCIA	MOVILIDAD	HEMODINAMICA	OXIGENACIÓN	NUTRICIÓN
1	Despierto y alerta (RASS 0 , + 1) (Glasgow 15)	Independiente. Deambula con ayuda	Sin soporte hemodinámico	Respiración espontánea y $FiO_2 < 0.4$	Dieta oral completa
2	Agitado. Inquieto. Confuso (RASS > +1) (Glasgow 13 - 14)	Limitada. Actividad cama-sillón	Con expansores plasmáticos	Respiración espontánea y $FiO_2 \geq 0.4$	Nutrición enteral Nutrición parenteral
3	Sedado con respuesta a estímulos. (RASS -1 a -3) (Glasgow 9 - 12)	Muy limitada, pero tolera cambios posturales	Perfusión de dopamina, adrenalina o noradrenalina. O uso de dispositivos de apoyo cardiopulmonares	Ventilación Mecánica no invasiva	Dieta oral líquida. Ingesta incompleta de alimentos
4	Coma. Sedado sin respuesta a estímulos. (RASS -4,-5) (Glasgow < 9)	No tolera cambios posturales. Decúbito prono	Con más de dos apoyos hemodinámicos de los anteriores	Ventilación mecánica invasiva	Dieta absoluta

BAJO RIESGO: 5-9, RIESGO MODERADO: 10-13, ALTO RIESGO: 14-20

PUNTUACIÓN TOTAL = ☐ **NIVEL DE RIESGO =** ☐

Version 2.1, 2021

DEFINICIONES DE LAS SUBESCALAS

Nivel de conciencia

1. ***Despierto y alerta: RASS: 0, +1***
   Paciente consciente y orientado en tiempo y espacio, obedece órdenes, responde y reconoce cualquier estimulo de su entorno. Paciente con Glasgow 15
2. ***Agitado. Inquieto. Confuso: RASS: > +1***
   Consciente, desorientado parcialmente o intermitentemente en tiempo y/o espacio. Respuesta inadecuada a estímulos. Paciente con Glasgow 13 a 14
3. ***Sedado con respuesta a estímulos: RASS -1 a -3***
   Paciente con Glasgow 9 a 12, o sedado con RASS -1 a -3.
4. ***Coma, sedado sin respuesta a estímulos: RASS -4 a -5***
   Paciente comatoso con Glasgow < 9, o sedado con RASS -4 a -5.

Movilidad

1. ***Independiente/Deambula con Ayuda***
   Paciente que camina solo o precisa algún sistema de apoyo para mantener el equilibrio
2. ***Limitada. Actividad Cama-Sillón***
   Paciente encamado que se moviliza el solo. Alterna periodos de reposo en cama con periodos de reposo en sillón. Puede mantenerse en pie con o sin ayuda.
3. ***Muy limitada, pero tolera cambios posturales***
   Paciente encamado que no se moviliza por sí sólo, pero al que se le pueden realizar cambios posturales sin repercusión hemodinámica ni respiratoria.
4. ***No tolera cambios posturales/Decúbito Prono***
   Paciente encamado que no se moviliza el solo ni existe posibilidad de cambios posturales. No debe movilizarse por inestabilidad hemodinámica o respiratoria.
   Paciente en decúbito prono.

Hemodinámica

1. ***Sin soporte hemodinámico***
   Paciente sin fármacos vasopresores, ni expansores plasmáticos ni dispositivos mecánicos de apoyo hemodinámico (ej: balón de contrapulsación intraaórtico).
2. ***Con expansores plasmáticos***
   Paciente que precisa de administración de hemoderivados, coloides o cristaloides para el mantenimiento de su hemodinámica.
3. ***Dopamina, adrenalina, noradrenalina o algún dispositivo de apoyo cardiopulmonar***
   El paciente requiere una de estas drogas en perfusión continua o de algún dispositivo de apoyo mecánico, ej: balón de contrapulsación intraaórtico, oxigenación por membrana extracorpórea, dispositivos de apoyo ventricular, para el mantenimiento de la hemodinámica
4. ***Con más de dos apoyos de los anteriormente descritos***
   El paciente requiere de más de dos apoyos de los anteriormente descritos para el mantenimiento de la hemodinámica.

Oxigenación

1. ***Respiración espontánea y baja FiO_2 (< 0.4)***
   Paciente que respira por si solo y que precisa aporte extra de oxígeno inferior al 40%.
2. ***Respiración espontánea y alta FiO_2 ($\geq$ 0.4)***
   Paciente que respira por si solo y que precisa aporte extra de oxígeno superior al 40%.
3. ***Ventilación mecánica no invasiva***
   El paciente requiere de ventilación mecánica no invasiva.
4. ***Ventilación mecánica invasiva***
   El paciente requiere de ventilación mecánica invasiva.

Nutrición

1. ***Dieta oral completa***
   Tolera líquidos y sólidos, manteniendo ingesta de alimentos que satisfacen sus necesidades
2. ***Nutrición Enteral / parenteral***
   Paciente con nutrición parenteral, enteral o ambas. El paciente puede estar simultáneamente ingiriendo algún alimento vía oral.
3. ***Dieta oral líquida/ ingesta incompleta de alimentos***
   Paciente con dieta inadecuada o incompleta para satisfacer sus necesidades y no está siendo alimentado por vía enteral o parenteral
4. ***Dieta absoluta***
   Paciente sin ningún tipo de aporte nutricional.

The COMHON Index (RASS = Richmond Agitation Sedation Scale)

Please circle the most appropriate sections of the chart below:

Score	Level of consciousness	Mobility	Haemodynamic	Oxygenation	Nutrition
1	Awake and alert (RASS 0, + 1) (Glasgow 15)	Independent, walking with help	No haemodynamic support	Spontaneous breathing and $FiO_2 < 0.4$	Full oral diet
2	Agitated, restless, confused (RASS > 1) (Glasgow 13 - 14)	Limited, bed-chair activity	Volume expanders	Spontaneous breathing and $FiO_2 \geq 0.4$	Enteral or parenteral feeding
3	Sedated but responsive (RASS -1 to -3) (Glasgow 9 - 12)	Very limited but tolerates position change	Dopamine or norepinephrine or adrenaline. Mechanical support	Non-invasive mechanical ventilation	Oral fluids. Incomplete oral feeding
4	Coma, sedated and unresponsive (RASS < -3) (Glasgow < 9)	Unable to change position; lying prone	Needing two of the above	Invasive mechanical ventilation	No feeding

LOW RISK: 5-9, MODERATE RISK: 10-13, HIGH RISK: 14-20

TOTAL PATIENT SCORE = ____ **RISK LEVEL =** ____

SUBSCALE DEFINITIONS

Level of consciousness

1. ***Awake and alert: RASS 0 to + 1***
   The patient is conscious and orientated to time and space, obeys commands and recognises and responds to any stimulus in their environment. Glasgow Coma Score 15.
2. ***Agitated/restless/confused: RASS > 1***
   The patient is aware but is partially or intermittently disorientated to time and/or space and responds inadequately to stimuli. Glasgow Coma Score 13 to 14.
3. ***Sedated but responsive: RASS -1 to -3***
   The patient has a Glasgow Coma Score of 9 to 12 or is sedated with RASS -1 to -3.
4. ***Coma, sedated and unresponsive: RASS -4 to -5***
   The patient is comatose with Glasgow Coma Score < 9 or sedated with RASS -4 to -5.

Mobility

1. ***Independent/walking with help***
   The patient walks alone or needs a support system to maintain balance.
2. ***Limited/bed-armchair activity***
   The patient is in bed and can move on their own. The patient has alternating periods of bed rest with periods of rest in a chair. The patient can stand up with or without assistance.
3. ***Very limited but tolerates change in position***
   The patient is in bed and cannot move without assistance but can be moved without affecting haemodynamic or respiratory status.
4. ***Unable to change position or lying prone***
   The patient is in bed and must not be moved due to haemodynamic or respiratory instability or the patient is lying in the prone position.

Haemodynamic

1. ***No haemodynamic support***
   The patient does not require vasopressor drugs or plasma expanders or mechanical haemodynamic support (e.g. intra-aortic balloon pump).
2. ***Volume expanders***
   The patient requires use of blood products, colloid or crystalloid to maintain haemodynamic status.
3. ***Dopamine or norepinephrine or adrenaline or cardiopulmonary mechanical support***
   The patient requires one or more of the above drugs by continuous infusion or cardiopulmonary mechanical assistance e.g. intra-aortic balloon pump, extra-corporeal membrane oxygenation, ventricular assist device, to maintain haemodynamic stability.
4. ***Needing two of the above***
   The patient requires two or more of the above supports to maintain haemodynamic stability.

Oxygenation

1. ***Spontaneous breathing and low FiO_2 (< .4)***
   The patient is breathing by themself and requires no extra oxygen or less then 40%.
2. ***Spontaneous breathing and high FiO_2 ($\geq$ .4)***
   The patient is breathing by themself and requires supplementary oxygen greater than 40%.
3. ***Non-invasive mechanical ventilation***
   The patient requires non-invasive mechanical ventilation.
4. ***Invasive mechanical ventilation***
   The patient requires invasive mechanical ventilation.

Nutrition

1. ***Full oral diet***
   The patient tolerates liquids and solids and is eating enough food to meet their needs.
2. ***Enteral nutrition / parenteral feeding***
   The patient is being fed with parenteral nutrition, enteral nutrition or both and may also be partially eating orally or not eating at all.
3. ***Oral fluids. Incomplete oral feeding***
   The patient has an inadequate or reduced diet that does not meet their needs and is not being enterally or parentally fed.
4. ***No feeding***
   The patient is not being fed at all.

Version 2.1, 2021

COMHON 指数 (RASS = Richmond 躁动镇静量表 【Richmond Agitation Sedation Scale】)

请在下面的图表中圈出最合适的部分:

分值	意识水平	活动能力	血流动力学	血氧	营养
1	清醒和警觉 (RASS 0, + 1) (格拉斯哥评分 15)	独立的，在帮助下行走	无血流动力学支持	自主呼吸和 $FiO_2 < 0.4$	完全经口饮食
2	烦躁, 不安, 意识混乱 (RASS > 1) (格拉斯哥评分 13 - 14)	受限制的, 床-椅活动	扩容制剂	自主呼吸和 $FiO_2 \geq 0.4$	肠内或肠外喂养
3	镇静 但有反应 (RASS -1 - -3) (格拉斯哥评分 9 - 12)	非常受限但容许体位改变	多巴胺或去甲肾上腺素或肾上腺素。机械辅助	无创机械通气	经口流质，不完全经口喂养
4	昏迷，镇静和无反应 (RASS < -3) (格拉斯哥评分 < 9)	无法改变体位；俯卧	需要以上两种	有创机械通气	禁食

低风险: 5-9, 中风险: 10-13, 高风险: 14-20

患者总分 = ____ **风险等级 =** ____

分量表定义

意识水平

1. ***清醒和警觉: RASS 0 到 +1***
   患者有意识，有时间和空间方向感，服从命令，识别和响应环境中的任何刺激。格拉斯哥昏迷评分 15 分。
2. ***烦躁/不安/意识混乱: RASS > 1***
   患者清醒，但部分或间歇性地对时间和/或空间失去方向感，对刺激反应不充分。格拉斯哥昏迷评分 13 到 14 分。
3. ***镇静但有反应: RASS -1 到 -3***
   患者的格拉斯哥昏迷评分 9 到 12 分，或镇静 RASS-1 到-3。
4. ***昏迷，镇静和无反应: RASS -4 to -5***
   患者昏迷，格拉斯哥昏迷评分<9，或镇静 RASS-4 至-5。

活动能力

1. ***独立/在帮助下行走***
   患者独立行走或需要支持系统来保持平衡。
2. ***受限制的/床-椅活动***
   患者在床上，可以自己移动。患者在椅子上休息的时间和在床上休息时间交替。患者在有协助和无协助下，均可站立。
3. ***非常受限但容许体位改变***
   患者躺在床上，没有协助不能移动，但可以在不影响血流动力学或呼吸状态的情况下移动。
4. ***无法改变体位或者俯卧***
   患者躺在床上，因血流动力学或呼吸不稳定而严禁移动，或患者俯卧位。

血流动力学

1. ***无血流动力学支持***
   患者不需要血管升压药物或血浆扩容制剂或机械血流动力学支持（如主动脉内球囊泵）。
2. ***扩容制剂***
   患者需要使用血液制品、胶体或晶体溶液来维持血流动力学状态。
3. ***多巴胺或去甲肾上腺素或肾上腺素或心肺机械辅助***
   患者需要通过持续输注以上的一种或更多的药物或心肺机械辅助，如主动脉内球囊泵、体外膜氧合、心室辅助装置，来维持血流动力学稳定性。
4. ***需要以上两种***
   患者需要两个或更多的上述支持，以维持血流动力学的稳定性。

血氧

1. ***自主呼吸和低 FiO_2 (< .4)***
   患者自主呼吸，不需要额外的吸氧或少于 40%。
2. ***自主呼吸和高 FiO_2 (≥ .4)***
   患者自主呼吸，需要大于 40%的额外吸氧。
3. ***无创机械通气***
   患者需要无创机械通气。
4. ***有创机械通气***
   患者需要有创机械通气。

营养

1. ***完全经口饮食***
   患者能吃液体和固体食物，并且吃了足够的食物来满足他们的需要。
2. ***肠内营养/肠外喂养***
   患者正在接受肠外营养、肠内营养或两者兼有，也可能部分经口进食或完全不经口进食。
3. ***经口流质，不完全经口喂养***
   患者不足或减少饮食且未满足他们的需要，以及没有进行肠内或肠内喂养。
4. ***禁食***
   患者被禁食。

版本 2.1, 2021

Appendix I: Phase Three translation and interrater reliability study ethics approval (Australian Catholic University)

[2021-17H] - Ethics application approved!

Kylie Pashley <Kylie.Pashley@acu.edu.au>
on behalf of
Res Ethics <Res.Ethics@acu.edu.au>
Tue 20/04/2021 2:21 PM

To: Paul Fulbrook <paul.fulbrook@acu.edu.au>; Josephine Lovegrove <josephine.lovegrove@myacu.edu.au>
Cc: Res Ethics <Res.Ethics@acu.edu.au>

Dear Applicant,

Chief Investigator: Professor Paul Fulbrook
C0-Investigators: Sandra Miles, Dr Mike Steele, Lin Zhang, Xian-Liang Liu, Mr Angel Cobas Vargas
Student Researcher: Josephine Lovegrove
Ethics Register Number: 2021-17H
Project Title: Interrater reliability, agreement and concurrent validity of a pressure injury risk assessment scale (the COMHON Index) in a Chinese intensive care setting
Date Approved: 20/04/2021
End Date: 30/04/2022

This is to certify that the above human ethics application has been reviewed by the Australian Catholic University Human Research Ethics Committee (ACU HREC). The application has been approved for the period given above.

Continued approval of this research project is contingent upon the submission of an annual progress report which is due on/before each anniversary of the project approval. A final report is due upon completion of the project. A report proforma can be downloaded from the ACU Research Ethics website.

Researchers are responsible for ensuring that all conditions of approval are adhered to and that any modifications to the protocol, including changes to personnel, are approved prior to implementation. In addition, the ACU HREC must be notified of any reportable matters including, but not limited to, incidents, complaints and unexpected issues.

Researchers are also responsible for ensuring that they adhere to the requirements of the National Statement on Ethical Conduct in Human Research, the Australian Code for the Responsible Conduct of Research and the University's Research Code of Conduct.

Any queries relating to this application should be directed to the Ethics Secretariat (res.ethics@acu.edu.au). Please quote your ethics approval number in all communications with us.

We wish you every success with your research.

Kind regards,

Kylie Pashley
on behalf of ACU HREC Chair, Assoc Prof. Michael Baker

Senior Research Ethics Officer | Research Services | Office of the Deputy Vice-Chancellor (Research)
Australian Catholic University
T: +61 2 9739 2646 E: res.ethics@acu.edu.au

Appendix J: Phase Three translation and interrater reliability study ethics approvals (Tenth People's Hospital of Tongji University) (Chinese Mandarin and English translation)

上海市第十人民医院伦理委员会审批件

声明：本伦理委员会按照国家卫计委和 CFDA 有关法规组成和工作，其审查和工作过程不受伦理委员会以外任何组织及个人的影响。

批件号：SHSY-IEC-4.1/20-258/01

审查日期：	2020-12-23, 12-25	本院伦理号：	20K170
审查会议地点：	NA	试验产品名称：	NA
研究项目名称：	压疮风险评估量表（COMHON 指数）中文版信度、一致性和同时效度研究		
审查文件：	详见随附“上海市第十人民医院伦理委员会审查文件清单”		
申办者/CRO：	NA		
组长单位名称：	NA		
主要研究者：	张琳	本院研究者/科室：	张琳/中医科
审查类别：	初始审查 √　复审□　修正案审查□　其他_____□		
伦理审查方式：	会议审查□　快速审查 √　紧急会议审查□		
主审委员：	于学靖 傅军		
审查结果：	1. 同意 √　修改后同意□　修改后重审□　不同意□ 2. 伦理委员会对该研究实施过程的年度/定期跟踪审查：是 √ 否□ 审查频度为研究批准之日起：3 个月□6 个月□ 12 个月 √ 3. 伦理委员会有权根据实际进展情况改变年度/定期跟踪审查频度。 4. 自批准之日起一年内项目未启动，该批件自动失效。		

主任或副主任委员签字：徐静旺
上海市第十人民医院伦理委员会（盖章）
日期：2020-12-30

注意：（请仔细阅读）

1. 本伦理委员会批准的项目为涉及人体的生物医学研究，必须严格按照所批最新版本的研究方案和知情同意书开展研究，并遵循国内相关法规指南要求。
2. 凡是涉及人类遗传资源出口或者按照国家规定必须经有关部门专项审批的内容，均需在项目执行前向有关部门申报并获得批准。
3. 本批件可能用于其他中心伦理委员会参考，如果对方案审查存在不同意见，请及时与本伦理委员会沟通。
4. 对已批准的研究方案、知情同意书等材料的任何修改及主要研究者更换等，须及时通知本伦理委员会重新审查，获得批准后执行。
5. 发生严重不良事件及影响研究风险受益比的非预期事件，须及时报告本伦理委员会。
6. 根据伦理委员会对年度/定期跟踪审查频度的意见，无论研究开始与否，请在年度/定期跟踪审查日到期前 1 个月提出年度/定期跟踪审查的申请。
7. 发现不依从/违反方案情况须及时报告伦理委员会审查。
8. 暂停/提前终止临床研究，请及时通知伦理委员会。
9. 完成研究，须提交结题报告供伦理委员会审查。

地址：上海市静安区延长路 301 号，电话：021-66301604

SHSY-IEC-BG/05.08/04.1 上海市第十人民医院伦理委员会审批件　　第 1 页 共 2 页

Ethics Review Document of Human Research Ethics Committee, Tenth People's Hospital of Tongji University

Declare: This ethics committee is constituted and works in accordance with the relevant regulations of the National Health Council and CFDA, and its review and working process are not affected by any organization or individual outside the ethics committee

Ethics approval Number: SHSY-IEC-4.1/20-258/01

Review date:	23-12-2020;25-12-2020	**Internal review number**	20K170
Review setting	NA	**Product number**	NA
Project title	Interrater reliability, agreement and concurrent validity of a pressure injury risk assessment scale (the COMHON Index) in a Chinese intensive care setting		
Application Documents	Refer to "The List of Ethics Review Documents for the Human Research Ethics Committee, Tenth People's Hospital of Tongji University"		
Applicant hospital/CRO	NA		
Chair unit	NA		
Principal Investigator	Lin Zhang;	**Major:**	Lin Zhang, Nursing
Review information	■ First Review ☐ Review again ☐ Revised version Review ☐ Others:_____		
Review type	■ Quick Review ☐ Meeting Review ☐ Urgent Meeting Review		
Chairmen:	Xuejin Yu; Jun Fu		
Review Results	1. ■ Agree ☐ Agree after revised ☐ Review again after revised ☐ Disagree 2. Does it need ongoing review? ■ Yes ☐ No 3. Review frequency (from the approved date) ☐ 6 months ■ 12 months 4. This approval will expire if the project not start within one year after approved.		
Comments of Human Research Ethics Committee	Chair, Human Research Ethics Committee Signature: The Human Research Ethics Committee, Tenth People's Hospital of Tongji University (stamp) Date: 30-12-2020		
Notes	1. Our committee approve the projects involve human related medical research, please conduct the research with the latest version of the research proposal strictly and follow the national and international laws and guidelines; 2. All contents involving the export of human genetic resources or subject to special examination and approval by relevant departments according to national regulations shall be reported to and approved by relevant departments before the implementation of the project; 3. In the course of study, any modification of the research design and the materials of the informed consent, please submit the modification application form and required materials, and must get the approval from HERC before the implementation. 4. To suspend or terminate the study, please inform the HERC in a timely manner.		

The Human Research Ethics Committee of the Tenth People's Hospital of Tongji University

	5. Any serious adverse events or unexpected events must be reported to the Human Research Ethics Committee immediately, and the Human Research Ethics Committee will review and make a new decision on registered study. 6. Any violation of ethics must be reported Human Research Ethics Committee immediately. 7. An annual progress report must be submitted to the Human Research Ethics Committee at one month before the due date. 8. The research must be undertaken within one year of the approval date. Otherwise this approval is automatically cancelled. 9. A final report must be submitted to the Human Research Ethics Committee when the project is completed.

The Human Research Ethics Committee, Tenth People's Hospital of Tongji University; Email: shsyiec@126.com; Contact Phone Number: 021-66301604. The composition and work of the Human Research Ethics Committee is strictly in accordance with China GCP and related regulations.

Appendix K: Phase Three concurrent validity testing ethical approval (Australian Catholic University)

[2022-2704N] - Ethics application approved!

Leanne Stirling <Leanne.Stirling@acu.edu.au>
on behalf of
Res Ethics <Res.Ethics@acu.edu.au>
Tue 7/06/2022 10:28 AM

To: Paul Fulbrook <paul.fulbrook@acu.edu.au>

Cc: Res Ethics <Res.Ethics@acu.edu.au>;'Josephine Lovegrove' <josephine.lovegrove@myacu.edu.au>;Sandra Miles <sandra.miles@acu.edu.au>;Michael Steele <Michael.Steele@acu.edu.au>

Dear Applicant,

Chief Investigator: Professor Paul Fulbrook
Lin Zhang, Dr Sandra Miles, Dr Mike Steele, Xian-Liang Liu, Angel Cobos Vargas
Student Researcher: Josephine Lovegrove,
Ethics Register Number: 2022-2704N
Project Title: New Application
Date Approved: 07/06/2022
End Date: 31/01/2023

This is to certify that the above human ethics application for access to non-identifiable data has been reviewed by the Australian Catholic University Human Research Ethics Committee (ACU HREC).

The HREC notes that the project will be using previously collected non-identifiable data which can be exempt from review according to the National Statement on Ethical Conduct in Human Research (NHMRC 2007) section 5.1.22 and 5.1.23.

The Australian Catholic University notes that permission to access the de-identified data has been granted by Lin Zhang (Tenth People's Hospital of Tongji University; HREC: SHSY-IEC-4.1/20-258/01) and Prof Paul Fullbrook (ACU HREC 2021-17H) and that the data will be provided in a non-identifiable format and that secure data transfer will be via ACU Cloudstor.

Researchers must immediately report to the HREC any matter that might affect the ethical acceptability of the protocol such as changes to the protocol, unforeseen circumstances or adverse effects on participants.

For our record-keeping purposes, we deem that this activity will be in progress until 28/10/2022, unless we hear from you to the contrary. It will then be classified as completed.

Please do not hesitate to contact the office if you have any queries.

We wish you every success with your research.

Kind regards,

Leanne Stirling
on behalf of ACU HREC Chair, Assoc Prof. Michael Baker

Research Ethics Officer | Research Services | Office of the Deputy Vice-Chancellor (Research)
Australian Catholic University
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Appendix L: Chinese Mandarin Braden scale

压疮危险因素 **BRADEN** 评分法

	1 分	2 分	3 分	3 分
感知 机体对压力引起的不适感的反应能力	**1** 完全受限：对疼痛刺激没有反应（没有呻吟，退缩或紧握）或者绝大部分机体对疼痛的感觉受限	**2** 极度受限： 只对疼痛刺激有反应。只能通过呻吟和烦躁的方式表达机体不适。或者一半以上的部位对疼痛或不适感感觉障碍	**3** 轻度受限： 对其讲话有反应但不是所有时间都能用语言表达不适感或需要翻身。或者机体的一到两个肢体的部位对疼痛或不适感感觉障碍。	**4** 没有改变： 对其讲话有反应。机体没有对疼痛或不适的感觉缺失
潮湿 皮肤处于潮湿状态的程度	**1** 一直处于潮湿状态：由于出汗，小便等原因皮肤一直处于潮湿状态每当移动病人或给病人翻身时就可发现皮肤是湿的	**2** 潮湿 皮肤经常但不是总是处于潮湿状态。床单每班至少换一次	**3** 偶尔处于潮湿状态：每天大概需要额外的换一次床单	**4** 很少处于潮湿状态： 通常皮肤是干的，只要按常规更换床单即可。
活动方式 躯体活动的能力	**1** 卧床 限制在床上	**2** 轮椅 行走能力严重受限或没有行走能力。不能承受自身的重量和/或在帮助下坐椅或轮椅	**3** 偶尔行走：白天在帮助或无需帮助的情况下偶尔可以走很短的一段路。每班中大部分的时间在床上或椅子上度过。	**4** 经常行走： 每天至少 2 次室外行走，白天醒着的时候至少每 2 小时行走 1 次。
活动能力 改变或控制躯体位置的能力	**1** 完全受限： 没有帮助的情况下躯体或四肢不能做哪怕是轻微的移动	**2** 重度受限：偶尔能轻微地移动躯体或四肢，但不能独立完成经常的或显著的躯体位置变动。	**3** 轻度受限 能独立经常轻微地改变躯体或四肢的位置	**4** 不受限 独立完成大的经常性的体位改变
营养 平常的食物摄入模式	**1** 重度营养摄入不足： 从来不能吃完一餐饭。很少能摄入所给食物量的 1/3。每天能摄入 2 份或以下的蛋白量（肉或者乳制品）。很少摄入液体。没有摄入流质饮食。或者禁食和/或清夜摄入或静脉输入大于 5 天	**2** 可能营养摄入不足：很少吃完一餐饭，通常只能摄入所给食物量的 1/2。每天蛋白质摄入量是 3 份肉或者乳制品。偶尔能摄入规定食物量。或者可摄入略低于理想量的流质或者是管饲	**2** 营养摄入充足 可摄入供给量的一半以上。每天摄入 4 份蛋白（肉、乳制品）。偶尔会拒绝肉类，如果供给食品通常会吃掉。或者管饲或 TPN 的量达到绝大部分的营养所需。	**4** 营养摄入极佳：每餐能摄入绝大部分食物。从来不拒绝食物。通常吃 4 份或更多的肉类和乳制品。两餐间偶尔进食。不需要其他补充食物。
摩擦力和剪切力	**1** 已成为问题： 移动时需要中到大量的帮助。不可能做到完全抬空而不碰到床单。在床上或者椅子上时经常滑落，需要大力帮助下重新摆体位。痉挛、挛缩或躁动不安通常导致摩擦	**2** 潜在问题 躯体移动乏力或者需要一些帮助。在移动过程中皮肤在一定程度上会碰到床单、椅子、约束带或其他设施。在床上或椅子上可保持相对好的位置，偶尔会滑落下来	**3** 没有明显问题 能独立在床上和椅子上移动，并具有足够的肌肉力量在移动时完全抬空躯体。在床上和椅子上总能保持良好的位置。	