INCONTINENCE-ASSOCIATED DERMATITIS IN THE ACUTE CARE SETTING: AN EXPLORATION OF THE PHENOMENON

Jill Leonie Campbell
B Health Sc (Nursing), Grad Dip (Wound Care)

Principal supervisor: Professor Fiona Coyer

Associate supervisor: Dr Sonya Osborne

Faculty of Health

Submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy

Queensland University of Technology
2016

Abstract

Preventing nosocomial skin injury in vulnerable acute care patients presents an ongoing challenge for clinicians. Threats to skin integrity in the acute hospital patient are complex, multidimensional, and inter-related, with a range of potential skin injuries the result. Incontinence-associated dermatitis (IAD) is one such skin injury, caused by chronic skin exposure to urine and/or faeces as a result of incontinence. This complex and painful condition presents with erythema, with or without blisters, erosion, or serous exudate. IAD can predispose to superficial pressure injury and/or *Candida* infection. It is a painful, debilitating condition, that can affect patient wellbeing, impact on the complexity and cost of care, increase the length of hospital stay, and expose patients to the risk of serious complications. These complications include susceptibility to developing a perineal infection (commonly with *Candida albicans*) or a pressure injury (PI).

However, despite the risks and challenges associated with IAD, there is a gap in understanding the extent of the risk and burden of IAD, in the general acute care setting, with no prevalence data available in Australia, and limited prevalence data available internationally. Furthermore, the natural history of the condition is not well understood, with a gap evident in the understanding of the epidemiology of *Candida* colonisation associated with IAD and incontinence, or the role of colonisation in the pathogenesis of IAD.

The literature review revealed that there was no comprehensive, conceptual skin injury framework available to guide this research. A multitude of skin injury-specific conceptual frameworks and consensus documents that address a range of nosocomial skin injuries, including IAD exist. However, a framework underpinned by the overarching concept of keeping skin safe from nosocomial injury in vulnerable, older hospital patients was lacking.

The broad aim of this thesis was to explore the phenomenon of incontinence-associated dermatitis (IAD) in the acute care setting. This involved an investigation of the prevalence of IAD in an Australian hospital, and also an examination of the

epidemiology of *Candida* colonisation and infection associated with continence status and IAD in acute care patients. Furthermore, this research aimed to present a new conceptual model in which to reconceptualise the phenomenon of IAD within the broader domain of maintaining skin integrity in this setting. An additional aim of the research was to test key constructs (selected based on gaps in the research) of the proposed model

The Skin Safety Model (SSM) was developed in response to the lack of a unified skin integrity framework. This unique model reconceptualises skin integrity into a single framework. The model encompasses the multidimensional and inter-related antecedents of injury, and positions the patient experience of a skin injury as the primary outcome. The SSM shows great promise in providing a new comprehensive theory with which to address the challenges of maintaining skin integrity for older adults in contemporary hospitals. The model is based on empirical research and expert consensus, so the constructs included in the model are valid and well-supported by evidence. The SSM is presented in Publication 1 of this thesis.

The specific aims of two studies utilising a quantitative methodology were to: i) determine the prevalence of incontinence and IAD in the acute care setting; ii) describe the products worn to manage incontinence, and the products provided at the bedside for perineal skin care; iii) determine estimates of *Candida* colonisation in continent compared to incontinent patients, as well as those with IAD; iv) investigate the association between *Candida* colonisation and clinical presentation of IAD at hospital admission; and v) investigate risk factors associated with *Candida* colonisation. A further aim of this thesis was to test a number of the constructs and associations in the new conceptual model with the specific research questions of the two studies.

To address the gap in understanding of the prevalence of IAD in the Australian acute care setting, Study 1 investigated the prevalence of IAD and incontinence in a major tertiary hospital in Australia. This study utilised a cross-sectional observational design and found that the prevalence of incontinence was 24%, with IAD present in 42% of those who were incontinent. Furthermore, Study 1 found that the prevalence of *Candida* infection in those with IAD was 32%. These results provide convincing evidence that incontinence and IAD constitute a

substantial threat to skin integrity in the acute care setting. Study 1 gave rise to Publications 2 and 3.

The combined IAD and annual PI survey protocol provided a unique opportunity to collect previously unrecorded, and, therefore, unrecognised incontinence and IAD data. Publication 3 presents the PI and IAD prevalence results from surveys before and after the introduction of the combined survey protocol. The surveys were conducted between 2009 and 2013, with the combined PI and IAD surveys undertaken from 2011-2013. PI prevalence in 2009 was 13% and decreased to 6% in 2013. IAD prevalence (calculated for the entire sample) was 10% in 2011, 3.6% in 2012 and 2.7% in 2013. The practicable and effective combined survey procedure was subsequently adopted by the facility as a standard protocol. Publication 3 presents the protocol, the PI and IAD prevalence rates before and after the introduction of the combined survey protocol, and highlights the sustained decrease in IAD and PI prevalence over time. In addition, Publication 3 presents a range of important issues that have clinical and practical implications for the conduct of future IAD prevalence surveys.

To address the gap in the understanding of the epidemiology of *Candida* colonisation associated with incontinence and IAD, Study 2 of this research program compared *Candida* colonisation rates between continent and incontinent patients and those with IAD. It recruited a purposive sample in three groups: continent; incontinent of urine; and incontinent of urine and faeces. The study, a pilot cross-sectional, observational design was conducted in the medical wards of a major tertiary hospital. This study found that on admission there was a non-significant trend towards greater *Candida* colonisation at the perianal site in incontinent patients (43%) than in continent patients (28%), with a similar non-significant trend found at the inguinal site for incontinent patients (24%), compared to continent patients (14%). No significant association was found between *Candida* colonisation and the clinical presentation of incontinence-associated dermatitis at hospital admission. The results of Study 2 are presented in Publication 4. This unique study is the first to provide data to fill the gap in the understanding of the epidemiology of *Candida* colonisation in these patients.

While the risk factors for *Candida* infection have been explored in a variety of patient groups, there is limited understanding of the risk factors for *Candida*

colonisation. It is known that colonisation is a prerequisite for infection; therefore, understanding the risks for colonisation may help to identify patients at risk of subsequent *Candida* infection. In response to the gap in the understanding of risk factors for *Candida* colonisation factors, Publication 5 reports on the analyses undertaken to investigate associations between *Candida* colonisation, and age, gender, administration of antibiotics, diabetes, body mass index (BMI), faecal quality and frequency, nutritional, or mobility status. No significant association between colonisation and gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or BMI was demonstrated. However, there was a non-significant trend towards the association between colonisation and greater antibiotic use, poorer nutritional status, and greater mobility limitation in the colonised group.

Maintaining skin integrity in the acute care setting, while a patient safety imperative, is complex, costly and challenging. The SSM provides a unique, integrated framework to guide skin integrity care in a holistic, comprehensive way. Furthermore, the research in this thesis tested a number of constructs in the SSM, with Study 1 and 2 finding significant results that supported the inclusion of several constructs in the model and confirming its validity. As a result of the exploration of one specific skin injury, IAD, in the present studies testing of all the constructs of the model was outside the scope of the research program.

This thesis makes several important contributions to the understanding of the phenomenon of IAD in the acute care setting. The findings of Study 1 provide compelling and previously unrecognised evidence that incontinence and IAD pose a considerable threat to skin integrity in acute care patients. Study 2 has contributed important and also previously unrecognised evidence regarding patterns of *Candida* colonisation according to continence and IAD status in acute care medical patients. Furthermore, the SSM reconceptualises the maintenance of skin integrity in acute care into a comprehensive and unified framework. By improving the understanding of IAD, and presenting a new skin integrity framework, this research contributes to the overall goal of maintaining skin integrity in the acute care setting. In addition, the research program enabled several recommendations to be made in regard to the need to adopt the constructs of the SSM in order to provide more comprehensive and holistic skin integrity care, the imperative to collect IAD and incontinence data to

improve understanding of the scope of these threats, and to align national skin integrity policy with the comprehensive framework proposed in this research.

Key Words

Candida albicans, colonisation, cross-sectional study, incontinence-associated dermatitis, incontinence, nosocomial skin injury, older adults, pressure injury, prevalence, skin safety, skin tear.

A Note Regarding Format

This dissertation is a thesis by publication. It contains five publications that have been published or are under blind-peer review by refereed journals; therefore, the wording in the journal publications are as published. The logical flow of the thesis is maintained by introducing these articles where they fit most appropriately into the thesis structure. All articles have been reformatted using APA referencing style and reconfigured to Word to provide consistent formatting throughout the thesis. Moreover, a continuous numbering system was applied to the tables and figures for consistency.

Table of Contents

List of Figures

List of Tables

List of Abbreviations

BMZ	Basement membrane zone
CI	Confidence interval
df	Degrees of freedom
DON	Director of Nursing
ED	Executive Director
HAPI	Hospital acquired pressure injury
HREC	Human Research Ethics Committee
IAD	Incontinence-associated dermatitis
IADIT	Incontinence-associated dermatitis intervention tool
IADS	Incontinence-associated dermatitis severity
LOHS	Length of hospital stay
MARSI	Medical adhesive-related skin injury
n	Number
NHMRC	National Health and Medical Research Council
NUM	Nurse Unit Manager
OECD	Organisation for Economic Cooperation and Development
PAT	Perineal assessment tool
PI	Pressure injury
PU	Pressure ulcer
PRN	Pro re nata (as required)
QUT	Queensland University of Technology
RBWH	Royal Brisbane and Women's Hospital
RCT	Randomised controlled trial
RN	Registered nurse
SGA	Subjective global assessment
SSM	Skin safety model
κ	Kappa
χ^2	Chi-squared test

List of Publications and Presentations

Publications

Campbell J. L., Coyer F.M., & Osborne S. R. (2016). The Skin Safety Model: Reconceptualising skin vulnerability in older Patients. *Journal of Nursing Scholarship, 48*(1),14-22.

Campbell J., Gosley S., Coleman K., & Coyer F. (2016). Combining pressure injury and incontinence-associated dermatitis prevalence surveys: An effective protocol? *Wound Practice and Research (24)*3, 170-177

Campbell J., Coyer F., Mudge A., Robertson I., & Osborne S. (2016). *Candida albicans* colonisation, continence status and incontinence-associated dermatitis in the acute care setting: A pilot study. *International Wound Journal*, doi: 10.1111/iwj.12630

Campbell J. L., Coyer F. M., & Osborne S. R. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting, *International Wound Journal, June 26* doi:10.1111/iwj.12322

Campbell J., Coyer F., Mudge A., & Osborne S. (2016). Risk factors for *Candida* colonisation at the perirectal site in individuals admitted to Internal medicine units. (This manuscript is to be submitted to the *Journal of Hospital Infection*).

Conference presentations

Campbell, J., Coyer F., & Osborne S. (2012) *Incontinence Associated Dermatitis; A prevalence study in the Australian acute care setting.* Oral presentation World Union of Wound Healing Societies 4th Congress, Japan.

Campbell J., Coleman K., Gosley S., & Coyer F. (2014). *Differentiating between pressure injury and incontinence-associated dermatitis: A neglected aspect of pressure injury prevalence audits.* Oral presentation, Australian Wound Management Association, National Conference, Gold Coast, Australia.

Campbell J**.,** Coyer F., & Osborne S., (2015). *Taking the next step in maintaining Skin integrity in older acute care patients: A new Skin Safety Model.* Poster presentation. National Pressure Ulcer Advisory Panel Biennial Conference. Orlando, Florida.

Campbell J**.,** Coyer F., & Osborne S. (2015). *Challenges and Opportunities; Conducting Skin Integrity Research in Acute Care, Lessons Learnt from the Pilot IntACt Study.* Accepted oral presentation, European Wound Management Association annual conference, London, England.

Publications Associated with Research

Beeckman, D., Campbell, J., Campbell, K., Chimentão, D., Coyer, F., Domansky, R. …Wing, L. (2015). Proceedings of the Global IAD expert Panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International. Retrieved from http://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf*

Campbell J., Haesler E., Kennerly S., & Yapp T. Special populations, older adults (2014). *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline.* E. Haesler (Ed.) National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Ulcer Alliance (2014). Cambridge Media: Perth, Australia.

Presentations Associated with Research

Campbell, J**.** (2011), *Incontinence Associated Dermatitis. Incontinence; the Australian Perspective.* Key Opinion Leaders Forum. Invited Speaker Continence Foundation Australia, Sydney, Australia.

Campbell, J**.** (2013). *Prevalence of IAD in the acute care setting*. Invited keynote speaker, 3M Skin Integrity Forum, Sydney, Australia.

Campbell J. (2014). *Incontinence-associated dermatitis in the acute care setting.* Invited plenary presentation. Urological Society of Australia and New Zealand 2014 Scientific Meeting. Brisbane, Australia.

Campbell J. (2014). *Incontinence – associated dermatitis.* Invited keynote speaker, Smith & Nephew Skin Integrity forum, Brisbane, Australia.

Campbell J. (2015). *Incontinence-associated dermatitis; moving prevention forward.* Invited plenary presentation. Chinese Wound, Ostomy and Continence Nurse's 12th Annual Congress. Hohhot, China.

Campbell J., & Coyer F. (2015). *Incontinence-associated dermatitis: Current evidence based approaches.* Invited speaker, Teleflex academy forum. Sydney and Brisbane.

Campbell J. (2015). *Incontinence-associated dermatitis; Current evidenc*e. Continence Foundation Australia National Conference, Melbourne. Invited speaker, Hartmann sponsored dinner.

Campbell J. (5th April 2016). *Model expands approach to skin care.* Bastian D., producer, audio podcast. Nursing Review http://www.nursingreview.com.au/2016/04/guide-maps-out-complexities-of-maintaining-skin-integrity/

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Signature:

Date: 19th October 2016

Acknowledgements

My sincere gratitude is extended to Professor Fiona Coyer and Dr Sonya Osborne. I am grateful to have had you as my supervisors; thank you for your wisdom, patience and mentorship.

To Dr Alison Mudge and Dr Ivan Robertson, thank you for your generous, patient and enthusiastic support of this project.

I have been the fortunate recipient of a Royal Brisbane and Women's Hospital Foundation grant and a Royal Brisbane and Women's Hospital scholarship. My sincere gratitude to the Foundation for this support.

I was the recipient of the 2015 Centaur Memorial Fund for Nurses scholarship. I acknowledge this financial support and the important work of the Centaur Fund who memorialise the nurses and medical personnel who lost their lives when the Australian Hospital Ship (AHS), Centaur, was sunk in 1943.

To the staff of the Royal Brisbane and Women's Hospital – my sincere thanks for the generous support and enthusiasm you all showed for this research. You are truly wonderful.

To the patients of the Royal Brisbane and Women's Hospital, your selfless research participation is a gift to us all; your profound generosity is beyond words.

I would like to thank the professional editors, Dr William Wrigley and Kylie Morris, who provided copyediting and proofreading services according to the university-endorsed guidelines and the Australian Standards for editing research theses.

For those friends and colleagues (too numerous to mention) who have offered advice, practical help and moral support so willingly and graciously – thank you.

To my family, Mum and Dad, Scott, Davina, Simon and Lara, thank you for your unwavering belief in me, for being beside me every single step of this journey, for being my cheer squad, no matter what, and for being excited at every tiny achievement. It means more than you will ever know.

Emma and Alec, I am richly blessed to have you in my life. Thank you for the priceless gifts of unending support, cooking, shopping, cleaning, unconditional love and allowing me to be absent.

For my husband, John, a partner is the one who truly understands this journey. There are no words; you simply took over and allowed me to pursue my dream. Without you, this would not have been possible. This is for you.

Chapter 1: INTRODUCTION

1.1 BACKGROUND

Threats to skin integrity in the acute hospital patient are complex, multidimensional, and inter-related, with a range of potential skin injuries the result. Incontinence-associated dermatitis (IAD) is one such skin injury, caused by chronic skin exposure to urine and/or faeces as a result of incontinence (Beeckman et al., 2015; Doughty et al., 2012; Gray et al., 2007). This complex and painful condition presents with erythema, with or without blisters, erosion, or serous exudate. IAD can predispose to superficial pressure injury and/or *Candida* infection. It is a painful, debilitating condition, that can affect patient wellbeing, impact on the complexity and cost of care, increase the length of hospital stay, and expose patients to the risk of serious complications. These complications include susceptibility to developing a perineal infection (commonly with *Candida albicans*) or a pressure injury (PI) (Beeckman, Van Lancker, Van Hecke, & Verhaeghe, 2014; Black et al., 2011; Gefen, 2014; Gray et al., 2007).

IAD and its complications pose a significant risk to the skin integrity and quality of life of acute care patients, as well as posing a considerable challenge for healthcare providers by way of prevention and management. However, despite the risks and challenges associated with IAD, there remains a gap in the understanding of the burden of IAD in the acute care setting, with no prevalence data available for the Australian setting. Internationally, the prevalence of IAD is reported to range from 20% to 50%; however, much of this data is drawn from the long-term and critical care settings (Arnold-Long, Reed, Dunning, & Ying, 2009; Bliss & Powers, 2011; Driver, 2007; Junkin & Selekof, 2007). The primary risk factor for developing IAD is incontinence (Beeckman et al., 2015), a condition common in older adults (Australian Institute of Health and Welfare, 2014; Lakhan et al., 2011). Incontinence is defined as the accidental or involuntary loss of urine from the bladder and/or faeces from the bowel (Abrams et al., 2010; Ahmed & Pearce, 2010; Homma, 2008; Inouye et al., 2007; Junkin & Selekof, 2007).

The prevalence of incontinence in the acute care setting is reported to range from 10%-43% for urinary incontinence, and 7%-33% for faecal incontinence

(Australian Institute of Health and Welfare, 2014; Ostaszkiewicz, et al., 2008). As a consequence of the high prevalence of incontinence, a high proportion of acute care patients are exposed to skin contact with urine and faeces, and are subsequently at risk of IAD and its complications (Ersser, Getliffe, D.Voegeli, & Regan, 2005).

Compelling arguments exist for improving the understanding of the prevalence of skin injuries in the acute care setting. Similar to the limited understanding of the prevalence of IAD in the acute care setting, there is little understanding of the epidemiology of *Candida* colonisation or infection in relation to continence status and IAD in the acute care setting. Infection with *Candida* is accepted as a common complication of IAD (Black et al., 2011; Doughty et al., 2012; Gray et al., 2007). *Candida* species (spp.) are common human fungal commensal organisms, which, in certain situations, can transform from harmless commensal to pathogen, resulting in serious invasive infections, or more commonly, superficial mucocutaneous infection (Charles et al., 2005; Clancy & Nguyen, 2012; Fidel, 1999; Odds, 1988). Reported predisposing factors for *Candida* spp. infections in the gastrointestinal or genitourinary tract include mucosal barrier impairment, extremes of age, female gender, administration of antimicrobial agents, diabetes, and the presence of increased bowel movements (Dorko, Virágová, & Pilipčinec, 2003; Fidel, 1999; Moran, Coleman, & Sullivan, 2012; Raz-Pasteur, Ullmann, & Berdicevsky, 2011). Despite the general acceptance of *Candida* infections as a complication of IAD (Black et al., 2011; Doughty et al., 2012; Gray et al., 2007), there remains a paucity of data explaining the prevalence of *Candida* colonisation in these patients, as well as empirical evidence to quantify the prevalence of *Candida* infection associated with IAD and incontinence.

One of the reasons for the lack of microbiological data reporting on the epidemiology of incontinence and IAD-associated *Candida* infections may be due in part to the common clinical practice of presumptive diagnosis based on skin assessment, followed by empirical treatment, without microbiological confirmation of the pathogen. Consequently, a significant gap exists in the understanding of the epidemiology of these incontinence and IAD-associated *Candida* infections (Foureur, Vanzo, Meaume, & Senet, 2006). It is understood that skin colonisation with *Candida* is a necessary precedent to mucosal infection (Moran et al., 2012); therefore, a prerequisite for understanding the epidemiology of *Candida* infections

associated with incontinence and IAD is an understanding of *Candida* colonisation in both continent and incontinent adults, and those with IAD. Further, the aetiological role of *Candida* in IAD has had limited empirical consideration in the adult population (Foureur et al., 2006).

In contrast to adult IAD, *Candida albicans* has been reported to have an aetiological role in paediatric diaper dermatitis. One paediatric study reported that *Candida* colonisation was significantly more common in the perianal skin, inguinal folds, and mouths of infants with diaper dermatitis, compared to infants without diaper dermatitis (Ferrazzini et al., 2003). Moreover, this study revealed that in infants with diaper dermatitis, higher levels of *Candida* colonisation correlated with diaper dermatitis severity (Ferrazzini et al., 2003). While paediatric data should not be extrapolated to adults due to differences in skin physiology, health status, and medications, the paediatric data does point to a potential role of *Candida* colonisation in the pathogenesis of IAD. Overall, understanding patterns of *Candida* colonisation and infection in these patients will contribute to the goal of maintaining skin integrity in the hospital setting.

Skin integrity breaches have the potential to cause significant morbidity and mortality. The ability of skin to perform its multiple, complex, and life-sustaining functions depends on the maintenance of its integrity (Di Meglio, Perera, & Nestle, 2011; Farage, Miller, Elsner, & Maibach, 2008). Threats to skin integrity are diverse, with intrinsic threats (particularly prevalent in individuals aged 65 years and older) arising from changes associated with ageing, mobility, continence, nutrition, and cognition, as well as the presence of multiple co-morbidities and polypharmacy (Inouye et al., 2007; Lakhan et al., 2011). Extrinsic threats to skin integrity arise from excess pressure, shear, friction and exposure to skin irritants, such as urine, faeces, and excess moisture. In addition, interaction with the healthcare environment, particularly acute care, can present multi-dimensional and complex difficulties (such as access to adequate nutrition, mobility limitations, alterations in continence status and unfamiliar environments) in maintaining skin integrity for the older patient, and for those managing their healthcare (Agarwal et al., 2012; Carville, 2012; Gray et al., 2012; Inouye et al., 2007; LeBlanc & Baranoski, 2011). When these multiple intrinsic and extrinsic threats interact, older acute care patients can become vulnerable to a range of nosocomial skin injuries (Australian Wound Management

Association, 2012; Black et al., 2011; Carville, 2012; Coleman et al., 2013; Gray, 2007; Inouye et al., 2007; Lakhan et al., 2011; LeBlanc & Baranoski, 2011; McNichol, Lund, Rosen, & Gray, 2013; National Pressure Ulcer Advisory, European Pressure Ulcer Advisory, & Pan Pacific Pressure Injury, 2014).

The term 'nosocomial' is defined as a disease or condition originating in a hospital (Martin, 2015); a nosocomial skin injury is, therefore, a skin injury acquired during an episode of hospital care. Maintaining skin integrity and preventing nosocomial skin injuries forms an integral component of safe and high quality healthcare, and is a priority in the patient safety mandate (Bry, Buescher, & Sandrik, 2012). The genesis of innovative solutions for maintaining skin integrity may be found in the development of new theories that integrate contemporary evidence into broad, overarching health service frameworks. These comprehensive frameworks will be more representative of the complexities and needs of the 21st century patient (Shortell &Singer, 2008). Currently, a plethora of skin-injury specific models that address IAD, skin tears, medical adhesive-related skin injury, peri-stomal or peri-wound moisture-associated skin damage, and intertriginous dermatitis guide skin integrity care in the acute care setting (Beeckman et al., 2015; Black et al., 2011; Carville et al., 2007; Doughty et al., 2012; Gray et al., 2007; Gray et al., 2011; LeBlanc & Baranoski, 2014; McNichol et al., 2013) (Beeckman et al., 2015; Black et al., 2011; LeBlanc & Baranoski, 2011; McNichol et al., 2013). These skin injuries cannot be neatly separated into distinct prevention and management silos. The complex, multidimensional and overlapping predisposing factors for skin injury mean that it is timely to reconconceptualise IAD, PIs, skin tears, and other nosocomial skin injuries into a unified, comprehensive skin integrity framework. Such a framework may have important benefits for patients and healthcare providers alike, possibly identifying previously unrecognised connections, relationships, and innovative solutions to skin integrity challenges.

This thesis proposes a new skin safety conceptual framework that encompasses multiple factors: the healthcare system, the patient, and situational stressors, as well as a multitude of skin injuries that may subsequently result. Adopting an overarching skin safety concept (rather than the concept of separate unrelated injuries) is timely given the challenges faced by healthcare providers in relation to the rapidly ageing population. The proposed framework, acknowledges

specific skin injuries, and reconceptualises these injuries within the broader framework of maintaining skin integrity, while situating the patient experience of a skin injury as the central outcome. This comprehensive approach to skin integrity may have the potential to improve patient outcomes, as well as improve healthcare effectiveness and efficiency in relation to delivering safe skin care to vulnerable patients.

Globally, populations are ageing (United Nations, 2011; World Health Organisation, 2011). Ageing is accompanied by an increase in chronic disease, disability and the development of geriatric syndromes, for example, incontinence, PI, cognitive impairment or falls (Ezeh, Bongaarts, & Mberu, 2012; Inouye, Studenski, Tinetti, & Kuchel, 2007; Lakhan et al., 2011; Levant, Chari & DeFrancis, 2015; Scommegna, 2012; Sourdet et al., 2015; World Health Organisation, 2011; Zisberg, Shadmi, Gur-Yaish, Tonkikh, & Sinoff, 2015). A significant consequence of the increase in complex and chronic health conditions associated with ageing is increased healthcare and hospital utilisation by older adults (United Nations, 2011; World Health Organisation, 2011). In Australia, between 2013-2014, 40% of hospitalisations were for people 60 years and older, yet this group accounted for only 13% of Australia's population (Australian Government, 2016). The increasing hospital utilisation by older adults means that consequently, the prevalence of patients with associated geriatric syndromes such as incontinence is likely to increase. This means that in the future, as a result of the increased prevalence of incontinence, the prevalence of IAD will also be likely to increase. Therefore, an urgent imperative exists to improve understanding of the prevalence of IAD, its pathogenesis, and the natural history of *Candida* colonisation and infections. This improved understanding of these dimensions of IAD will inform the development of innovative and effective IAD prevention and management strategies, and more broadly, inform the goal of maintaining skin integrity in acute care patients.

Internationally, the most widely recognised nosocomial skin injury is a PI, with hospital acquired prevalence ranging from 6.4%-5% between 2006 to 2009 respectively in the United States (Goldberg, 2012), 7%-9% between 2007-2011 respectively in Australia (Mulligan, Prentice & Scott, 2011), and an overall prevalence of 18% in Europe and the United Kingdom in 2007 (Vanderwee, Clark, Dealey, Gunningberg & Defloor, 2007). Considered to be largely preventable, PIs

impact on morbidity, mortality, and service delivery in the acute care setting (National Pressure Ulcer Advisory, European Pressure Ulcer Advisory, & Pan Pacific Pressure Injury, 2014). While pressure injuries are regarded as nosocomial injuries, and subsequently reported as adverse events, other nosocomial skin injuries such as IAD or skin tears are rarely reported as adverse events, and in some situations are even considered to be an inevitable consequence of ageing (Carville, Leslie, Osseiran-Moisson, Newall, & Lewin, 2014; White, 2001). Categorising these skin injuries as inevitable can mean that they may ultimately be under-recognised under-treated and result in adverse outcomes for patients and healthcare providers.

Categorising these skin injuries as inevitable may partly explain the limited prevalence data available to inform an understanding of the burden of these injuries in the acute care setting. By comparison, there is a wealth of PI prevalence data available nationally and internationally (Mulligan, Prentice, & Scott, 2011; Pieper & National Pressure Ulcer Advisory, 2012). In Western Australia, innovative, state-wide wound prevalence surveys were undertaken between 2007 and 2011 by WoundsWest, to determine the prevalence of wounds (including hospital acquired, surgical and chronic wounds) in public hospitals (Mulligan et al., 2011). These surveys reported that the prevalence of hospital-acquired PIs in Western Australia ranged from 9% in 2008 to 6% in 2009 and 7% in 2011.

PI prevalence data forms an essential component of the quality and safety mandate (Baharestani et al., 2010; Pieper & National Pressure Ulcer Advisory, 2012); therefore, comparison of PI prevalence is common, within facilities over time, and benchmarking with other facilities nationally and internationally. However, benchmarking other nosocomial skin injuries such as IAD or skin tears, either within injury categories, or to understand the prevalence of these injuries comparative to each other is not common practice. However, the WoundsWest surveys provide one of the few data sets that allow for comparison of the prevalence of PI and skin tears (Mulligan et al., 2011). In the same surveys, during the same period, the prevalence of hospital-acquired skin tears ranged between 6% and 7%. (Mulligan et al., 2011), revealing strikingly similar prevalence rates to PIs (6% - 9%) in those surveys. The WoundsWest surveys did not collect prevalence data for IAD (J. Prentice, personal communication, November 19, 2015), meaning that comparison of IAD, PI, and skin tear prevalence rates was not possible. One of the few acute care studies that allows

for comparison of IAD and PI prevalence rates revealed almost identical prevalence rates for PI (21.7% in incontinent patients) and IAD (20% in the same incontinent cohort) (Junkin & Selekof, 2007). The limited prevalence data available for these skin injuries may reflect their status as a lesser patient safety priority than PIs. However, the acute care prevalence data for these injuries (albeit limited) highlight that the burden of these other nosocomial skin injuries parallels the prevalence of PI, and constitute a serious threat to skin integrity in the acute care setting.

IAD is a common, complex, and painful condition that results from incontinence, and can expose patients to serious complications, such as infection or PI. Substantial gaps in the understanding of the prevalence of IAD, incontinence, the epidemiology of *Candida* colonisation and infection highlight the urgent need to improve the empirical evidence related to these aspects of IAD and associated infection in order to advance the broader imperative of maintaining skin integrity in the acute care patient.

1.2 SIGNIFICANCE AND SCOPE

This research is significant in that it has provided the first empirical evidence of the prevalence of IAD in the Australian acute care setting. Until this study the prevalence of IAD in this setting was unknown, meaning that consequently this skin injury was under-reported and poorly understood, with health care providers unaware of the considerable threat to skin integrity that IAD poses for these patients. Prevalence data is essential to inform the delivery of quality healthcare, guide decision-making in relation to resource allocation, patient safety initiatives, clinical governance, and for tracking quality initiatives (Pieper, with the National Pressure Ulcer Advisory, 2012). Prior to this study, IAD was not a priority for patient safety in Australia. However, as a result of the research, IAD prevalence is now measured annually in the research facility, with the adoption of the protocol employed in the study. The research facility has also changed the terms of reference of its PI Prevention Committee to include all iatrogenic skin injuries, and has also renamed the committee, The Skin Safety Committee (personal communication, K. McDonough, 9 November, 2012). This means that IAD prevention and management have become a priority in maintaining skin integrity in this facility. Furthermore, the state-wide annual PI prevalence audit conducted by the Patient Safety and Quality

Improvement Service Clinical Excellence Division, as a result of the research, has added a category to its data collection instrument to identify the presence of IAD.

In addition to understanding the prevalence of IAD, the research investigated a key aspect of one of the complications of IAD, namely infection. *Candida* albicans is the most common aetiological organism for IAD and incontinence-associated perineal infection, yet there is limited understanding of the epidemiology of *Candida* colonisation or infection in relation to continence status or IAD. This study has provided the first empirical research informing *Candida* colonisation patterns, association between *Candida* colonisation and clinical presentation of IAD, and risk factors for colonisation in these patients. This research identifies an important, potentially pathogenic *Candida* reservoir in these patients, advances the understanding of the epidemiology of *Candida* colonisation in patients with IAD, provides evidence regarding risk factors for colonisation, and provides a unique frame of reference for investigating the association between *Candida* and IAD. This data may in turn lead to improved understanding of the pathogenesis of *Candida* infection and IAD in incontinent patients.

Preventing nosocomial injury is an integral component of providing safe and high quality healthcare. In addition to the patient safety and quality healthcare mandate, the increasing cost and complexity of healthcare and the rapidly ageing population mean that there are multiple challenges, ultimately resulting in healthcare systems that are under considerable strain. Therefore, innovative solutions are required to meet these challenges to (The Health Roundtable, 2012). A new conceptual model is proposed, the Skin Safety Model (SSM), that encompasses multiple factors: the healthcare system, the patient, and situational stressors, skin injuries that may subsequently result and positions the patient experience of a skin injury as the primary outcome. Adopting a comprehensive and unified skin safety model is timely given the challenges faced by contemporary healthcare providers. This model may reduce duplication, omission or fragmentation of skin integrity care, guide healthcare providers in developing improved holistic models of skin integrity care, improve efficiencies and effectiveness, and ultimately assist in the improvement of patient outcomes.

Key constructs of this model were empirically tested according to the gaps identified in the literature. It was outside the scope of this thesis to empirically test

all of the constructs of the model. However, several of the constructs of the model that were tested were found to be significant, providing empirical support for their inclusion.

This research is significant in that it has contributed to the understanding of several aspects of the phenomenon of IAD in the acute care setting. As a result of the research, anecdotal evidence suggests that awareness of IAD as an important skin injury has increased in the research facility, and has been recognised as an important skin injury in the statewide PI prevalence audit. Improved understanding of the extent of IAD as well as patterns of *Candida* colonisation can, in turn, inform the development of appropriate and holistic prevention and management plans. The SSM proposed in this research provides a unique and comprehensive framework to guide skin integrity care, including the prevention and management of the phenomenon of IAD.

1.3 AIMS AND RESEARCH QUESTIONS

The broad aims of this thesis by publication were to explore the phenomenon of incontinence-associated dermatitis (IAD) in the acute care setting by investigating the prevalence of IAD in an Australian hospital, to gain an understanding of the products used for perineal skin care and incontinence containment, factors which may influence the development of IAD, and also to investigate the epidemiology of *Candida* colonisation and infection associated with continence status and IAD in acute care patients. Furthermore, this research aimed to present a new conceptual model in which to reconceptualise the phenomenon of IAD within the broader domain of maintaining skin integrity in this setting. An additional aim of the research was to test key constructs (selected based on gaps in the research) of the proposed model.

Research Questions

The research program was guided by the following questions:

1. What is the prevalence of incontinence (urine and faecal) in the acute care setting?
2. What is the prevalence of IAD in the acute care setting?

3. What are the products worn to manage incontinence, and the products provided at the bedside for perineal skin care?
4. Is colonisation with *Candida albicans* more common at hospital admission in incontinent patients compared with continent patients?
5. In incontinent patients (urinary and faecal), is there an association between *Candida albicans* colonisation and clinical presentation of IAD?
6. In acute care medical patients, are gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or body mass index (BMI) risk factors for *Candida* colonisation?

1.4 OPERATIONAL DEFINITIONS

There are several key terms that require explanation or definition at the outset of this research program, as follows:

Candida albicans is the most common human fungal coloniser (Jarvis, 1996). *Candida albicans* can reside as an asymptomatic commensal organism in the rectum, vagina, and oral cavity. There are certain conditions in both host and pathogen under which *Candida albicans* can convert from harmless commensal to serious pathogen (Anaissie, Pfaller, & McGinnis, 2003; Fidel, 1999; Jarvis, 1996; Moran et al., 2012).

Colonisation is defined as the presence, growth, and multiplication of a microorganism in or on a host, with no obvious clinical signs, symptoms, or immune response seen in the host at the time the microorganism is isolated. In many situations, colonisation is a necessary precursor to infection. (Fidel, 1999; Jarvis, 1996)

Commensal is defined as an association between two organisms whereby the commensal derives benefit from the association, but the host derives neither benefit nor harm (Singleton & Sainsbury, 2012).

Faecal incontinence is defined as an involuntary loss of liquid or faeces ranging from minor faecal soiling, to urge incontinence, or passive faecal incontinence (Ahmed & Pearce, 2010)

Incontinence is defined as the inability to control the flow of urine and/or stool any time in the preceding 24 hours (Junkin & Selekof, 2007).

Incontinence-associated Candida infection

The term incontinence-associated *Candida* infection is proposed and used throughout this thesis to ensure clarity with reference to incontinence, IAD, and *Candida* infections. Terms commonly used in the literature, such as secondary *Candida* infection or superimposed *Candida* infection imply a possible causal relationship between IAD and *Candida* infection; however, this relationship is uncertain.

Urinary incontinence is defined as any involuntary loss of urine (Abrams et al., 2010). Urinary incontinence has multiple sub-categories, including stress, urge or mixed urinary incontinence, enuresis, nocturnal enuresis, continuous urinary incontinence, or disturbance in bladder sensation (Abrams et al., 2010; Homma, 2008; Inouye et al., 2007).

Incontinence-associated dermatitis (IAD) is defined as erythema and oedema on the surface of the skin, sometimes accompanied by bullae with serous exudate, erosion, or infection in response to chronic skin exposure to urine and or faeces (Doughty et al., 2012; Gray et al., 2007; Gray et al., 2012).

1.5 THESIS OUTLINE

This thesis is a body of original work presented in five publications. Each publication informs subsequent research, as well as being a unique contribution to knowledge in the field. The thesis is presented in 10 chapters (see Figure 1.1).

Chapter 1, the introductory chapter, provides the background and significance of the research program. It details the research questions for the study phases and provides an overview of the research methods.

Chapter 2 presents an examination of the literature related to the overarching concept of maintaining skin integrity (including the phenomenon of IAD) for older adults within the context of the challenges faced by providers of 21st century healthcare. A narrative synthesis of the literature informed the development of a conceptual framework that underpins this thesis, and is presented in Publication 1:

Campbell J., Coyer F., & Osborne S. (2016). The Skin Safety Model: Reconceptualising skin vulnerability in older patients. *Journal of Nursing Scholarship, 48*(1), 14-22.

Chapter 3 presents a review of the literature pertaining to IAD, a historical perspective, risk factors, physiology of skin injury related to skin exposure to urine and faeces, clinical presentation of IAD, and subsequent complications. Chapter 3 also presents a review of *Candida albicans*.

Chapter 4 presents the results of a study investigating the magnitude of IAD in an Australian acute care facility. This chapter constitutes Publication 2 of this research program. The results of this study identified that the prevalence of IAD and *Candida* infection in patients with IAD was a significant problem in the acute care setting. This study also tests several constructs of the Skin Safety Model. The results of this study contribute unique and previously unknown IAD prevalence data, and informed the research questions and methodology for study two of this research program. Chapter 4 includes Publication 2:

Campbell J. L., Coyer F. M., & Osborne S. R. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting, *International Wound Journal,* doi:10.1111/iwj.12322.

Chapter 5 presents a review of pressure injury prevalence before (2009-2010) and after (2011-2013) the commencement of a protocol that combined pressure injury and IAD prevalence surveys, as well as a review of the IAD prevalence following the commencement of the combined audit protocol.

Chapter 5 includes Publication 3:

Campbell, J., Gosley, S., Coleman, K., & Coyer, F. (2016).Combining pressure injury and incontinence-associated dermatitis prevalence surveys; An effective protocol? *Wound Practice and Research, 24*(3). 170-177.

Chapter 6 details the research methods, research questions, research design, and justification, sampling strategies, instrument development, recruitment processes, data collection, data analysis plan, and overview of the pertinent ethical consideration for Study 2.

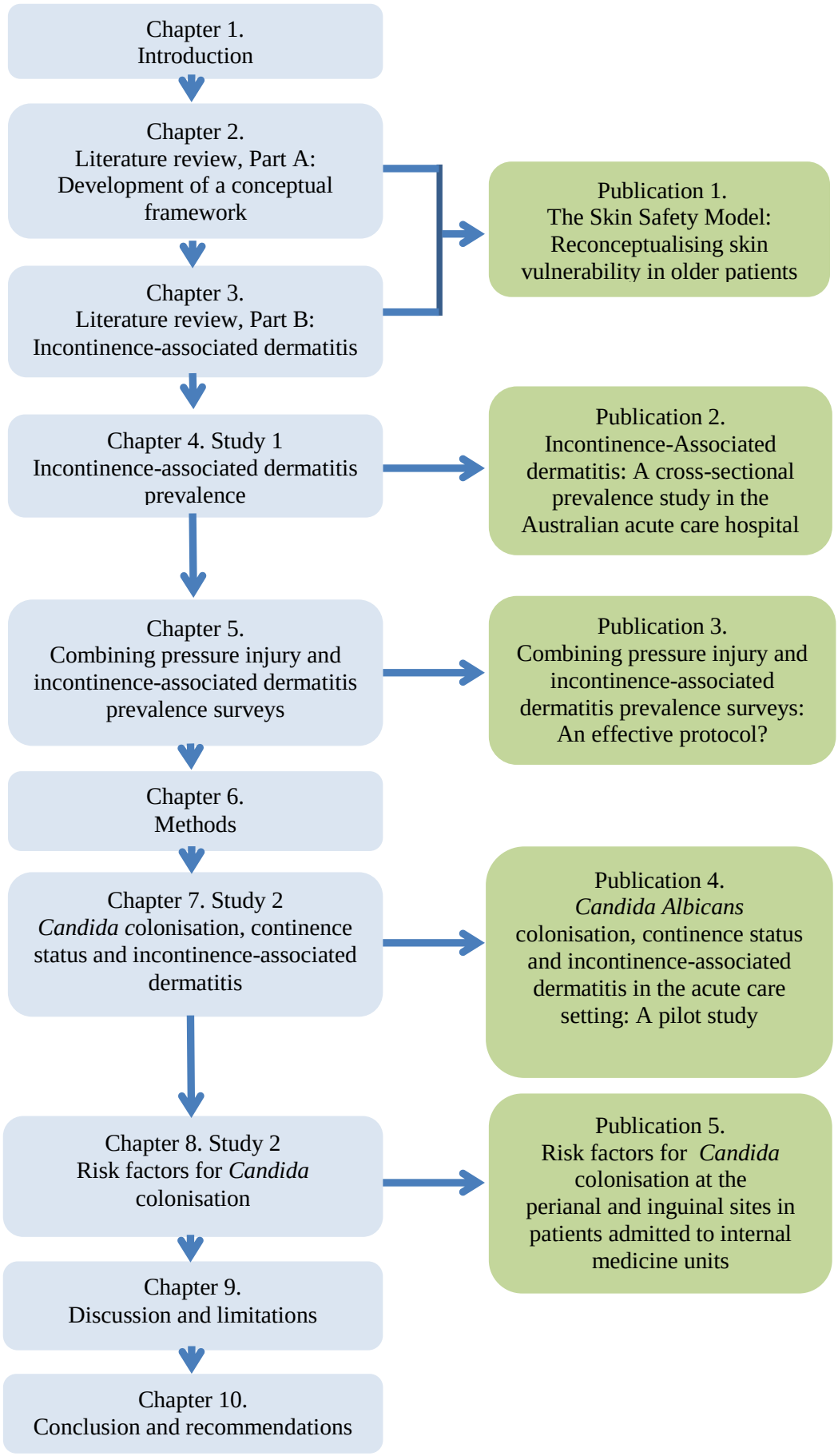


Figure 1.1 Schema of thesis.

Chapter 7 presents the results of Study 2 that compared the *Candida albicans* colonisation levels in continent and incontinent patients, as well as those with IAD. In addition, this study tests several constructs of the Skin Safety Model.

Chapter 7 includes Publication 4:

Campbell J., Coyer, F., Mudge A., Robertson I., & Osborne S. (2016). *Candida albicans* colonisation, incontinence-associated dermatitis and continence status in the acute care setting: A pilot study. *International Wound Journal*, doi: 10.1111/iwj.12630

Chapter 8 presents an investigation of risk factors associated with *Candida albicans* colonisation at the perianal and inguinal region of both continent and incontinent patients. It includes Publication 5:

Campbell J., Coyer, F., Mudge A., & Osborne S. Risk factors for *Candida* colonisation at the perianal and inguinal sites in individuals admitted to acute medical wards. (This manuscript is to be submitted to the *Journal of Hospital Infection*).

Chapter 9 presents a discussion of the Skin Safety Model, and a discussion of the testing of the model, using the study variables. Furthermore, the major findings, implications and limitations of the research are discussed, as well as an examination of the overall implications of this body of research that presents theoretical and empirical evidence that contributes to the understanding of the phenomenon of IAD in the acute care setting.

Chapter 10 concludes this thesis by presenting a summary of the research, and proposing eight recommendations in the domains of the implications for practice, education, policy, and future research.

1.6 SUMMARY

This chapter has provided the framework for this thesis presented by publication. It introduced the research problem, presented its background significance and scope, and the research questions for each study were specified. The next chapter presents a detailed literature review that informs the development of the

Skin Safety Model, which was the conceptual framework developed to underpin this thesis.

Chapter 2: LITERATURE REVIEW, PART A - THE SKIN SAFETY MODEL: RE-CONCEPTUALISING SKIN VULNERABILITY IN OLDER PATIENTS

2.1 INTRODUCTION

This chapter presents the literature review, Part A, and introduces the conceptual framework that underpins this research program. The conceptual framework presented represents the first publication of this thesis. The aim of this chapter is to provide the contextual background and rationale for the development of the skin safety conceptual framework for older acute care patients. While the research program investigated the phenomenon of IAD in the acute care setting, it is critical to explore IAD within the broader context of skin injury vulnerabilities, the changing health and care needs of contemporary patients, as well as the challenges faced by modern healthcare providers.

2.1.1 Chapter overview

This chapter highlights the unprecedented challenges faced by contemporary healthcare providers. Rapidly changing causes of illness, disability and death, ageing populations, increasing demands on hospital services, and the expectation that healthcare will be safe and of high quality, are issues that are exacerbated by fiscal constraints, and result in healthcare providers facing a period of enormous change. Ageing of the global population has resulted in increased utilisation of hospital resources in the 65 years and older age group. The increase in chronic disease, geriatric syndromes, and frailty that affect older adults results in complex healthcare needs for this group. (Ezeh, Bongaarts, & Mberu, 2012; Inouye et al., 2007; Lakhan et al., 2011; Levant, Chari & DeFrancis, 2015; Scommegna, 2012; Sourdet et al., 2015; World Health Organisation, 2011; Zisberg, Shadmi, Gur-Yaish, Tonkikh, & Sinoff, 2015). Therefore, new and innovative paradigms are urgently required to meet the needs of these complex and vulnerable patients. The conceptual framework presented in this chapter is a unique paradigm that was developed against the background of the complexities of contemporary healthcare delivery.

2.2 LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK

2.2.1 Contemporary healthcare challenges

The convergence of multiple challenges, including rapidly ageing populations, financial constraints, and increasing complexity of patient illness, subsequent increase in healthcare utilisation, and the requirement to provide safe, quality healthcare, has resulted in healthcare systems that are under extreme strain (Roundtable, 2012). The significant increase in average life expectancy that occurred during the 20th century reflects a great human achievement. However, the rapidity with which these demographic changes have taken place has left most healthcare providers struggling to cope (Kowdley & Ashbaker, 2011; World Health Organisation, 2011). Compounding the challenges of the ageing population is the rapidly escalating cost of healthcare provision, with healthcare expenditure outstripping growth in gross domestic product in countries across the globe (Kowdley & Ashbaker, 2011; Stabile et al., 2013). Management of the burgeoning prevalence of chronic, non-communicable diseases consumes a major share of healthcare resources. In the United States, 70% of the annual 2.2 trillion dollar health expenditure is spent on the treatment of chronic disease (Kowdley & Ashbaker, 2011). In the early part of the 21st century, healthcare providers face challenges that are unparalleled. Thus, urgent and unparalleled solutions are required to meet the rapidly changing needs and expectations of the contemporary healthcare consumer.

Ageing populations

Global population ageing has resulted from declining fertility rates and increasing life expectancy (United Nations, 2011; World Health Organisation, 2011). The average life expectancy of a child born in 1900 was 50 years; however, today the average life expectancy is 81 years, with the excetion of Africa, where the average life expectancy is 51 years as a result of the acquired immune deficiency syndrome pandemic (World Health Organisation, 2011). The most rapid life expectancy gains have been seen in East Asia, where it has increased from 45 years in 1950, to 74 years in 2011 (World Health Organisation, 2011). The number of people aged over 60 years is projected to increase from nearly 800 million in 2011, to two billion in 2050, with the number of individuals aged over 80 years projected to increase almost eight-fold, reaching 400 million in 2050 (United Nations, 2011). The proportion of people over 65 is predicted to rise during the period from 2010 to 2050 from 16% to

27% in Europe, from 13% to 22% in the United States, and from 23% to 38% in Japan, while China will experience a staggering increase from 8% to 23%, representing a threefold rise in the over 60s age group (Ezeh et al., 2012; Hou & Li, 2011). India will experience an increase in the ages 60 and older from 8% in 2010 to 19% in 2050, with India's overall population (currently 1.2 billion) expected to overtake China as the world's most populous country by 2020 (Scommegna, 2012).

Ageing and healthcare utilisation

The ageing demographic has resulted in increased utilisation of healthcare services and hospital bed days by older age groups internationally (Schofield & Earnest, 2006; Scommegna, 2012). In the United States in 2010, adults aged 85 and over accounted for 9% of hospital discharges, yet constituted only 2% of the population, with the rate of hospitalisation five times higher for the 85 and over age group compared to those under 65 years (Levant, 2015). Statistical modelling by Schofield and Earnest (2006) predicted that the proportion of bed days utilised by the 65 and older age group will increase from 47% in 2005 to 67% in 2050. Australian trends in increasing health service utilisation by older adults are consistent with other countries. In Australia, between 2011 and 2012, around 20% of people aged 65 or older had been admitted to hospital, compared to 11% of younger people in the same time period (Australian Institute of Health and Welfare, 2014). Furthermore, while the 60 years and older age group only accounted for 13% of Australia's population between 2013-2014, this age group accounted for 40% of hospitalisations (Australian Government, 2016). In Australia, between 2007-2008, across 23 major diagnostic categories average length of stay for patients 75 years or older was higher than patients aged 65-74 years, with the exception of the category diseases of the eye which was the same for both age groups (Brown, Abello & Thurecht, 2011). A study of presentations to Australian public hospital emergency departments, between 1999 and 2009 found that the highest per capita increase was among the 85 year and older age group. In this group, 61% of emergency department presentations resulted in admission, compared to 21% in patients aged 20-59 years (Lowthian et al., 2012).

In 2014-2015, there were three million more hospital admissions than between 2004-2005 (Duckett, 2016). One author claims that just over one fith of the increase in hospital admissions was attributable to the increase in the number of people aged 70 years and over, making this a relatively small contributer to the

growth in hospital admssions (Duckett, 2016). Pressures on demand for hospital services due to due to the ageing population have been offset by policies such as changing patterns of care, early discharge and same day treatments, but maximum efficiency gains have been obtained (Duckett, 2016; Schofield & Earnest, 2006). However, hospital admission raates preseent just one facet of the healthcare utilisation picture. It remains that the length of stay for older patients is longer than younger patients, 47% of hospital beds in Australia are occupied by older patients, and the trend towards population ageing will see about three-quarters of bed days required by older patients by 2050 (Brown, Abello & Thurecht, 2011; Schofield & Earnest, 2006).

Chronic disease

The trend towards ageing has been accompanied globally by a shift in the leading causes of disease from infectious and parasitic diseases (the major threats at the beginning of the 20th century) to the current burgeoning prevalence of chronic, non-communicable diseases. These chronic diseases most commonly affect older people, and include heart disease, diabetes, cancer, and mental health conditions, such as Alzheimer's disease and depression (Scommegna, 2012; World Health Organisation, 2011). The trend towards increasing chronic disease is having a significant global impact, affecting people in all countries. By 2030, more than 87% of the disease burden in those aged 60 years and older in all countries will be attributed to chronic non-communicable conditions (Scommegna, 2012; World Health Organisation, 2011).

Moreover, ageing individuals can suffer from more than one chronic, comorbid condition, with Australian data showing that 31% of people aged over 65 have one chronic condition, 25% have two chronic conditions, 13% have three chronic conditions, and 8% have four or more (Australian Institute of Health and Welfare, 2012). Ageing is accompanied not only by an increase in the number of chronic conditions, but also by the so-called geriatric syndromes, multifactorial health conditions that result from accumulated effects in multiple systems. These syndromes include incontinence, falls, pressure injury, delirium, and functional decline (Inouye et al., 2007). The prevalence of geriatric syndromes in the acute care setting is extremely high, with 95% of patients over 70 years having at least one geriatric syndrome prior to admission, with two thirds experiencing between one and

three syndromes (Lakhan et al., 2011). When pre-existing geriatric syndromes and chronic illness are superimposed by an acute illness and subsequent need for hospital admission, the complexity of the care needs of that individual increase substantially.

Healthcare reform

In response to the aforementioned challenges, healthcare reform is taking place in many countries. There is a pressing need for transition to care that is more responsive to the complex needs of contemporary patients. According to the American Nurses Association, bold initiatives are required to shape fundamental reforms (American Nurses Association, 2008). The key issues for global health reform have been identified as equitable access, quality and safety, cost, and workforce considerations (Anderson, 2010; American Nurses Association, 2008; Australian Government, 2014; Porter, 2010; Shortell & Singer, 2008).

In addition to the drivers of healthcare reform, there is growing recognition that non-biomedical factors in health, such as inadequate hospital environments for the elderly, inappropriate healthcare management strategies, and poor adaptation of the healthcare system to the needs of the frail elderly result in a condition known as hospital-associated disability. This disability occurs whereby older patients admitted to hospital can experience preventable functional decline as a result of admission (Sourdet et al., 2015). It can be argued that the emergence of this phenomenon is the result of a combination of contemporary healthcare challenges, and provides further rationale for healthcare reform.

Safety and quality

Keeping patients safe from harm is legitimate expectation of health care consumers and a universal concern of health care providers. Patient safety has come to be synonymous with quality healthcare, with the Institute of Medicine in the United States considering patient safety indistinguishable from quality care (Kohn, 2000). Patient safety is defined by the WHO (n.d., para 1) as the 'prevention of errors and adverse effects to patients associated with healthcare'. The Agency for Healthcare, Research and Quality, Patient Safety Network (AHRQ PS Net, n.d., para 1), defines patient safety as 'freedom from accidental or preventable injuries produced by medical care'. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of avoidable adverse events. Other definitions of patient safety highlight that the prevention of harm is dependent on a

system that prevents errors and learns from them, and is built on a culture of safety that involves healthcare professionals, organisations and patients (Kohn, 2000; Youngberg, 2013).

Operationalising patient safety and quality within an organisation requires a system of clinical governance. This is defined as a systematic and integrated structure that ensures health systems, clinicians and staff work towards and are held accountable for delivering safe and quality health care, while continually improving the quality of their services (Australian Commission on Safety and Quality in Healthcare, 2012; Travaglia, Spigelman & Braithwaite, 2011). Sound clinical governance requires effective planning and leadership, appropriate resource allocation, reliable systems for ensuring the quality of clinical care, effective use of data and information to monitor and report on performance and well-designed systems for identifying and managing risk (Australian Commission on Safety and Quality in Healthcare, 2012).

Powerful illustrations of the relationships between clinical governance, patient safety and quality can be found in the report of the enquiry into the Mid Staffordshire NHS Foundation (Francis, 2010). This enquiry found that hundreds of patients died between 2005 and 2009 in the Mid Staffordshire Trust as a result of the failure of the healthcare leadership, clinical governance and organisational culture of ignoring patient needs in favour of meeting the system needs. The effects of these failures manifested in multiple ways; however, in regard to skin integrity there were reports of patients developing serious PIs that remained untreated, patients not being fed or provided fluid, and patients left in beds contaminated with their own urine and faeces, all of which were due to poor staff morale and safety culture, staff shortages and lack of basic resources such as clean linen. The tragedies that occurred at the Mid Staffordshire Trust provide compelling evidence that clinical governance, patient safety and skin safety are inextricably linked, and that failures at the governance level are almost certainly likely to result in patient injury.

Patient safety programs require valid, reliable and meaningful data, with common metrics including measures that seek to identify, measure and eliminate error as well as injuries (Scanlon, Karsh & Saran, 2008; Youngberg, 2013). A common example of the use of these metrics is the use of PI prevalence surveys to examine factors that contribute to PIs, assess the efficacy of prevention protocols,

assess quality of care and guide resource allocation decisions (Baharestani, 2009). A further metric is the use of the risk-based patient safety measurement, or hazard identification, which focuses on identifying risks in the system that may ultimately lead to injury (Scanlon et. al., 2008). Organisations are responsible for identifying and responding to error and injury, and also for assessing and responding to potential risks (Scanlon et. al., 2008; Youngberg, 2013).

Rising cost of healthcare

Universally, healthcare spending is increasing, with data from the Organisation for Economic Cooperation and Development (OECD), revealing an average per capita increase of more than 70% between 2000 and 2010 (Organisation for Economic Cooperation and Development, 2015; Stabile et. al., 2013), with the rate of per capita spending for healthcare provision for older people accelerating more rapidly than any other group (Organisation for Economic Cooperation and Development, 2015; Stabile et al., 2013). In Australia, health expenditure between 2008-2009 for people aged 85 and older was almost 20 times higher per person compared to expenditure on children aged between five and 14 years (Australian Institute of Health and Welfare, 2016).

Increases in healthcare expenditure can be attributed to the rapidly rising costs of hospital services, the development of new medical technologies in the form of new drugs, devices, or services, as well as the costs associated with addressing the upsurge in chronic disease and increased hospital utilisation by the ageing population (Kowdley & Ashbaker, 2011; Organisation for Economic Cooperation and Development, 2015; Stabile et al., 2013; Wallner & Konski, 2008). Hospital care is the single largest health expenditure, amounting to nearly one third of total spending in OECD countries. Efforts are being made to contain the cost burden, with the most frequent strategies to curb spending in hospitals in these countries reported as postponing staff replacement and delaying investment in infrastructure (Organisation for Economic Cooperation and Development, 2015). Populous countries such as China and India face the same challenges as other countries in the provision of health and hospital services, but with the additional pressure of the sheer number of ageing people threatening to overwhelm the health infrastructure (Fang et al., 2015; Scommegna, 2012; World Health Organisation, 2011).

As has been highlighted in the previous sections, contemporary healthcare providers are under enormous strain as a result of population ageing, the increase in chronic disease and the rapidly rising cost of healthcare. While dealing with these challenges, healthcare providers are required to provide safe and quality care, within an effective clinical governance framework, while constantly demonstrating quality improvement. The systems required to deliver safety and quality create a further level of complexity for healthcare providers to navigate. While the requirement for the provision of safe and quality healthcare is not questioned, safety and quality must be delivered in the challenging environment of shrinking resources and rapidly increasing demand.

2.2.2 IAD nomenclature

Despite growing understanding of IAD, and the impacts it has on patients and healthcare systems, the nomenclature of the condition remains imprecise. Gray and colleagues (2007) first proposed the term IAD in 2007. Prior to this definition, IAD was known by a range of different terms, such as perineal dermatitis, moisture dermatitis, intertrigo, heat rash, or even pressure injury. However, the term IAD is not recognised by NANDA International, Inc. (Herdman, 2012), nor does IAD have a specific code in the International Statistical Classification of Diseases and Related Health Problems (ICD-10, 2016; World Health Organisation, 2004).

2.2.3 Specific IAD conceptual frameworks

Despite the fact that skin injury from incontinence in adults is not a new phenomenon, IAD research has only appeared in the nursing literature in the last two decades. While a number of IAD frameworks have been advanced, none integrate IAD into the broader, comprehensive and holistic construct of maintaining skin integrity. In 1993, Brown and Sears (1993) proposed a perineal dermatitis conceptual framework that recognised that diaper dermatitis or perineal dermatitis affected all age groups, races, and genders in any healthcare setting. They recognised that not all individuals who have incontinence develop perineal dermatitis; therefore, the condition should be preventable with the implementation of nursing care interventions. Brown and Sears (1993) identified that there were similarities between risk factors for pressure injury and perineal dermatitis. The conceptual framework they proposed grouped risk factors for perineal dermatitis into three constructs, namely: 1) tissue tolerance, including subcategories of age, health status, nutrition,

oxygenation, perfusion, temperature; 2) perineal environment with subcategories of character and type of incontinence, mechanical chaffing, inducing agents, and increased skin permeability; and 3) toileting ability, with mobility, sensory perception, and cognitive awareness constituting the subcategories. They identified that the manifestation of perineal dermatitis consisted of objective signs, including erythema, swelling, vesiculation, oozing, crusting, and scaling, while subjective symptoms included tingling, itching, burning, and pain. This framework identified that perineal dermatitis (IAD) and PI share some common risk factors, that is tissue tolerance, mobility and cognition impairment. This framework, focused on perineal dermatitis while briefly acknowledging common risk factors for IAD and PI but did not constitute a comprehensive skin integrity model.

In 1996, Jetter and Lutz proposed a conceptual framework describing the aetiology of IAD in adults, not as a single event, but as a cascade of interacting events that weaken the skin and create vulnerability to damage. This framework identified that risk factors for weakened skin are found in excess moisture which leads to increased friction, shear, skin permeability and microbial load while skin exposure to faeces results in damage from enzyme attack, altered pH, and increased skin permeability. Subsequent frequent washing, leads to further skin irritation, They proposed that weakened skin is vulnerable to incontinence dermatitis.

In 2007, Farage, Miller, Berardesca, and Maibach presented a comprehensive conceptual framework that highlighted multiple factors that contribute to the morbidity associated with incontinence dermatitis in older people. This model identified that compromised aged skin results from skin contact with the irritants urine and faeces, and that skin damage is exacerbated by factors such as decreased mobility, impaired cognition, inadequate care and attention, diminished tissue regeneration capacity, compromised physical health, and lower immune function.

In 2009, Beeckman, Schoonhoven, Verhaeghe, Heyneman and Defloor presented a further conceptual framework detailing the aetiology of IAD. This conceptual framework was based on the work of Jetter and Lutz (1996) and also Newman, Wallace, D. and Wallace J. (2001), and identified urine, faeces, double incontinence, and frequent cleansing as factors that eventually, via a series of interactions, create weakened skin and IAD. The IAD conceptual model presented by Langemo, Hanson, Hunter, Thompson, and Oh (2011) was a departure from the

conceptual models proposed up to this point in time. Other models included extrinsic patient factors and even care processes, for example, frequent skin cleansing, as having aetiological roles in the development of IAD. However, Langemo et al.'s (2011) model focused only on the effects of the urine, faeces, and bacterial overgrowth leading to weakened skin, and subsequently resulting in IAD.

The conceptual frameworks that have been discussed deal primarily with the aetiology of IAD. Brown and Sears (1993) identified factors such as patient factors in the construct of tissue tolerance and mobility, and sensory and cognitive awareness in the construct of toileting ability, while Jetter and Lutz (1996) mentioned pressure, poor nutrition and disease as contributing factors for skin breakdown in their framework. Several models also proposed that inappropriate incontinence care processes may constitute IAD risk factors (Beeckman et al., 2009, Brown & Sears, 1993; & Farage et al., 2007). The framework proposed by Farage et al. (2007) is a comprehensive model that encompasses multiple factors and, in addition, addresses skin vulnerability to injury experienced by older adults when exposed to urine and faeces. Risk factors for IAD identified in these conceptual frameworks are also identified in a range of conceptual frameworks as being key risk factors for other skin injuries, such as PI, skin tears and medical adhesive-related skin injury (Campbell, 2009; García-Fernández, Agreda, Verdú, and Pancorbo-Hidalgo, 2014; LeBlanc & Baranoski, 2014; McNicol, Lund, Rosen & Grey, 2013). These models address a specific skin injury, perhaps reflecting the specialty focus of broader contemporary healthcare delivery. The exception is the model presented by Garcia- Fernández et al., 2014, who proposed a theory for the development of dependence related skin lesions that were considered as PIs. These injuries include moisture, friction, combined pressure-moisture or combined pressure-friction lesions that a range of skin injuries. While these frameworks identify the complexity of the antecedents for IAD, including patient and care factors, and Garcia- Fernández et al. (2014) include several injuries into a single model, no overarching framework was available that united these skin integrity risk factors into a single comprehensive model.

2.3 LITERATURE GAP

The literature search for this thesis identified the lack of a conceptual framework in which to contextualise IAD as a component of a comprehensive,

overarching framework that is concerned with the wider imperative of maintaining skin integrity in the acute care setting. Existing IAD guidelines and frameworks, while presenting and distilling the most contemporary evidence into important documents (Beeckman et al., 2015; Doughty et al., 2012; Gray et al., 2007), continue to address IAD as a discrete skin injury, distinct and unrelated to other skin injuries and separated from the wider overarching imperative of maintaining skin integrity. Consistent with the frameworks that address IAD, there are multiple skin injury-specific frameworks that deal with a range of other nosocomial skin injuries including, skin tears, intertriginous dermatitis, peristomal or periwound moisture-associated skin damage or medical adhesive-related skin injury (Black et al., 2011; LeBlanc & Baranoski, 2011; McNichol et al., 2013). A conceptual framework that provides a link unifying the array of these individual skin integrity models into a congruent, overarching theory is lacking. Approaches to maintaining skin integrity in the acute care setting that are guided by a series of individual concepts and frameworks, which may ultimately result in fragmented, duplicated, or even missed care, and furthermore, may foster siloed care (Blackman et al., 2014; Shortell & Singer, 2008).

2.4 SKIN SAFETY MODEL

It is against this background of the complex needs of the ageing population, and the challenges faced by modern healthcare providers, including the imperative to provide safe quality care and the need for a comprehensive, overarching theory that the Skin Safety Model (SSM) is proposed. Older hospital patients are vulnerable to multiple skin injuries as a result of complex, chronic and inter-related health conditions, geriatric syndromes and disability, as well as interactions with the healthcare system. The aim of the SSM is to provide a unique and overarching theory that addresses the holistic skin integrity vulnerabilities in older acute care patients. The SSM moves away from addressing single skin injuries and towards an inclusive, holistic model for skin safety. This transition from a single injury approach to an overarching, integrated skin integrity approach aligns with the broader healthcare reform agenda, that is, reform that is focused on consumer-driven, patient-centred, holistic models of care. (American Nurses Association, 2008).

According to Fawcett and DeSanto-Madeya (2013), a conceptual framework provides a frame of reference, and functions to ‘organise and visualise abstract and

general phenomena and relations between various phenomena encompassed by the model' (p. 13). The SSM presented in this chapter provides a new frame of reference for maintaining skin integrity into a single model, and represents a unique and comprehensive approach to maintaining skin integrity in the acute care setting. It highlights the interplay of and relationship between multiple elements, including abstract and general phenomena such as patient factors, care delivery systems, and acute situational stressors (for example, an acute illness or trauma that requires hospital admission) that may combine or even interact synergistically to result in a skin injury. The specific phenomenon of IAD is situated within the broader framework. The premise of the SSM is based on the understanding that skin is a complex organ, impacted on by a vast array of factors, extending beyond individual patient factors to include systems and situational stressors. Maintaining skin safety, particularly in the older acute care patient is complex and challenging. The SSM can guide clinicians in consideration and recognition of a broad range of factors that influence skin integrity in the older acute care patient.

The following manuscript represents Publication 1 of this thesis and presents the SSM, which underpins the program of research.

Campbell J. L., Coyer F. M., & Osborne S. R. (2016). The Skin Safety Model: Reconceptualising skin vulnerability in older patients. *Journal of Nursing Scholarship*, *48*(1), 14-22.

This manuscript was published in the *Journal of Nursing Scholarship*, which has a wide international readership, and an impact factor of 1.6. The article was selected as *Journal of Nursing Scholarship* Editor's choice for January 2016. The article has cited in the *Journal of Nursing Studies*, which has an impact factor of 2.9 Furthermore, this publication was featured in the April/May 2016 edition of *Nursing Review*, with a Podcast recorded with the first author. The podcast features on the *Nursing Review* website, http://www.nursingreview.com.au/2016/04/guide-maps-out-complexities-of-maintaining-skin-integrity/

2.5 PUBLICATION 1

The Skin Safety Model: Re-conceptualising Skin Vulnerability in Older Patients.

Abstract

Purpose: To develop a unique Skin Safety Model (SSM) that offers a new and unified perspective on the diverse yet interconnected antecedents that contribute to a spectrum of potential iatrogenic skin injuries in older hospitalised adults.

Organising construct: Discussion paper

Methods: A literature search of electronic databases was conducted for published articles written in English addressing skin integrity and iatrogenic skin injury in elderly hospital patients between 1960 and 2014.

Findings: There is a multiplicity of literature outlining the aetiology, prevention, and management of specific iatrogenic skin injuries. Complex and inter-related factors contribute to iatrogenic skin injury in the older adult, including multiple co-morbidities, factors influencing healthcare delivery, and acute situational stressors. A range of injuries can result when these factors are complicated by skin irritants, pressure, shear, or friction; however, despite skin injuries sharing multiple antecedents, no unified, over-arching skin safety conceptual model has been published.

Conclusions: The Skin Safety Model (SSM) presented in this paper offers a new, unified framework that encompasses the spectrum of antecedents to skin vulnerability, as well as the spectrum of iatrogenic skin injuries that may be sustained by older acute care patients. Current skin integrity frameworks address prevention and management of specific skin injuries. In contrast, the SSM recognises the complex interplay of patient and system factors that may result in a range of iatrogenic skin injuries. Skin safety is reconceptualised into a single model that has the potential for application at the individual patient level, as well as healthcare systems and governance levels.

Clinical relevance: Skin safety is concerned with keeping skin safe from any iatrogenic skin injury, and remains an ongoing challenge for healthcare providers. A

conceptual framework that encompasses all of the factors that may contribute to a range of iatrogenic skin injuries is essential, and guides the clinician in maintaining skin integrity in the vulnerable older patient.

Key words: Older adult, acute care, skin safety, incontinence-associated dermatitis, pressure ulcer.

Introduction

Skin is the largest organ in the human body and is vulnerable to a multitude of threats. Vulnerability to skin integrity threats is particularly marked in older individuals (Carville, 2012). While the impact of pressure ulcers (PUs) in the acute setting is well understood, there are a range of potential iatrogenic skin injuries that are often regarded as an inevitable part of ageing, yet remain under-appreciated, under-reported, and somewhat invisible within this setting. Beyond PUs, other iatrogenic skin injuries include skin tears, medical adhesive-related skin injury (MARSI), incontinence-associated dermatitis (IAD), peri-stomal or peri-wound moisture-associated skin damage (MASD), and intertriginous dermatitis (ITD) (see Table 2.1). Skin integrity threats in older individuals arise from interactions between skin changes associated with ageing, presence of multiple co-morbidities, polypharmacy, changes in mobility, continence, and cognition; as well as the risks of acute illness and subsequent hospitalisation. Maintaining skin integrity in the older acute care patient is an ever-present challenge for healthcare providers. These challenges are compounded by shrinking financial and clinical resources, a rapidly ageing population, and the expectation that patients remain safe from harm.

For several decades, pressure ulcer (PU) prevention has been the primary focus of maintaining skin integrity. Moreover, the terms ‘pressure ulcer prevention’ and ‘maintaining skin integrity’ have, to some extent, become interchangeable. However, like pressure ulcers, the prevalence of these other skin injuries is significant (see Table 2.1), yet unlike PUs, their impact in the acute care setting is under-appreciated. These iatrogenic skin injuries have the potential to impact on morbidity, mortality, cost, and burden of care, in addition to causing pain, disfigurement, or disability. Importantly, *any* skin injury sustained in the delivery of healthcare should be classified as an adverse event. Further, research is emerging that strategies to prevent one iatrogenic skin injury can have positive effects on

preventing other skin injuries, thus highlighting the inter-connection between seemingly distinct skin injuries (Coyer et al., 2015).

Historically, despite shared risk factors, skin injury prevention and management programs address a single skin injury (for example PU). For individuals, under-appreciation of the complexity and scope of skin integrity risks can result in adverse skin integrity outcomes. For healthcare providers, this singular approach to skin injury prevention and management can result in fragmented, duplicated, inconsistent care that often takes place in silos. In response to the range of potential iatrogenic skin injuries, a multitude of injury-specific conceptual frameworks have been published (Beeckman et al., 2015; Black et al., 2011; LeBlanc & Baranoski, 2011; McNichol et al., 2013). However, to our knowledge, there is no framework that represents a unified, holistic paradigm for maintaining skin integrity. This gap represents an opportunity for an innovative paradigm shift. This paper presents a framework that views skin as a complex organ, vulnerable to a multitude of threats and injuries. These diverse yet inter-related injuries can result from complex interactions between patient and systems factors, as well as acute situational stressors. The framework draws together important concepts into a single unified paradigm, highlighting the inter-connection of the spectrum of skin frailty antecedents and resultant skin injuries. This paper argues that the imperative to prevent the diverse range of iatrogenic skin injuries in older hospitalised patients warrants a new skin safety conceptual framework.

Table 2.1

Skin Injuries - Definitions and Significance of the Problem

Term	Definition	Significance of the problem
Pressure ulcer	A localised injury to the skin and/or underlying tissue, usually over a bony prominence, resulting from sustained pressure (including pressure associated with shear), (National Pressure Ulcer Advisory et al., 2014).	6.3-16.6% in acute care, with stage 1and 2 PUs making up the majority of lesions (50% -55%) (National Pressure Ulcer Advisory et al., 2014).
Incontinence-associated dermatitis (IAD)	Skin damage associated with exposure to urine or stool. It is a type of irritant dermatitis found in patients with urinary/and or faecal incontinence (Beeckman et al., 2015).	Prevalence data for general acute care is limited. Two studies in acute care range from 3.9-10% of overall samples, and 20-42% of incontinent patients in the samples (Campbell, Coyer, & Osborne, 2014; Junkin & Selekof, 2007).
Intertriginous dermatitis (ITD)	ITD is an inflammatory dermatitis of opposing skin surfaces caused by moisture, commonly found in the inframammary, axillary and inguinal skin folds (Black et al., 2011).	One hospital study of 1162 female patients reported 11.2% had ITD beneath the breasts (McMahon, 1991). A survey of 100 obese individuals found 63% had more than one skin problem (Brown, Wimpenny, & Maughan, 2004).
Peri-wound dermatitis	Maceration of periwound skin caused by excess wound exudate. In some cases, it may extend beyond 4cm from the wound edge (Colwell et al., 2011).	No prevalence data for this condition has been published.
Peri-stomal dermatitis	Inflammation and erosion of the skin related to moisture that begins at the stoma/skin junction and can extend outward in a radius (Colwell et al., 2011).	There is a wide range reported (10-70%) due to variable definitions and assessment of peristomal skin conditions (Colwell et al., 2011).
Skin tear	A wound caused by shear, friction, and/or blunt force, resulting in separation of skin layers. A skin tear can be partial-thickness (separation of the epidermis from the dermis) or full thickness (separation of both epidermis and dermis from underlying structures) (LeBlanc & Baranoski,2011).	Studies conducted in Western Australian hospitals between 2007-2011 found skin tear prevalence to range from 8-10%, with the majority of skin tears being hospital acquired (Carville et al., 2014).

Term	Definition	Significance of the problem
Medical adhesive related skin injury	Erythema and/or other manifestation of cutaneous abnormality (including, but not limited to, vesicle, bulla, erosion or tear) persists 30 minutes or more after removal of the adhesive (McGahan, Kucharski, & Coyer, 2012).	Prevalence data is scarce. Skin stripping in the paediatric setting ranges from 8-17%, with prevalence of tension blisters ranging from 6-41% in an adult orthopaedic setting (McNichol, Lund Rosen & Gray, 2013).

Aim

The aim of this paper is to develop a unique Skin Safety Model (SSM) that offers a new and unified perspective on the diverse, yet interconnected antecedents that contribute to a spectrum of potential iatrogenic skin injuries in older hospitalised adults.

Methods

A review of the literature was conducted to identify current frameworks, consensus documents, guidelines, or position statements in the area of maintaining skin integrity. Electronic databases including PubMed/Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Web of Science, and Cochrane Library were searched for literature published between 1960 and December 2014. The year 1960 was chosen to capture seminal papers addressing PU aetiology published in that decade. The search strategy was limited to human subjects and those published in English speaking countries. The search was conducted using the key words: skin integrity, skin injury, skin safety, iatrogenic skin injury, pressure sore, pressure ulcer, pressure injury, bedsore, decubitus ulcer, moisture lesion, perineal dermatitis, IAD, moisture-associated skin damage, ITD, skin tear, peri-stomal skin injury, peri-wound skin injury, MARSI, patient safety, quality improvement, and combined with additional key words including conceptual, framework, model, theoretical, guideline, and consensus statement. Meta-analyses and systematic reviews (Level I), randomised controlled trials (Level II), pseudo-randomised controlled trials (Level III-1), and comparative studies with or without concurrent controls (Levels III-2 and III-3) exploring risk factors, aetiology, prevention, treatment or management of skin injury of any type regardless of outcomes were included using the National Health and Medical Research Council (NHMRC) hierarchy of evidence (National Health Medical Research Council, 2000). The search also included searches of websites of relevant national and international organisations, government websites, and conference proceedings. A hand search of reference lists of relevant articles was undertaken.

Results

The search results yielded 2,980 records, and after excluding duplicates, 2,851 titles were screened. Two independent reviewers evaluated 179 potentially

relevant abstracts with, 21 papers meeting the criteria for inclusion in this review. Papers included presented a conceptual framework, theory, model, consensus, guideline, or position statement related to skin integrity, iatrogenic skin injury, pressure sore, pressure ulcer, pressure injury, bedsore, decubitus ulcer, moisture lesion, perineal dermatitis, IAD, moisture-associated skin damage, ITD, skin tear, peri-stomal skin injury, peri-wound skin injury, or MARSI. Papers were excluded if they tested effectiveness of a single intervention. A narrative synthesis was undertaken.

Narrative Synthesis of the Literature

Skin integrity risk is defined by the international nursing diagnosis group, NANDA International, Inc. (Herdman, 2012) as a 'patient being at risk for alteration in epidermis and/or dermis' (p. 437), and classifies skin integrity risk in the domain of safety/protection. Despite this broad definition, maintaining skin integrity has become a surrogate term in the literature for pressure ulcer (PU) prevention. However, beyond PUs, older patients can be at risk for a range of iatrogenic skin injuries. Prevention of hospital acquired PUs has shaped policy, funding, and research agendas internationally, and has been the primary activity in maintaining skin integrity in the acute care setting. Multiple conceptual frameworks (Braden & Bergstrom, 1987; Coleman et al., 2014; DeFloor, 1999; National Pressure Ulcer Advisory, European Pressure Ulcer Advisory, & Pan Pacific Pressure Injury, 2014) have been published that address pressure ulcer risk factors and aetiology. However, publication of a range of consensus documents has resulted in increased appreciation of other iatrogenic skin injuries (Beeckman et al., 2015; Black et al., 2011; LeBlanc & Baranoski, 2011; McNichol et al., 2013). These injuries include incontinence-associated dermatitis (IAD) (Beeckman et al., 2015), intertriginous dermatitis, peristomal or periwound moisture-associated skin damage (MASD) (Black et al., 2011), skin tears (LeBlanc & Baranoski, 2011) or medical adhesive-related skin injury (MARSI) (McNichol et al., 2013) (see Table 2.1).

A compelling argument in support of an integrated skin safety paradigm is an appreciation of the multiple contributing factors that many iatrogenic skin injuries share. A recent narrative synthesis of 54 published studies, with more than 34,000 participants was conducted by Coleman and colleagues (2013), to identify pressure ulcer risk factors. The most common PU risk factors identified were in the domains

of mobility/activity, perfusion, PU status, skin moisture, age, haematological measures, and general health status. They concluded that a complex interplay of factors, rather than a single risk factor increased the probability of PU development. It is noteworthy that these PU risk factors are also cited as risk factors for other iatrogenic skin injuries, such as skin tears or IAD (Beeckman et al., 2015; LeBlanc & Baranoski, 2014). However, apart from the work of García-Fernández, Agreda, Verdú, and Pancorbo-Hidalgo (2014) proposing the mechanism for dependence-related lesions, and the work of Campbell (2009), recognising the association between PU and frailty, there is a general paucity of research exploring shared and synergistic factors contributing to iatrogenic skin injury in older adults.

While iatrogenic skin injuries share multiple contributing factors, prevention and management of these skin injuries is commonly undertaken in silos. This siloed approach can result in fragmented, duplicated, or inconsistent care, as well as a multitude of conceptual frameworks and consensus documents addressing individual skin integrity outcomes (Brown & Sears, 1993; Coleman et al., 2014; Doughty et al., 2012; LeBlanc & Baranoski, 2011). To our knowledge, there is no over-arching skin integrity framework recognising shared risk factors and acknowledging a variety of potential outcomes.

In the last three decades, several conceptual frameworks have been published that deal specifically with pressure ulcer aetiology. A seminal paper by Braden and Bergstrom (1987) identified tissue tolerance and pressure as critical determinants of pressure ulcer development. Subsequently, the term tissue tolerance has been used throughout PU literature to denote the ability of the skin and supporting structures to endure the effects of pressure without adverse sequale (Benoit & Mion, 2012; Coleman et al., 2014; DeFloor, 1999; National Pressure Ulcer Advisory et al., 2014). Further, a central concept in these frameworks is the recognition that risk of PU development results from an interplay between multiple factors, including individual tissue tolerance, and the influence of the type, intensity, and duration of an external force acting on the body. In addition to recognising the influence of tissue tolerance and external forces acting on the body, Defloor's model (1999) includes nursing and medical interventions as determinants of both pressure and shear, and ultimately PU development. The recent conceptual model proposed by Garcia-Fernandez et al. (2014) moves beyond considering only PU aetiology, to identify shared risk factors

common to pressure ulcers and other dependence lesions, suggesting a growing appreciation of shared antecedents of iatrogenic skin injury.

Consensus documents dealing with skin injuries other than PUs reveal several common themes regarding skin injury contributing factors and aetiology (Brown & Sears, 1993; Coleman et al., 2014; Doughty, 2012; LeBlanc & Baranoski, 2011). Firstly, the response to potentially harmful forces acting on skin is highly influenced by tissue tolerance and is unique to each individual. Secondly, that impaired tissue tolerance is a key aetiological factor for *any* iatrogenic skin injury, not just pressure ulcers. Tissue tolerance is a construct that varies slightly between authors, but is consistently linked with an individual's advancing age, pre-existing health status, and comorbidities, nutrition, medications, perfusion, oxygenation, mobility, and sensory perception. Finally, elements that threaten skin integrity in vulnerable individuals are pressure, shear, friction, moisture, and trauma.

Pressure ulcer prevention strategies are well documented in the literature, and include nursing and medical interventions (such as skin assessment, repositioning, and appropriate equipment selection) (National Pressure Ulcer Advisory et al., 2014). The impact of healthcare interventions on skin integrity outcomes is largely under-appreciated in PU or other skin integrity conceptual frameworks. Defloor's (1999) insightful inclusion of the influence of healthcare systems factors (such as medical and nursing interventions) as PU risk factors demonstrates a comprehensive framework that moves beyond physiological and biomechanical causes of PU and recognises broader threats to skin integrity.

Recognition of healthcare systems and processes as a potential component of a risk profile is echoed in the quality health outcomes model proposed by Mitchell, Ferketich and Jennings (1998). This model proposed the existence of dynamic feedback between patients, healthcare interventions, *and* the system in which care was provided. Further, they asserted that patient characteristics directly affected the intervention outcome. Their model highlights the need for consideration of the influence of organisational or system factors on outcomes, and that interventions should be evaluated within the context of interactions and feedback between the patient and the system (Mitchell et al., 1998). While not specifically dealing with PU or skin integrity, Mitchell and colleagues' model (1998) supports Defloor's (1999) contention that systems and process elements (i.e., nursing and medical

interventions) should be considered in care delivery and subsequent patient outcomes.

Overall, there is agreement in the literature that iatrogenic skin injuries result from complex, multifactorial, and interconnected threats. It is clear from the literature review that the phenomenon of *skin safety,* or iatrogenic skin injury, as a holistic concept is not represented. The term skin safety used in this paper denotes the protection from possible alteration or injury to the epidermis and/or dermis in the older patient resulting from the interplay between multiple and complex threats to skin integrity. While there is a significant body of literature regarding PU aetiology, prevention and management, and similarly, a growing body of research addressing other discrete iatrogenic skin injuries, a gap remains in the conceptualisation of skin vulnerability to injury as an over-arching phenomenon.

A Model for Skin Safety

In a single model, the SSM (see Figure 2.1) guides clinicians in the recognition and consideration of diverse yet inter-related contributing factors in the aetiology of a range of iatrogenic skin injuries and subsequent outcomes. The model consists of four domains or constructs: (a) potential contributing factors to skin injury, (b) exacerbating elements, (c) potential skin injury, and (d) potential outcomes of skin injury. Within each domain is a subset of determinants, which can be considered as dynamic, or on a continuum. There are a myriad of combinations of these determinants, with varying severity, relevance, or impact for each individual. The determinants have the potential to change according to a specific situation, interaction with other domains, or the passage of time. The relationship between the potential contributing factors and exacerbating elements domains is represented by a plus symbol to indicate the cumulative or magnifying effect of the first domain on the second. The relationship between the exacerbating elements and potential skin injuries domains is represented by an arrow, indicating the potential range of consequences (that is skin injuries) that flow from interactions between the previous two domains. An arrow represents the direct relationship between the potential skin injury and the final domain, the range of potential outcomes as experienced by an individual.

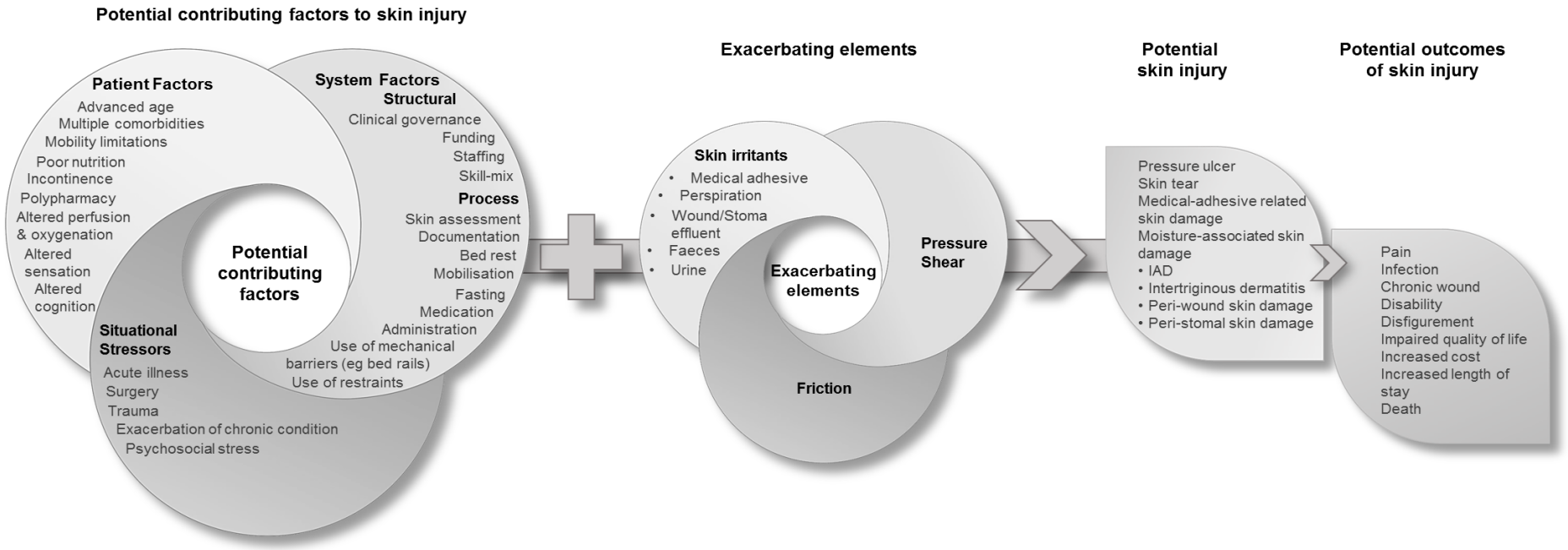


Figure 2.1 Skin Safety Model.

Patient Factors

Patient factors in the SSM are determinants situated within the domain of potential contributing factors to skin injury. The determinants constituting patient factors are advanced age, multiple co-morbidities, mobility limitations, poor nutrition, incontinence, factors affecting perfusion and oxygenation, polypharmacy, alterations in sensation, and cognition. Ageing is associated with the presence of accumulating chronic illnesses, multi-morbidity, and geriatric syndromes (Dagmar 2013, Inouye et al., 2007; Lakhan et al., 2011). The term geriatric syndrome/s refers to multifactorial health conditions that result from accumulated effects in multiple systems, and describes conditions in older people that are not categorised as discrete diseases, including incontinence, falls, PUs, delirium, and functional decline (Inouye et al., 2007). Multiple co-morbidities add cost and complexity to healthcare due to disease interactions and the resultant complexity of the required care (Greene, Dasso, Ho, & Genaidy, 2014). It is clear that the presence of multiple disease states and geriatric syndromes influence all body systems, including skin.

System Factors

Systems factors are determinants also situated within the domain of potential contributing factors to skin injury. A system is defined as a set of things working together as parts of a mechanism or an interconnecting network, to form a complex whole (Fowler H. W., Fowler F. G., & Crystal, 2011). The system represented in the SSM denotes the organised agency where care of the patient happens, specifically the hospital (McClellan et al., 2014; Mitchell et al., 1998). The domain of the system of care is conceptualised in the SSM as comprising both structural and process elements (Mitchell et al., 1998). Structural elements of the system can include clinical governance, safety culture, funding models, leadership, staffing, and skill–mix (Mitchell et al., 1998; Youngberg, 2013). A process is defined as a series of actions or steps taken in order to achieve a particular end (Fowler H. W. et al., 2011). Process elements represented in the SSM refer to direct and indirect interventions and activities by which care is delivered (Mitchell et al., 1998; Youngberg, 2013). The process elements in the SSM refer to interventions and activities that influence skin integrity outcomes, for example: skin assessment, documentation, bed rest, mobilisation, fasting, medication administration, use of mechanical barriers (such as restraints or bed rails), or tethers (such as catheters, drains or intravenous lines) (Bry

et al., 2012; Montalvo, 2007; Youngberg, 2013). Ultimately, structural and process elements of the system interact to affect patient outcomes (Mitchell et al., 1998), in this case, skin integrity outcomes.

The means by which a hospital receives its funding is integral to the system of care and has a profound influence on its structures and processes. Traditionally, many healthcare systems have been provider or supply driven, whereby separate elements of care are remunerated (McClellan et al., 2014). The goal of provider or supply driven funding models is to improve patient access to service and outcomes (Solomon, 2014). An example of the use of funding systems being used as leverage to influence skin integrity outcomes is seen in the reduction of reimbursement for treatment of hospital acquired pressure ulcers (HAPUs), or the introduction of financial incentives for HAPU prevention. It can be argued that funding disincentives for specific aspects of skin safety (i.e., PU prevention) may foster a narrow focus on a specific activity (to avoid financial penalty), while opportunities to provide broader overarching skin safety programs are potentially overlooked (McClellan et al., 2014).

The structure and process by which nursing care is delivered within the hospital system can influence skin integrity outcomes. Missed nursing care is seen as a systems error of omission (Kalisch, Landstrom, & Hinshaw, 2009), and may include missing scheduled repositioning, not undertaking a skin inspection, inappropriate management of incontinence, or missed feeding. These aspects of care all have a direct role in maintaining skin integrity, therefore, if any or all of these aspects of care are delayed, incomplete, or even omitted, skin injury may result (Kalisch et al., 2009). Predictors of missed care in a recent study (Blackman et al., 2014) included nursing resource allocation, workload intensity, and workload predictability. It can be seen that the structure and process by which nurses are able to provide care has a direct impact on PU risk and subsequent outcomes, and warrants consideration in the broader skin safety paradigm.

Situational Stressors

A situational stressor is a further determinant in the domain of potential contributing factors to skin injury. A situational stressor is conceptualised in the SSM as an acute event, illness, or trauma requiring a hospital admission for an older individual. A situational stressor may be a fall resulting in trauma, an acute infection, or an exacerbation of a pre-existing condition. Increases in an individual's

vulnerability to stressors such as infection, injury, surgery, or hospitalisation can result in significant and sometimes fatal declines in health (Fried et al., 2001). The combination of multiple patient factors interacting with the complex hospital system, compounded by an individual's lack of capacity to respond to these stressors, can potentially lead to a multiplicity of adverse events, including iatrogenic skin injury.

Exacerbating Elements

The next domain in the SSM is exacerbating elements, conceptualised by the determinants pressure, shear, friction, or the presence of irritants on the skin. Exposure to one or a combination of these determinants can result in skin injury. These skin integrity threats have been well defined and conceptualised in the literature (Beeckman et al., 2015; Gefen, 2014; Gray, 2007; National Pressure Ulcer Advisory et al., 2014; Oomens, Bader, Loerakker, & Baaijens, 2015; Shaked & Gefen, 2013).

Potential Skin Injuries

The fourth domain in the SSM is potential iatrogenic skin injuries, with the determinants being PU, skin tears, IAD, intertriginous dermatitis, and MARSI. These injuries are the result of the interactions and convergence of the domains of potential contributing factors and exacerbating elements. For instance, an older person who is able to mobilise at home, but falls frequently, may be vulnerable to skin tears as a result. However, if a situational stressor is experienced (for example, acute diarrhoea requiring hospital admission), the same individual is likely to be at increased risk of PU and IAD, as well as concomitant skin tear risk. Due to the multiple shared contributing factors, older patients can be simultaneously at risk of a range of different skin injuries.

Potential Outcomes of a Skin Injury

The potential outcome of a skin injury constitutes the final domain of the SSM. Regardless of aetiology, disruption to skin integrity can impact on wellbeing and predispose an individual to infection, pain, increased morbidity, and mortality with the attendant increase in the demand on healthcare services (Carville, 2012). The experience of a skin injury is highly individual, can change over time, and can impinge on all domains of wellbeing (physical, mental, social, and spiritual/cultural) (Augustin et al., 2012). The inclusion of potential outcomes of skin injury in the

SSM is unique. Rather than limiting the framework to identifying the skin injury, recognition of the patient's experience of iatrogenic skin injury is fundamental for delivery of holistic person-centred care.

Shifting the Paradigm From Prevention to Skin Safety

The SSM proposes a paradigm shift away from specific skin injury prevention towards a holistic patient-centred goal of maintaining skin integrity. Patient individuality in the context of multiple and shared risk factors is a central premise of the SSM, allowing numerous skin integrity outcomes to be accommodated in a single integrated framework. The SSM recognises that dynamic and individual interactions between skin injury antecedents may result in different outcomes for each individual. Managing multiple individual risks separately may result in competing risk assessments, care pathways, systems demands, and priorities; ultimately resulting in fragmented or duplicated care. The SSM provides a single integrated framework to facilitate skin integrity management at the individual patient level.

Contemporary patient care is compounded by traditional biomedical models of disease that have a linear focus on aetiology, pathological processes and ultimately specific clinical outcomes (Chiarelli, Bower, Wilson, Attia, & Sibbritt, 2005). This specialised care delivery can result in the perception of the hospital being a series of departments or silos (with each concerned with their own budgets and performance indicators) delivering fragmented care, rather than being a fully integrated process or continuum of care (Shortell & Singer, 2008). The impact of the multifactorial complexity and individuality of the patient can be easily lost in the specialty silo (Denham, 2009; Inouye et al., 2007). Multiple narrow condition focused care paradigms, with attendant narrow solutions, and the potential for duplication and inconsistency, is neither sustainable, nor desirable in the modern healthcare environment. Improving care delivery and systems requires initiatives that address multiple problems across a continuum of care.

Vulnerability to iatrogenic skin injury in the older acute care patient results from the convergence of multiple complex factors. An appreciation of the complexity and diversity of all of these factors can create the circumstances whereby genuine holistic care can be planned and delivered, with the overall goal of care being skin safety/the prevention of iatrogenic skin injury. The SSM encompasses this

complexity and offers a theoretical foundation for innovative skin injury prevention in the acute care environment.

Conclusion

Maintaining skin integrity in the older hospitalised adult is a priority for healthcare providers. Diverse antecedents interact synergistically to cause a range of possible iatrogenic skin injuries. These injuries have implications for patients and the healthcare system alike, including pain and suffering, as well as increased cost and length of hospital stay. This paper has presented a model formulated from a review of the literature for conceptualising skin safety in a unified way. The SSM moves beyond physiology and biomechanics to encompass and reconceptualise varied and complex factors that can converge, interact, and ultimately lead to skin injury in older patients. However, the SSM is not a risk assessment tool; rather, it is a framework to guide clinicians and healthcare providers in the recognition and consideration of the complexity of skin injury aetiology. Further testing and validation of the SSM is required. Opportunities for further research include the development and validation of an integrated skin safety risk assessment tool. Research and quality activities, such as PU prevalence and incidence studies in the acute care setting could be expanded to encompass data collection on any concurrent iatrogenic skin injury, rather than simply determining PU status. Reframing quality indicators to include an organisation's response to skin risk rather than PU management and prevention may result in improved overall patient outcomes, as well as improved system efficiencies. The paradigm shift from focus on specific skin injury prevention to an appreciation of over-arching skin integrity vulnerability in the older adult patient is timely in light of the challenges healthcare systems are facing. A comprehensive and innovative approach to skin safety is essential to deal with increasing patient age, acuity, and complexity, increasing fiscal challenges, and the fundamental expectation that healthcare is safe.

References

Augustin, M., Carville, K., Clark, M., Curran, J., Flour, M., Lindholm, C., … &Young, T.. (2012). International consensus: optimising wellbeing in people living with a wound. An expert working group review. London: *Wounds International.* Retrieved from http://www.woundsinternational.com/media/issues/554/files/content_10309.

Aydin, C., Donaldson, N., Stotts, N. A., Fridman, M., & Brown, D. S. (2015). Modeling hospital-acquired pressure ulcer prevalence on medical-surgical units: Nurse workload, expertise, and clinical processes of care. *Health Services Research, 50*(2), 351-373.

Beeckman, D., Campbell, J., Campbell, K., Chimentao, D., Coyer, F., Domansky, R., …Wang, L. (2015). Proceedings of the Global IAD expert Panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International*. Retrieved from http://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf

Benoit, R., & Mion, L. (2012). Risk factors for pressure ulcer development in critically Ill patients: A conceptual model to guide research. *Research in Nursing & Health, 35*(4), 340-362.

Black, J., Gray, M., Bliss, D., Kennedy-Evans, K., Logan, S., Baharestani, M., . . . & Ratliff, C. (2011). MASD part 2: Incontinence-associated dermatitis and intertriginous dermatitis: a consensus. *Journal of Wound Ostomy & Continence Nursing, 38*(4), 359-370.

Blackman, I., Henderson, J., Willis, E., Hamilton, P., Toffoli, L., Verrall, C., . . . & Harvey, C. (2014). Factors influencing why nursing care is missed. *Journal of Clinical Nursing,24*,47-56.

Braden, B., & Bergstrom, N. (1987). A conceptual schema for the study of the etiology of pressure sores. *Rehabilitation Nursing, 12*(1), 47-56.

Brown, & Sears, M. (1993). Perineal dermatitis: A conceptual framework. *Ostomy and Wound Management, 39*(7), 20-22, 24-25.

Brown, J., Wimpenny, P., & Maughan, H. (2004). Skin problems in people with obesity. *Nursing Standard, 18*(35), 38-42.

Bry, K. E., Buescher, D., & Sandrik, M. (2012). Never say never: A descriptive study of hospital-acquired pressure ulcers in a hospital setting. *Journal of Wound Ostomy and Continence Nursing, 39*(3), 274-281.

Campbell, J., Coyer, F., & Osborne, S. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting. *International Wound Journal*. doi:10.1111/iwj.12322

Campbell, K. E. (2009). A new model to identify shared risk factors for pressure ulcers and frailty in older adults. *Rehabilitation Nursing, 34*(6), 242-247.

Carville, K. (2012). *Wound care manual* (6th ed.). Perth: Silver Chain Foundation.

Carville, K., Leslie, G., Osseiran-Moisson, R., Newall, N., & Lewin, G. (2014). The effectiveness of a twice-daily skin-moisturising regimen for reducing the incidence of skin tears. *International Wound Journal, 11*(4), 446-453.

Chiarelli, P., Bower, W., Wilson, A., Attia, J., & Sibbritt, D. (2005). Estimating the prevalence of urinary and faecal incontinence in Australia: systematic review. *Australasian Journal on Ageing, 24*(1), 19-27.

Coleman, S., Gorecki, C., Nelson, E. A., Closs, S. J., Defloor, T., Halfens, R., . . . & Nixon, J. (2013). Patient risk factors for pressure ulcer development: Systematic review. *International Journal of Nursing Studies, 50*(7) 974-1003.

Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., . . . & Nelson, E. A. (2014). A new pressure ulcer conceptual framework. *Journal of Advanced Nursing, 70*(10), 2222-2234.

Colwell, J. C., Ratliff, C. R., Goldberg, M., Baharestani, M. M., Bliss, D. Z., Gray, M., . . . & Black, J. M. (2011). MASD Part 3: Peristomal moisture-associated dermatitis and periwound moisture-associated dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 38*(5), 541-553.

Coyer, F., Gardner, A., Doubrovsky, A., Cole, R., Ryan, F. M., Allen, C., & McNamara, G. (2015). Reducing pressure injuries in critically ill patients by using a patient skin integrity care bundle (InSPiRE). *American Journal of Critical Care , 24*(3), 199-209.

DeFloor, T. (1999). The risk of pressure sores: A conceptual scheme. *Journal of Clinical Nursing, 8*(2), 206-216.

Denham, C. R. (2009). The no outcome-no income tsunami is here: Are you a surfer, swimmer, or sinker? *JONA's Healthcare Law, Ethics, and Regulation, 11*(2), 57-69.

Doughty, D. (2012). Differential assessment of trunk wounds: Pressure ulceration versus incontinence associated dermatitis versus intertriginous dermatitis. *Ostomy Wound Management, 58*(4), 20-22.

Doughty, D., Junkin, J., Kurz, P., Selekof, J., Gray, M., Fader, M., . . . & Logan, S. (2012). Incontinence-associated dermatitis: Consensus statements, evidence-based guidelines for prevention and treatment, and current challenges. *Journal of Wound Ostomy and Continence Nursing, 39*(3), 303-315.

Fowler, H. W., Fowler, F. G., & Crystal, D. (2011). *The concise Oxford dictionary of current English*. Oxford: Oxford University Press.

Fried, L. P., Tangen, C. M., Walston, J., Newman, A. B., Hirsch, C., Gottdiener, J., . . . & McBurnie, M. A. (2001). Frailty in older adults: Evidence for a phenotype. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 56*(3), M146-M156.

García-Fernández, F. P., Agreda, J. J. S., Verdú, J., & Pancorbo-Hidalgo, P. L. (2014). A new theoretical model for the development of pressure ulcers and other dependence-related lesions. *Journal of Nursing Scholarship, 46*(1), 28-38.

Gefen, A. (2014). From incontinence associated dermatitis to pressure ulcers. *Journal of Wound Care, 23*(7), 345.

Gray, M., Bliss, D., Doughty, D., Ermer-Seltun, J., Kennedy-Evans, K., & Palmer, M. (2007). Incontinence-associated dermatitis: a consensus. *Journal of Wound Ostomy & Continence Nursing, 34*(1), 45-56.

Greene, R. A., Dasso, E., Ho, S., & Genaidy, A. M. (2014). A Person-Focused Model of Care for the Twenty-First Century: A System-of-Systems Perspective. *Population Health Management, 17*(3), 166-171.

Herdman, T. (2012). *Nanda international nursing diagnoses: Definitions & classification, 2012-2014*. Oxford: Wiley-Blackwell.

Inouye, S. K., Studenski, S., Tinetti, M. E., & Kuchel, G. A. (2007). Geriatric syndromes: Clinical, research, and policy implications of a core geriatric concept. *Journal of the American Geriatrics Society, 55*(5), 780-791.

Junkin, J., & Selekof, J. L. (2007). Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of Wound Ostomy and Continence Nursing, 34*(3), 260-269.

Kalisch, B. J., Landstrom, G. L., & Hinshaw, A. S. (2009). Missed nursing care: a concept analysis. *Journal of Advanced Nursing, 65*(7), 1509-1517.

Lakhan, P., Jones, M., Wilson, A., Courtney, M., Hirdes, J., & Gray, L. C. (2011). A prospective cohort Study of geriatric syndromes among older medical patients admitted to acute care hospitals. *Journal of the American Geriatrics Society, 59*(11), 2001-2008.

LeBlanc, K., & Baranoski, S. (2011). Skin tears: State of the science: Consensus statements for the prevention, prediction, assessment, and treatment of skin tears. *Advances in Skin & Wound Care, 24*(9), 2-15.

LeBlanc, K., & Baranoski, S. (2014). Skin tears: The forgotten wound. *Nursing Management, 45*(12), 36-46.

McClellan, M., Kent, J., Beales, S. J., Cohen, S. I., Macdonnell, M., Thoumi, A., . . . & Darzi, A. (2014). Accountable care around the world: A framework to guide reform strategies. *Health Affairs 33*(9), 1507-1515.

McNichol, L., Lund, C., Rosen, T., & Gray, M. (2013). Medical adhesives and patient safety: State of the science: Consensus statements for the assessment, prevention, and treatment of adhesive-related skin injuries. *Journal of Wound Ostomy and Continence Nursing, 40*(4), 365-380.

Mitchell, P. H., Ferketich, S., & Jennings, B. M. (1998). Quality health outcomes model. American Academy of Nursing Expert Panel on Quality Healthcare. *Image Journal of Nursing Scholarship, 30*(1), 43-46.

Montalvo, I. (2007). The National Database of Nursing Quality Indicators (NDNQI). *Online Journal of Issues in Nursing, 12*(3), 13p.

National Health Medical Research Council. (2000). How to review the evidence: Systematic identification and review of the scientific literature. Retrieved from http://www.nhmrc.gov.au/publications/synopses/_files/cp65.pdf

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance. (2014). *Prevention and treatment of pressure ulcers: Clinical practice guideline* (E. Haesler Ed.). Perth, Australia: Cambridge Media.

Oomens, C. W., Bader, D. L., Loerakker, S., & Baaijens, F. (2015). Pressure induced deep tissue injury explained. *Annals of Biomedical Engineering , 43*(2), 297-305.

Shaked, E., & Gefen, A. (2013). Modeling the Effects of moisture-related skin-support friction on the risk for superficial pressure ulcers during patient repositioning in bed. *Frontiers in Bioengineering and Biotechnology 1*, 9.

Shortell, S. M., & Singer, S. J. (2008). Improving patient safety by taking systems seriously. *The Journal of the American Medical Association, 299*(4), 445-447.

Solomon, S. (2014). Health reform and activity-based funding. *The Medical Journal of Australia, 200*(10), 564.

Youngberg, J. (2013). *Patient safety handbook,* (2nd ed.). Burlington: Jones and Bartlett Learning.

2.5.1 Research published following Publication 1

Research published after Publication 1 of this thesis identified that there are a range of factors that occur during a hospital admission that can lead to functional decline in elderly patients. These factors include poor mobilisation, inappropriate use of incontinence aids, indwelling urinary catheters, poor continence management, under-nutrition, and hospital environments that are noisy, disorienting, and socially isolating (Admi, Shadmi, Baruch, & Zisberg, 2015; Sourdet et al., 2015; Zisberg et al., 2015). This research demonstrates a growing appreciation of the challenges of the hospital environment for older patients, and healthcare systems that may not be equipped to deal with their complex needs, and as such, pose a threat to this group. While these findings cite functional decline rather than skin injuries as primary outcomes, analogies can be drawn regarding the premise of the SSM (Campbell, Coyer, & Osborne, 2015), in that interactions between complex and multifactorial antecedents have the potential to result in a wide range of adverse outcomes.

2.6 CHAPTER SUMMARY

The literature review revealed that contemporary healthcare faces multiple challenges from unsustainable increases in healthcare expenditure, rapidly ageing populations, and changing patterns of disease and disability. Globally, these rapid changes have become the drivers for 21st century healthcare reform. Contemporary healthcare continues to be delivered in specialty silos, yet this system of care is at odds with the complex care needs of contemporary patients, and even creates situations in which care is fragmented, duplicated or missed. Parallels between contemporary healthcare delivery and contemporary skin integrity practices can be observed. Like contemporary healthcare, skin integrity care is frequently delivered in silos, as is evidenced by the multiple, individual skin injury frameworks, as well as being influenced by the traditional biomedical model of disease, which focuses on aetiology, pathological processes and ultimately specific clinical outcomes (Chiarelli, Bower, Wilson, Attia, & Sibbritt, 2005). In addition, maintaining skin integrity in the modern healthcare environment is also affected by increasing patient complexity resulting from chronic, comorbid diseases, geriatric syndromes and frailty. At the same time, skin integrity care grapples with similar challenges faced by other healthcare providers; that is, providing cost-effective, efficient care, and offering innovative solutions to contemporary challenges.

Until now, a unifying skin safety framework has been lacking. The literature review culminated in the development of the SSM, an overarching evidence-based framework that guides skin integrity decision-making while appreciating the complexity of the contemporary acute care patient. The SSM addresses the conceptual and clinical need for a comprehensive framework that guides skin care in the older acute care patient, and constitutes the conceptual framework that underpins this research.

The following chapter presents a review of the literature pertaining to skin structure and function, skin changes associated with ageing, a historical overview of IAD research, as well as IAD pathophysiology, risks, clinical presentation, and complications.

Chapter 3: LITERATURE REVIEW, PART B - INCONTINENCE-ASSOCIATED DERMATITIS AND INCONTINENCE-ASSOCIATED *CANDIDA* INFECTION

3.1 INTRODUCTION

This chapter presents a review of the literature on IAD, including its aetiology, risk factors, and prevalence in the acute care setting. Understanding the structure and function of skin, its critical barrier function, and the unique skin changes experienced by older adults forms the foundation for understanding the pathophysiology of IAD. Furthermore, an overview of the effects of moisture, urine, and faeces on skin barrier function as a result of incontinence, the effects of occlusion (as a result of wearing an incontinence aid) on skin, and the clinical presentation of IAD are presented in this chapter. The complications of IAD, including *Candida albicans* infection, are also discussed.

3.1.1 Literature search strategy

The search strategy for this chapter is per the search strategy detailed in Chapter 2, with the addition of the search terms, incontinence-associated dermatitis, perineal dermatitis, diaper dermatitis, moisture-associated skin damage, combined with additional key words including aetiology, prevention, management, risk factor/s, risk assessment, complication/s, superimposed, secondary, fungal, *Candida*, *albicans*, and colonisation. The literature for this chapter was searched between 1985 and December 2014. The year 1985 was chosen to capture seminal papers addressing IAD in the early 1990s.

3.1.2 Incontinence

IAD is a condition resulting from chronic skin exposure to urine and faeces due to incontinence. In order for an individual to develop IAD, they must be incontinent (Gray et al., 2007), therefore, an appreciation of incontinence is essential in order to understand IAD. Incontinence is defined as the unwanted and involuntary leakage of urine and/or faeces (Abrams et al., 2010; Ahmed & Pearce, 2010; Homma, 2008; Inouye et al., 2007; Junkin & Selekof, 2007). It can affect any age

group, but is more common in older adults, with more than half of incontinent individuals aged over 50 years, and those aged over 65 years are 12 times more likely to experience severe incontinence (Australian Institute of Health and Welfare, 2014). The prevalence of incontinence in the acute care setting is poorly understood (Ostaszkiewicz et al., 2008). One study conducted in this setting in the United States found the prevalence of incontinence to be 19.7% (Junkin & Selekof, 2007). Another study reported the prevalence of incontinence to range from 10%-43% for urinary incontinence and 7%-33% for faecal incontinence (Ostaszkiewicz et al., 2008). In Australia, a study investigating the prevalence of geriatric syndromes in the acute care setting, found that the prevalence of bladder incontinence in a cohort of 570 medical patients aged over 70 years was 44% (Lakhan et al., 2011). The prevalence of incontinence is an indicator of the magnitude of risk of IAD in a given group of patients (Ersser et al., 2005). However, while it is clear the prevalence of incontinence is significant, and set to rise and, like the prevalence of IAD, it remains poorly understood in the hospital setting.

3.1.3 Skin structure and function

Skin is the largest and most visible organ in the body. It is divided into three distinct layers: firstly, the epidermis or outer layer; secondly, the dermis, known as the factory of the skin; and finally, the hypodermis, which is the supporting layer of the skin (Carville, 2012). The epidermis, the outermost skin layer, varies in thickness according to location, and is comprised of stratified squamous epithelial cells or keratinocytes (Rolstad, Ermer-Seltun, & Bryant, 2011). The epidermis itself consists of a further five layers; from the very outer layer, the stratum corneum, followed by the stratum lucidum, the stratum granulosum, the stratum spinosum, and finally the stratum germinativum or basale (2015; Carville, 2012; Wysocki, 2007). Stem cells in the basal layer of the epidermis divide and form differentiated keratinocytes that mature and travel upwards to the stratum corneum. As these keratinocytes travel through the epidermal layers, they become flat, densely packed and anucleate, eventually forming the stratum corneum (Rolstad et al., 2011). The process of epidermal turnover takes approximately 28 days, but can be accelerated in some skin diseases and be significantly slower in older age, sometimes up to 42 days (Fore, 2006; Rolstad et al., 2011). An intact epidermis is responsible for the important

barrier function of the skin (Carville, 2012; Ersser et al., 2005; Wysocki, 2007) (see Section 3.1.4).

The basement membrane zone (BMZ), or dermal-epidermal junction, anchors the epidermis to the dermis (Wysocki, 2007). The BMZ is divided into two zones—the lamina lucida and lamina densa. The proteins present at the BMZ, such as fibronectin, laminin, type IV collagen, and heparin sulphate, all play a role in cellular adhesion or anchoring the epidermis to the dermis (Wysocki, 2007). Flattening of the dermo-epidermal junction as a result of loss of dermal papillae and reduced interdigitation between layers results in less resistance to shearing forces and an increased vulnerability to skin injury (Farage, Miller, Elsner & Maibach, 2013).

Skin is the interface between the internal and external environment and is required to perform multiple functions in order to maintain homeostasis (Carville, 2012; Ersser et al., 2005; Fore, 2006). These functions include protection against a multitude of external agents, including chemical, thermal, and mechanical insults, moisture, microorganisms, electromagnetic radiation; and protection against dehydration (Carville, 2012; Fore, 2006). The essential protective sensory function of skin is facilitated by receptors that respond to pain, heat, cold, touch pressure, and vibration. Thermoregulation is another vital function and occurs by a variety of mechanisms, for example, radiation of heat from blood vessels and excretion and evaporation of sweat (Carville, 2012; Wysocki, 2007). Skin also facilitates the synthesis of vitamins and hormones, as well as playing a role in immunity (Baroni et al., 2012; Carville, 2012; Di Meglio, Perera, & Nestle, 2011b). Finally, the cosmetic function of skin (cosmesis) is a key function of psychosocial health (Carville, 2012).

3.1.4 Skin barrier function

As discussed in the previous section, a vital function of the skin is to provide an effective barrier between the internal and external environment (Gray, 2004; Menon & Kligman, 2009; D.Voegeli, 2012). Understanding the skin's barrier function is of particular importance in understanding, preventing, and managing IAD. The ability of the skin to function effectively as a barrier depends on several factors, including the integrity of the skin and its structure, the presence of inter- and extra-cellular lipids, and the skin's pH (Gray, 2004).

The skin's barrier function is found in the stratum corneum and was demonstrated in 1953 by the seminal work of Blank (1953). An intact stratum corneum or outer skin layer is a vital component of the physical barrier (Menon & Kligman, 2009). The stratum corneum is organised into two compartments, comprising corneocytes, 18-20 layers thick enveloped in a lipid matrix. This structure has been described as resembling 'bricks and mortar' (Michaels, Chandrasekaran, & Shaw, 1975). The corneocytes are held together by corneodesosomes, which gradually degrade to allow for the desquamation of the outermost corneocytes (Menon, Cleary, & Lane, 2012). The lipids surrounding the corneocytes contain a range of ceramides, cholesterol, and free fatty acids that provide the permeability barrier. The stratum corneum also contains lipolytic and proteolytic enzymes that contribute to its biochemical activities (Menon et al., 2012; Menon & Kligman, 2009). While the extracellular space in the stratum corneum (the so-called mortar) is hydrophobic, the corneocytes themselves maintain their hydrophilic nature from keratins and natural moisturising factors found within the corneocytes (Menon et al., 2012; D.Voegeli, 2012). The role of the natural moisturising factor is to maintain skin hydration, plasticity, and allow the effective function of desquamation, ultimately supporting skin barrier function (Rawlings, Scott, Harding, & Bowser, 1994).

The pH of skin ranges from 4.2-5.6, with the slightly acidic pH commonly known as the acid-mantle (Carville, 2012;Wysoski, 2007). The acidic skin surface provides several important functions. Firstly, acidic pH provides a defence against invading organisms. Normal skin flora growth is optimal at acidic pH levels, whereas pathogenic bacteria and yeast such as *Candida albicans* flourish at neutral or raised pH levels (Ali & Yosipovitch, 2013; Baroni et al., 2012; Lambers, Piessens, Bloem, Pronk, & Finkel, 2006). Secondly, acidic skin pH plays a role in maintaining the skin barrier function. Lipid processing enzymes responsible for a competent skin barrier in the stratum corneum are dependent on an acidic pH (Ali & Yosipovitch, 2013; Baroni et al., 2012). Studies have shown that elevations of skin pH reduce the activity of ceramide-generating enzymes and increase the activity of serine proteases, resulting in a disturbed skin barrier (Ali & Yosipovitch, 2013). Furthermore, skin pH changes are involved in the pathogenesis of irritant contact dermatitis, atopic dermatitis, acne vulgaris, and *Candida albicans* infections (Baroni et al., 2012).

Overall, disruptions to the skin barrier function form the basis for IAD. There are multiple factors that cause disturbances to the skin barrier. These factors and their impact on the skin barrier function are discussed in the following sections.

3.1.5 Effects of moisture, urine, and faeces on skin barrier function

Moisture from urine, liquid faeces, and perspiration is responsible for a significant component of the skin damage seen in IAD. Urine is typically 95% water, with a variety of solutes present, including urea; however, the duration of moisture exposure is the most important skin irritation factor (Gray et al., 2011). A study conducted by Mayrovitz and Sims (2001) found that pads saturated with synthetic urine and applied to the forearms of healthy volunteers resulted in significant reductions in skin hardness, temperature, and blood flow during pressure load, leading the authors to conclude that skin wetness results in skin injury. Water also increases skin permeability, allowing for the passage of irritants that can create allergic or contact dermatitis (Tsai & Maibach, 1999; D.Voegeli, 2013). Furthermore, the presence of moisture, exacerbated by occlusion, removes the stratum corneum lipids and natural moisturising factors leading to dry and cracked skin (Tsai & Maibach, 1999). Excess moisture also disrupts the stratum corneum intercellular space and causes stratum corneum swelling (Tsai & Maibach, 1999; D.Voegeli, 2013). In addition to stratum corneum disruption, excess skin moisture creates injury by increasing the coefficient of friction (that is the measurement of the amount of friction existing between two surfaces) resulting in a chaffing injury as well as increased susceptibility to pressure injury (Gefen, 2014; Reger, 2010).

Skin contact with bacteria in faeces also contributes to loss of skin barrier function. Bacteria in faeces cause skin damage by converting urea from urine to ammonia, which in turn raises the skin pH and reactivates the digestive enzymes lipase and protease that are present in faeces (Berg, Milligan, & Sarbaugh, 1994; Farage, Miller, Berardesca et al., 2007; Gray et al., 2007). Furthermore, liquid faeces are the highest in digestive enzymes, explaining in part why individuals who have liquid faecal incontinence suffer from greater skin irritation (Beeckman et al., 2015; Farage, Miller, Berardesca et al., 2007; Gray et al., 2007; Nix, 2002). It has been shown that patients with urinary and faecal incontinence and/or liquid faeces are more likely to develop IAD (Beeckman et al., 2015; Gray et al., 2007).

3.1.6 Occlusion

Skin occlusion, resulting from the requirement to wear incontinent aids or pads can potentially cause several deleterious effects, including reduction in evaporative water loss, increases in skin pH, increases in local skin temperature, and microbial populations (Aly, Shirley, Cunico, & Maibach, 1978; Fidel, 1999; Honig, 1983; Tsai & Maibach, 1999; Zhai & Maibach, 2002). Further, occlusion increases local skin pH, which has been demonstrated to be a risk factor for the development of *Candida* infections (Ali & Yosipovitch, 2013; Baroni et al., 2012).

3.1.7 Effects of ageing on skin

As an individual ages, a range of changes in skin structure and function become apparent that can lead to vulnerability to a range of injuries and diseases (Farage et al., 2008). Influenced by intrinsic and extrinsic factors, skin changes include biochemical alterations, reduction in neurosensory perception, and skin permeability, changes in response to injury and repair ability. (Farage et al., 2008; Lawton, 2007). Physiological skin changes result in the loss of dermal and subcutaneous tissue, with a loss of as much as 20% of dermal thickness (Farage et al., 2008; LeBlanc & Baranoski, 2011). Thinning and flattening of the dermal-epidermal junction occurs, decreasing junctional strength (Farage, Miller, Elsner & Maibach, 2013). Decreased production and increased degradation of collagen, as well as a decline in elastin production and organisation results in thinning and atrophy of the dermis. This causes loss of tensile strength and skin elasticity (LeBlanc & Baranoski, 2011; Thomason & Hardman, 2009). This loss of elasticity results in skin becoming more vulnerable to injury from mechanical forces such as shearing and friction (Carville, 2012; LeBlanc & Baranoski, 2011). Further, thinning of the hypodermis combined with the aforementioned factors predisposes an individual to injury from excessive pressure (Wysocki, 2007).

Skin circulation is diminished due to the decline and disorganisation of capillaries and small vessels, as well as reduced vessel density, with decreased vascularity and atrophy of the dermis and hypodermis (LeBlanc & Christensen, 2011; Wysocki, 2007). The immune and inflammatory responses are impaired, with decreased numbers of Langerhans' cells (antigen-presenting cells), as well as cells and melanocytes (cells responsible for pigmentation) (Carville, 2012; Farage et al., 2008; LeBlanc & Baranoski, 2011; Wysocki, 2007). In addition, the loss of

superficial pain sensation, as well as a delay in pain perception, creates vulnerability to injury as the skin's early warning signals, that is pain, erythema, and oedema do not appear as quickly in aged skin as in younger persons (Farage et al., 2008).

The aged individual may have impaired wound healing as a result of reduced immune response, angioneogenesis, fibroblast function, and epidermal proliferative capacity (Thomason & Hardman, 2009; Wysocki, 2007). Skin deterioration and concomitant comorbidities predispose older individuals to a multitude of potential skin integrity threats. Understanding the unique vulnerability of aged skin is especially important for the clinician who provides healthcare for this population.

3.1.8 Incontinence-associated dermatitis: A historical perspective

IAD affects all age groups, from infants to the elderly, all races and genders, and can be found in incontinent individuals in community, long term, and acute care settings (Brown & Sears, 1993). In infants, IAD is known as diaper dermatitis or napkin rash (Brookes, Hubbert, & Sarkany, 1971; Brown & Sears, 1993) and has been researched extensively for the last 50 years (Benson, Slobody, Lillick, Maffia, & Sullivan, 1947; Brookes et al., 1971; Ferrazzini et al., 2003; Gokalp, Aldirmaz, Oguz, Gultekin, & Bakici, 1990; Goldstein, 1949; Hayakawa & Matsunaga, 1987; Honig, 1983; Kayaoglu, Kivanc-Altunay, & Sarikaya, 2015; Keiter, 1970; Koblenzer, 1973; Leonard, 1967; Litchfield, 1959; Zimmerer, Lawson, & Calvert, 1986). Research into adult IAD did not commence in earnest until the early 1990s.

During the last two decades, nurses have driven the IAD research agenda, with some of the earliest research conducted in 1991 by Lyder, Clemes-Lowrance, Davis, Sullivan, and Zucker, (1992). This group investigated the efficacy of a structured skin care regimen to prevent perineal dermatitis in geriatric psychiatry inpatients. Lyder et al.'s (1992) research identified that the combination of skin exposure to both urine and faeces increases the incidence of perineal dermatitis and concluded that that the use of a structured skin care regimen is warranted for the prevention of the condition.

In 1993, a conceptual framework addressing the predisposing factors for perineal dermatitis was proposed by Brown and Sears. Identified predisposing factors were categorised according to tissue tolerance (age, health status, nutrition, oxygenation, perfusion, and temperature), perineal environment (character and type

of incontinence, mechanical chafing, inducing agents, and increased skin permeability), and toileting ability (mobility, sensory perception, and cognitive awareness) (Brown & Sears, 1993).

In 2007, the release of the seminal consensus document by Gray et al. proposed the term IAD. This term was chosen as it accurately reflected the response of the skin to exposure to urine and/or faeces, specifically identifying the source of the irritant and acknowledging that a larger area of skin than the perineum is affected. A definition of IAD was also proposed by Gray et al. (2007): 'the response of the skin to chronic exposure to urine or faecal materials (inflammation and erythema with or without erosion or denudation)' (p. 46). The consensus document (Gray et al., 2007) also acknowledged that IAD can affect an extensive area of skin, namely the perineal and perianal areas, labial folds, scrotum, groins, lower abdomen and upper inner thighs region of incontinent individuals. Gray and colleagues (2007) identified gaps in the understanding of IAD and outlined areas where further research was needed, including understanding of the prevalence of the condition, particularly in the acute care setting, and understanding of the epidemiology and pathophysiology of IAD.

A further expert consensus conference was convened in 2010, with its outcome being the publication of consensus statements regarding the prevention and treatment of IAD, as well as the identification of unresolved issues including challenges with the differential assessment of IAD and pressure injuries, as well as the assessment, prevention, and management of IAD (Doughty et al., 2012). Overall, there was agreement that the key components of an effective program for IAD prevention included gentle cleansing with a no rinse pH neutral cleanser, application of a moisture barrier product, and the use of a moisturiser to maintain skin barrier function (Doughty et al., 2012).

Issues surrounding the accurate classification of IAD and pressure injuries were recognised by Defloor, Schoonhoven, Vanderwee, Weststrate, and Myny, (2006), who found that IAD was frequently misclassified as a stage I or II pressure injury. Subsequently, in 2007, the National Pressure Ulcer Advisory Panel (Black et al., 2007) issued an update regarding the description of stage II pressure injuries stating that this category should not be used to describe 'skin tears, tape burns, perineal dermatitis, maceration or excoriation' (p. 40). In response to these

challenges, Beeckman, Schoonhoven, Boucque, Van Maele, and Defloor, (2008) developed an e-learning tool to assist clinicians to improve the accuracy of differentiating these lesions.

3.1.9 IAD risk assessment and categorisation

IAD, unlike PI, does not have accepted or standardised risk assessment tools, nor an agreed categorisation system. A range of categorisation tools have been proposed, including the IAD Assessment and Intervention Tool (IADIT), (Junkin & Selekof, 2008), the Incontinence-Associated Dermatitis and its Severity (IADS) Instrument (Borchert, Bliss, Savik, & Radosevich, 2010), and the Skin Assessment Tool (SAT) (Kennedy & Lutz, 1996), with the Perineal Assessment Tool (PAT) proposed by Nix in 2002. However, while some of these tools have been used for research, their use in clinical practice remains limited. This may be, in part, because of a lack of evidence regarding improvements to clinical decision-making and care with their use (Beeckman et al., 2015).

3.1.10 IAD risk factors

The primary risk factor for IAD is skin contact with urine and /or faeces. The type of incontinence influences the level of risk, with patients with faecal incontinence with liquid faeces combined with urinary incontinence having the highest risk. The risk is lower for those with formed faeces, followed by a lower risk for those with urinary incontinence only (Beeckman et al., 2015). The use of skin occluding incontinence pads are also constitutes an IAD risk factor. In addition, poor skin condition, impaired mobility, impaired cognitive awareness, inability to perform personal hygiene, pain, pyrexia, poor nutrition status, and critical illness are also recognised as contributing factors for IAD (Beeckman et al., 2015; Bliss, Savik, Harms, Fan, & Wyman, 2006; Brown & Sears, 1993; Gray et al., 2007; Junkin & Selekof, 2007; Kottner, Blume-Peytavi, Lohrmann, & Halfens, 2014; D. D.Voegeli, 2013). Older age does not appear to be an independent risk factor for IAD development; however, older age is associated with a higher prevalence of IAD (Beeckman et al., 2015; Kottner et al., 2014).

3.1.11 Clinical presentation of IAD

IAD initially presents with mild erythema, ranging from pink to red in individuals with light skin, and may present in individuals with darker skin tones as

yellow, white, or even dark purple (Beeckman et al., 2015; Farage, Miller, Berardesca et al., 2007; Junkin & Selekof, 2008). Secondary to inflammation, erythematous areas may feel warm to the touch, and may be indurated (Beeckman et al., 2015). Erythema may be followed by skin erosion, with epidermal damage varying in depth. In some cases, the entire epidermis may be eroded, revealing a moist weeping dermis. Lesions, such as papules, pustules, bullae, or vesicles may also be present (Beeckman et al., 2015; Farage, Miller, Berardesca et al., 2007). Affected areas have poorly defined edges and present as patchy or continuous over large areas (Beeckman et al., 2015). If a patient is able to communicate, they may describe burning, pruritis, or tingling sensations (Gray et al., 2007), or pain, with the pain of IAD being likened to a burn (Junkin & Selekof, 2007).

3.2 IAD COMPLICATIONS

IAD can cause several complications, including the development of PI, infection (commonly with *Candida albicans*), pain and decreased quality of life.

3.2.1 Pressure injury

Incontinence and increased skin moisture have been widely accepted as risk factors for PI development (Baharestani et al., 2010; National Pressure Ulcer Advisory et al., 2014). One study demonstrated that patients who are incontinent and immobile have a 37.5% increased risk of developing a PI (Maklebust & Magnan, 1994). More recently, there has been a new understanding of the role of IAD as a risk factor for PI development. Gefan (2014) identified that IAD decreases the tolerance of skin for superficial PI by several mechanisms. Firstly, inflammation associated with IAD increases the local skin temperature, secondly, the skin-clothing or skin-support coefficient of friction is increased due to wetness, and finally, the moist environment causes vasoconstriction, which causes wrinkling of the skin. All of these effects ultimately result in increased shear loads on the skin. A systematic review and meta-analysis conducted by Beeckman and colleagues (2014) to identify the association between IAD and PIs found an association between IAD, incontinence, and moisture and PI development, although the authors advised that methodological issues in the included studies should be considered when interpreting the results of the review (Beeckman et al., 2014).

3.2.2 *Candida* infection

Candida infection is reported as a frequent complication of IAD (Black et al., 2011; Farage, Miller, Berardesca et al., 2007; Gray et al., 2007; D.Voegeli, 2013). *Candida albicans* is more than one of almost 200 species in the *Candida* genus, and by far the most common and important species for humans is *Candida albicans* (Fidel, 1999; Moran et al., 2012; Odds, 1988). *Candida* species are classified as yeasts, that is, having a primarily unicellular mode of development. *Candida* grows as an oval-shaped budding yeast (blastospore or blastoconidia), as pseudohyphae, or as true hyphae. The blastospore is present in the commensal state, while the hyphal form of *Candida albicans* is often observed in the infective state (Fidel, 1999; Odds, 1988). This organism can exist as a harmless commensal or transform into a serious pathogen, capable of causing superficial or invasive disease. *Candida albicans* colonises the genitourinary and gastrointestinal tracts and can be recovered from intertriginous areas but is rarely recovered from glabrous skin (Black et al., 2011; Fidel, 1999; Moran et al., 2012; Odds, 1988; Tobin et al., 2013)

Candida infection results from the overgrowth of an individual's endogenous colonising *Candida* species (most commonly *Candida albicans*) (Beeckman et al., 2015; Farage, Miller, Berardesca et al., 2007; Gray et al., 2007; D.Voegeli, 2013). The risk factors or triggers for the transformation of *Candida* from commensal to pathogen are unclear, but it is thought that local skin environments that result in increased temperature, moisture, and pH, such as that found in those wearing an incontinent pad favour *Candida* growth (Aly et al., 1978; Fidel, 1999; Honig, 1983; Tsai & Maibach, 1999; Zhai & Maibach, 2002). *Candida* infection associated with IAD can present as either a bright red maculopapular rash spreading from a central area, with satellite lesions (characteristic of *Candida* infection) at the edge of the rash extending into normal skin, or non-specific confluent papules, making clinical diagnosis difficult (Beeckman et al., 2015; Habif, 2015).

The prevalence of *Candida* infection associated with incontinence and IAD in the acute care setting is poorly understood. There is also a gap in the availability of microbiological data that confirms the diagnosis of *Candida* infection associated with IAD. This gap may be due, in part, to current clinical practice. The mainstay of diagnosis of a suspected *Candida* infection associated with IAD is visual inspection, commonly followed by empirical treatment. However, visual assessment can be

inaccurate, as the presentation of a *Candida* infection can vary from a central maculopapular rash, with characteristic satellite lesions, to a non-specific confluent rash (Habif, 2015; J. Sobel, personal communication, April 3, 2014). Therefore, while these presentations may be characteristic of *Candida* infection, they are not unique to *Candida* infections and could be attributed to other causes (Odds, 1988). This can result in *Candida* infections being under or over-estimated in clinical practice (Odds, 1988). Moreover, the presence of *Candida* on a microbiological specimen in the absence of clinical signs or symptoms does not necessarily constitute a *Candida* infection, rather it may represent colonisation. A positive result on a microbiological specimen should be interpreted with caution and simultaneous consideration of the clinical picture, otherwise over-estimation of the *Candida* infection may result (Odds, 1988).

3.3 CHAPTER SUMMARY

After the initial literature review for this thesis, a further international IAD expert panel was convened in 2014 to review IAD knowledge deficits, and to advance best practice principals to address these gaps. The resultant publication is a detailed expert consensus document (Beeckman et al., 2015) that recommends that the term, IAD should be defined and included in the World Health Organisation's ICD-10, which will subsequently result in consistent terminology for the condition. The expert panel also proposed a new IAD severity categorisation tool, involving a straightforward, three-category instrument that, while requiring validation, has the potential for acceptance and use in clinical practice. The panel also recommended a change to the IAD prevention protocol which involved replacing skin moisturisation as a standard component of the skin care regime with the step 'restore' (p. 15), whereby skin moisturiser is used only when necessary to restore or maintain the integrity of the skin's barrier function (Beeckman et al., 2015). Furthermore, the panel identified areas for future research, including further IAD prevalence and incidence studies using standardised definitions and methodology, research into the natural history of IAD, including the aetiology, pathophysiology, and progression of the condition (Beeckman et al., 2015).

Overall, the literature review revealed that IAD poses a significant skin integrity threat to acute care patients, is a painful condition, places patients at risk of infection and PI, is costly to treat, impacts negatively on quality of life, can result in

loss of independence, and increases the burden of care (Beeckman et al., 2015; Doughty et al., 2012). Understanding the magnitude and pathogenesis of IAD, including *Candida* colonisation and infection can inform the development of prevention and management strategies and importantly, contextualise IAD within the broader framework of maintaining skin integrity. An understanding of the prevalence of IAD is imperative to guide decision-making and care planning at the individual patient level and the wider healthcare level. Chapter 4 presents Publication 2 of this thesis: an investigation of the prevalence of incontinence and IAD in the Australian acute care setting.

Chapter 4: INCONTINENCE-ASSOCIATED DERMATITIS: A CROSS-SECTIONAL PREVALENCE STUDY IN THE AUSTRALIAN ACUTE CARE HOSPITAL SETTING - STUDY 1

4.1 INTRODUCTION

This chapter comprises Publication 2, which represents Study 1 of this thesis.

Campbell J. L., Coyer F. M., & Osborne S. R. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting, *International Wound Journal*, doi:10.1111/iwj.12322

This publication was published in the *International Wound Journal*, which has an impact factor of 2.15. The publication has been cited five times, including a citation by Beeckman and colleagues (2015) in a seminal IAD global consensus document.

The aim of this study was to determine the prevalence of incontinence and incontinence-associated dermatitis (IAD) in the Australian acute care setting.

This study addressed the following research questions:

1. What is the prevalence of incontinence (urine and faecal)?
2. What is the prevalence of IAD?
3. What are the products worn to manage incontinence, and the products provided at the bedside for perineal skin care?

4.1.1 Prevalence studies

Understanding the scope of a problem or condition is the critical first step in developing effective prevention and management strategies (Coggon, Barker, & Rose, 2003). A common method employed to understand the magnitude of conditions in healthcare facilities is to determine the prevalence of the condition. Prevalence is a measure of the proportion of a population that has a specific

occurrence at a specific time, and represents the disease burden of a population (Gordis, 2009; Oleckno, 2008). In addition to determining the burden or magnitude of a condition at a point in time, prevalence studies can also be used to assess quality of care and effectiveness of prevention protocols (Baharestani et al., 2009a; Pieper & National Pressure Ulcer Advisory, 2012).

However, prevalence studies are difficult and costly to perform and require a significant number of adequately trained personnel (Ashmore, Ruthven, & Hazelwood, 2011; Prentice, Stacey, & Lewin, 2003). Many factors can influence the results of these studies, including the definitions of the epidemiological terms used (that is, prevalence or incidence), source of the data (for example, from direct skin inspection, data extraction from care records, or adverse event registers), the skill of assessors in identifying PI and differentiating between other lesions such as IAD, case mix, length of time over which data are collected and data reporting (Baharestani et al., 2009a; Defloor et al., 2005). Overall, prevalence surveys require extensive planning to ensure they are valid and reliable (Ashmore, et al., 2011; Prentice et al., 2003).

Inter-rater reliability can be an important element of prevalence survey methodology. It is defined as agreement or consistency among raters, or the extent to which raters judge phenomena in the same way (Vogt, 2005). A seminal study by Prentice and colleagues (2003) proposed a detailed PI prevalence methodology. In particular, with reference to inter-rater reliability, the procedure included the requirement for an education program for surveyors that encompassed training on staging of PIs according to the NPUAP classification system (Bergstrom et al., 1992) followed by inter-rater reliability testing, using multiple choice questions and clinical photographs to identify PI stages. In 2005, the European Pressure Ulcer Advisory Panel (EPUAP) (Defloor et al., 2005) statement on prevalence and incidence monitoring of PI occurrence specifically stated that it is essential that surveyors be able to distinguish PIs from other lesions, such as incontinence damage. For more than a decade recommendations have been made to ensure surveyors have the knowledge and skill to classify PIs accurately, and to differentiate them from other lesions, commonly IAD. The procedures for PI prevalence surveys are relevant for IAD prevalence surveys and were adapted for use in Study 1.

4.1.2 Challenges in understanding incontinence-associated dermatitis prevalence in acute care

There is limited empirical data available that sheds light on the prevalence of IAD in the general acute care setting. Prevalence ranges from 20% to 50%, but several of these studies reported IAD prevalence in critically ill patients (Bliss et al., 2000; Driver, 2007), while the study by Arnold-Long et al. (2011) reported IAD prevalence in long term acute care. One of the few studies conducted in the general acute care setting reported IAD prevalence to be 20% in the incontinent patients in the sample (Junkin & Selekof, 2007).

The reasons for limited IAD prevalence data in the acute care setting may be multifactorial. Firstly, limited systematic evaluation for IAD takes place as part of the skin assessment, with generally scant systematic or organisational recognition of IAD as a nosocomial skin injury. This can result in at best, ad hoc IAD specific prevention procedures, policies, or IAD prevalence surveys (Beeckman, 2016; Beeckman et al., 2015). Secondly, there is a lack of standardisation of diagnostic criteria and established IAD categorisation instruments (see Section 3.1.7) (Borchert et al., 2010; Gray et al., 2012; Junkin & Selekof, 2008), as well as a lack of an agreed IAD prevalence survey methodology that may contribute to the prevalence being under-estimated or unrecognised at all. Finally, difficulties faced by clinicians when distinguishing between IAD and PIs, and the potential for IAD to be misclassified as a stage I or II PI can result in the prevalence of IAD being under-estimated (Beeckman et al., 2015; Defloor et al., 2006; Doughty, 2012; Mahoney, Rozenboom, Doughty, & Smith, 2011).

4.1.3 Incontinence-associated dermatitis prevalence survey methodology

In the absence of an agreed methodology for the IAD prevalence surveys, the best available evidence and recommendations for the conduct of PI prevalence surveys was reviewed and adapted for this study (Baharestani et al., 2009b; Beeckman, Defloor, Demarré, Van Hecke, & Vanderwee, 2010; Defloor et al., 2006; Junkin & Selekof, 2007; National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009; Prentice et al., 2003). The decision to adapt PI prevalence methodology for Study 1 was based on several factors, including the similarity between the shared risk factors for IAD and PI (Doughty, 2012), the

understanding that IAD and PI often co-exist and are co-located, and the imperative for accurate IAD and PI prevalence data (Defloor et al., 2006; Mahoney et al., 2011).

Direct skin inspection is accepted as the gold standard methodology for PI prevalence studies, with the proviso that data collectors have adequate skill in classifying PIs and differentiating them from other lesions such as IAD (Baharestani, 2009b; Defloor, 2005; Pieper & National Pressure Ulcer Advisory Panel, 2012). One of the primary reasons for the recommendation for direct skin inspection is the recognition that clinical documentation is often poor with respect to PIs (Baharestani et al., 2009b; Bethell, 2002; Defloor et al., 2005; Gunningberg, Donaldson, Aydin, & Idvall, 2012).

4.2 PUBLICATION 2

Incontinence-Associated Dermatitis: A Cross-Sectional Prevalence Study in the Australian Acute Care Hospital Setting

Abstract

The purpose of this cross sectional study was to identify the prevalence of incontinence and incontinence-associated dermatitis in Australian acute care patients, describe the products worn to manage incontinence, and products at the bedside to provide perineal skin care. Data were collected over two days at a major Australian teaching hospital on 376 inpatients. The mean age of the sample was 62 years and 52% were male. The prevalence rate of incontinence was 24% (n = 91). Urinary incontinence was significantly more prevalent in females (10%) than males (6%) $\chi^2(1, N = 376) = 4.458$, $p = .035$. Incontinence-associated dermatitis occurred in 10% (n = 38) of the sample, with 42% (n = 38) of incontinent patients having incontinence-associated dermatitis. Semi-formed and liquid stool were significantly associated with incontinence-associated dermatitis $\chi^2(1, N = 376) = 5.520$, $p = .027$. Clinical indication of fungal infection was present in 32% (n = 12) of patients with incontinence-associated dermatitis. Absorbent disposable briefs were the most common incontinence aids worn (80%, n = 70), with soap/water and disposable washcloths the most commonly available (60%, n = 55) clean–up products present at the bedside. Further data are needed to validate this high incontinence-associated dermatitis prevalence. Studies that address the prevention of incontinence-associated dermatitis and effectiveness of management strategies are also required.

Key words*:* Acute care, cross-sectional study, incontinence-associated dermatitis, incontinence, prevalence.

Key Messages

- Nearly one in four hospitalised adults experience incontinence, with more than 40% of those having incontinence-associated dermatitis (IAD).
- Semi-formed and liquid stool are associated with IAD.
- Older patients are significantly more likely to experience incontinence than younger patients.
- More data are needed about IAD prevalence and management in the acute care setting in Australia.
- This is the first Australian study to report both the prevalence of incontinence and IAD in the acute care setting, and to differentiate IAD from pressure injury and clinical indication of fungal infection.

Introduction

Incontinence-associated dermatitis (IAD) is a complex, painful condition that is expensive and hard to treat (Doughty et al., 2012; Gray et al., 2007). It occurs in the perineum, labial folds, groin, upper thighs, buttocks, rectal area, and gluteal cleft, as well as areas where increased friction occurs between skin and clothing, or skin and absorptive devices (Black et al., 2011; Gray, 2011). IAD is characterised by inflammation and erythema, and may have blisters, erosion, denudation, or serous exudate (Gray et al., 2007; Junkin & Selekof, 2008). This results in high cost to the individual in pain and suffering, increased morbidity, and increased length and cost of the hospital stay (Junkin & Selekof, 2008).

Until recently, there was no international agreement on the name of the condition, its definition, or its implications for clinical practice. However, in 2007 a seminal consensus document by Gray et al. (2007) defined IAD as the response of the skin to chronic exposure to urine and faecal materials (inflammation and erythema with or without erosion or denudation). This definition acknowledges the source of the irritant, the response of the skin to that irritant, and that an area beyond the perineum is commonly affected. The standardised definition will allow researchers and clinicians to generate and compare data using a uniform conceptualisation of the condition.

Excess moisture on the skin acts as an irritant and contributes to skin breakdown and increased susceptibility to pressure injury from friction and shear (Black et al., 2011; Doughty et al., 2012; Gray, 2007; Gray et al., 2007; Gray et al., 2011). Moisture damaged skin can be vulnerable to infection with *Candida albicans* or coliform bacteria (Black et al., 2011). Wearing an absorptive containment product (pad) causes occlusion, resulting in increased (more alkaline) baseline skin pH, increased moisture from perspiration, and compromised skin barrier function (Gray et al., 2007; Gray et al., 2012b). The alkaline pH of urine promotes activity of the digestive enzymes lipases and proteinases in faeces, which in turn makes keratin in the stratum corneum vulnerable to breakdown (Black et al., 2011). Wet skin is less resistant to injury from friction, and is at increased risk of erosion from rubbing on bed linens or incontinence pads (Black et al., 2011; Gray et al., 2012b; Junkin & Selekof, 2007). Exposure to both faeces and urine is more damaging to skin than exposure to urine alone (Bliss, Savik, Harms, Fan, & Wyman, 2006).

Identification of IAD depends on skin inspection and accurate differentiation between other skin lesions, particularly pressure injury. Studies indicate that the differential diagnosis between a pressure injury and IAD is difficult, with IAD frequently misclassified by nurses as a pressure injury (Beeckman et al., 2008; Doughty et al., 2012). In fact, the National Pressure Ulcer Advisory Panel (NPUAP) recommends that the stage II pressure injury category should not be used to describe skin tears, tape burns, perineal dermatitis, maceration, or excoriation (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009). IAD also needs to be differentiated from intertriginous dermatitis, a moisture associated skin injury resulting from trapped moisture and friction in skin folds. (Black et al., 2011; Bliss & Powers, 2011; Doughty et al., 2012; Gray, 2007). IAD has further been confused with fungal or bacterial infections, as well as other dermatological conditions (Farage, Miller, Elsner, & Maibach, 2007). Misclassification of these lesions can result in poor patient outcomes, as well as in the inappropriate and ineffective use of healthcare resources (Beeckman, Schoonhoven, Verhaeghe, Heyneman, & Defloor, 2009a). The primary goal of the prevention and treatment for IAD is to minimise skin exposure to irritants (Black et al., 2011).

Understanding IAD requires an appreciation of incontinence, a condition associated with significant morbidity, decreased quality of life, as well as being a burden for carers and the healthcare system. Urinary incontinence is an involuntary leakage of urine (Abrams, Blaivas, Stanton, & Andersen, 1988) and while no consensus definition exists for faecal incontinence, its generally accepted definition is involuntary loss of solid or liquid stool (Halland & Talley, 2012). Incontinence occurs more frequently in older adults, although it can affect any age group (Junkin & Selekof, 2007; Lakhan et al., 2011). Further, faecal incontinence is the second leading cause of admission to long-term care in the United States (Beitz, 2006).

Prevalence of incontinence among patients in the acute care setting is estimated to range from 10% to 37% (Junkin & Selekof, 2007; Lakhan et al., 2011; Ostaszkiewicz et al., 2008). Incontinence in the critical care environment ranges from 12% to 30% (Bliss, Johnson, Savik, Clabots, & Gerding, 2000; Driver, 2007) and in long-term acute care settings is 22% for urinary incontinence and 57% for faecal incontinence (Arnold-Long, Reed, Dunning, & Ying, 2011). Limited data exists identifying the scope of incontinence or demographic variables associated with incontinence in the Australian acute care setting.

IAD also presents challenges for the acute care setting where the prevalence ranges from 20% to 50% (Arnold-Long et al., 2011; Bliss et al., 2000; Driver, 2007; Gray et al., 2012b; Junkin & Selekof, 2007). The prevalence of IAD in adults in Australian acute care hospitals is not known. Prospective Australian data are needed to provide insights into the scope of both incontinence and IAD in the acute care setting to aid healthcare providers in the development of prevention and management strategies.

Aims

The purpose of this study was to explore incontinence and IAD in the Australian acute care hospital setting. Specific research aims were to:

- identify the prevalence of incontinence (urine and faecal),
- identify the prevalence of IAD, and
- describe the products worn to manage incontinence and products at the bedside to provide perineal skin care.

Methods

Study design

A cross-sectional study design was used.

Study setting and sample

This study was conducted at a 929-bed major acute care teaching hospital in southeast Queensland, Australia. The facility provides acute care over a comprehensive range of specialities including medicine, surgery, orthopaedics, oncology, obstetrics, gynaecology, intensive care, burns, and trauma. It is the largest tertiary referral hospital in Queensland, providing care in 2012 to almost 94,000 inpatients (Royal Brisbane and Women's Hospital Marketing and Communications, 2013).

Hospitalised adults aged 18 years and older, admitted to the facility were eligible for inclusion. Patients were surveyed from Internal Medicine, Surgery, Critical Care (which includes a 36 bed intensive care unit and an 18 bed transit ward attached to the emergency department), Cancer Care, and Women's and Newborns (only adults were surveyed from this service) admitting services. Patients from maternity and mental health services were excluded from the study.

Operational definitions

- Incontinence is the inability to control the flow of urine and/or stool any time in the preceding 24 hours (Junkin & Selekof, 2007). Patients with indwelling urinary catheters were deemed continent of urine for the analysis. The presence of a urinary catheter prevents urine from coming into contact with skin, and therefore removes the source of irritation (urine) necessary for the development of IAD. Patients with faecal containment devices were deemed incontinent of faeces due to the high likelihood of faecal leakage from the containment device resulting in faecal contact with skin. These categorisations are consistent with previous studies (Halfens et al., 2013; Junkin & Selekof, 2007).
- IAD is the presence of any skin redness with or without erosion due to skin contact with urine and/or faeces (rather than other sources of moisture) on the buttocks, coccyx, rectal area, scrotum, labia, lower abdomen, upper thighs, gluteal cleft, or groins in an incontinent patient (Gray et al., 2007).

- Fungal infection is based on the clinical presentation of a central maculopapular rash with characteristic satellite lesions in patients with IAD (Black et al., 2011; Zulkowski, 2012). No microbiological testing was performed to confirm the presence of a fungal infection in this study. This is consistent with current clinical practice, as well as a previous IAD study (Junkin & Selekof, 2007). Diagnosis of superficial fungal infection relies more heavily on clinical findings and less on laboratory support (Maertens, 2007; Richardson, 2012).
- Pressure injuries are a localised injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009). Pressure injuries were staged according to the Australian pressure injury staging guidelines at the time of data collection (Australian Wound Management Association, 2001).

Measures

Continence Status and Products: Continence status, incontinence containment, clean-up and skin protection products, as well as demographic data were recorded on a data collection instrument that was designed by the Principal Investigator (JC), based on a literature review (see Appendix C). The instrument was pilot tested with 10 registered nurses at the research site and face validity established. Minor changes to the wording and layout of the continence section of the tool were made based on feedback from the pilot group. Demographic data collected were age, gender, and admitting service.

Stool Quality Assessment: Stool quality was measured based on the Bristol Stool form scale (see Appendix D), but collapsed into dichotomous variables: formed, which equates to type 1- 4 on the Bristol Stool form scale; and semiformed-liquid, equates to type 5-7 (Lewis & Heaton, 1997).

IAD Severity: IAD severity was measured by clinicians with the Skin Assessment Tool (SAT) (Kennedy & Lutz, 1996) (see Appendix A). This tool does not require the patient to report symptoms (Gray, 2007; Junkin & Selekof, 2008), nor does it assess pain. The SAT was designed to derive a cumulative IAD severity score with a numerical score assigned according to severity within each of three categories:

skin redness, area of skin breakdown (cm^2), and erosion. A cumulative severity score (maximum score = 10) is the sum of the scores for the three categories. It has good inter-rater reliability, κ =0.81 (95% CI, 0.69 - 0.87), for skin observation, (Beeckman, Verhaeghe, Defloor, Schoonhoven, & Vanderwee, 2011). Word descriptors were assigned to match numerical severity categories. Numerical cut-off points for each category were determined by consensus from a panel of experts comprising the authors and three wound care clinicians with 40 combined years of experience in the specialty. The cut points are 0 = no IAD; 1-3 = mild IAD; 4-6 = moderate IAD; 7-9 = severe IAD; 10 = extreme IAD.

Procedures

Prior to data collection, all research assistants (*n* =30; comprising registered nurses, an occupational therapist and a medical practitioner) were trained in the identification of IAD, pressure injury, and fungal infection. Inter-rater reliability was established at the conclusion of the education session by scores on a multiple-choice test of clinical photographs of a variety of IAD lesions, pressure injuries, and fungal infections. The test required participants to differentiate between IAD, pressure injury, and a fungal infection, as well as classify the IAD images according to the study instrument. A score of 80% was required for the research assistant to participate in the study. The use of photographs to test inter-rater reliability has previously been used (Beeckman et al., 2007; Beeckman et al., 2008; Defloor & Schoonhoven, 2004). Research assistants also were trained in study procedures.

This study was conducted over two consecutive days in November 2011 by the principal investigator (JC) and 30 research assistants. Skin inspections were conducted by the research assistants on all eligible, consenting patients. The incontinent management product the patient was wearing was recorded. Each patient's buttocks, coccyx, rectal area, scrotum, labia, lower abdomen, upper thighs, gluteal cleft, and groins were inspected and loss of skin integrity classified as IAD, PI, or clinical indication of fungal infection. Continence data were collected, and for those who were incontinent, the type of incontinence was obtained from the patient, bedside nurse, and/or clinical records. Stool quality and frequency data for faecally incontinent patients were collected from the patient, bedside nurse, and/or clinical records. Data were also recorded on the type of incontinence clean up and skin protection products at the bedside. When patients were absent from the ward at the

time of data collection, the research assistants returned and included those present when possible. Demographic data were collected on all patients. To assure accuracy, the principal investigator (JC), who is a skin integrity expert, conducted an independent pelvic girdle inspection on all cases identified by the research assistants as having IAD and validated the SAT score.

Ethical Considerations

The study was approved by the Human Research Ethics Committees for both the research site and the university. Written information about the study was distributed to all eligible patients the day prior to data collection. Patients provided verbal consent as required by the Human Research Ethics Committees (see Appendices E & F).

Statistical Methods

Participants were assigned a study number and all data were de-identified. Data were entered into Statistical Packages for Social Sciences (SPSS) (Version 20.0, Armonk, NY, USA). A random 10% of data entry was crosschecked for accuracy. Incomplete data were coded as missing data.

Descriptive statistics were used to describe study variables (means and standard deviations for continuous variables; frequencies and percentages for categorical variables). Prevalence of incontinence was calculated by the total number of incontinent patients in the sample divided by the total number of study patients. Prevalence of IAD was calculated by the total number of IAD cases in the sample divided by the total number of study participants. Prevalence of IAD among incontinent patients was calculated by the total number of IAD cases divided by the total number of incontinent participants. Bivariate analysis using descriptive correlational statistics (Chi-square test for independence with Yates continuity correction and Fisher's exact test, where expected cell counts were less than five) were used to explore characteristics of sample with incontinence and IAD. *p* values less than 0.05 were considered statistically significant. Direct logistic regression analysis was performed to predict whether independent variables gender, admitting service and age predict the outcome, incontinence. The variables entered into the model were based on what is known about incontinence; in particular, association with increasing age, association with being female, and the prevalence of geriatric syndromes, specifically incontinence in medical patients (Lakhan et al., 2011). In

addition, selection of these independent variables facilitates comparison of our results with other studies providing clinical applicability. The Hosmer-Lemeshow test was used to examine the goodness of fit of the logistic regression model.

Results

Of the 552 patients assessed for eligibility (see Table 4.1, and Figure 4.1), 545 patients were eligible, 379 patients consented to take part and were surveyed. Data for 376 patients were included in the analysis. Three patients were excluded from analyses, as the screening tool was not completed. The mean age of the sample was 62 (*SD* = 19.3) years and 52% (*n* =194) of patients were male (see Table 4.2). The mean age of incontinent patients (*n* = 91) was 70 years (*SD* = 17.4), and the mean age of patients with IAD (*n* = 38) was 75 years (*SD* = 15.3) Patients were admitted most frequently to the internal medicine (44%, *n* = 167) and surgical services (39%, *n* = 146). The Hosmer-Lemeshow test was used to examine the goodness of fit of the logistic regression model. The result was non-significant, χ^2 (8, *N* = 379) = 3.03, *p* = .932, indicating that the model fit was satisfactory.

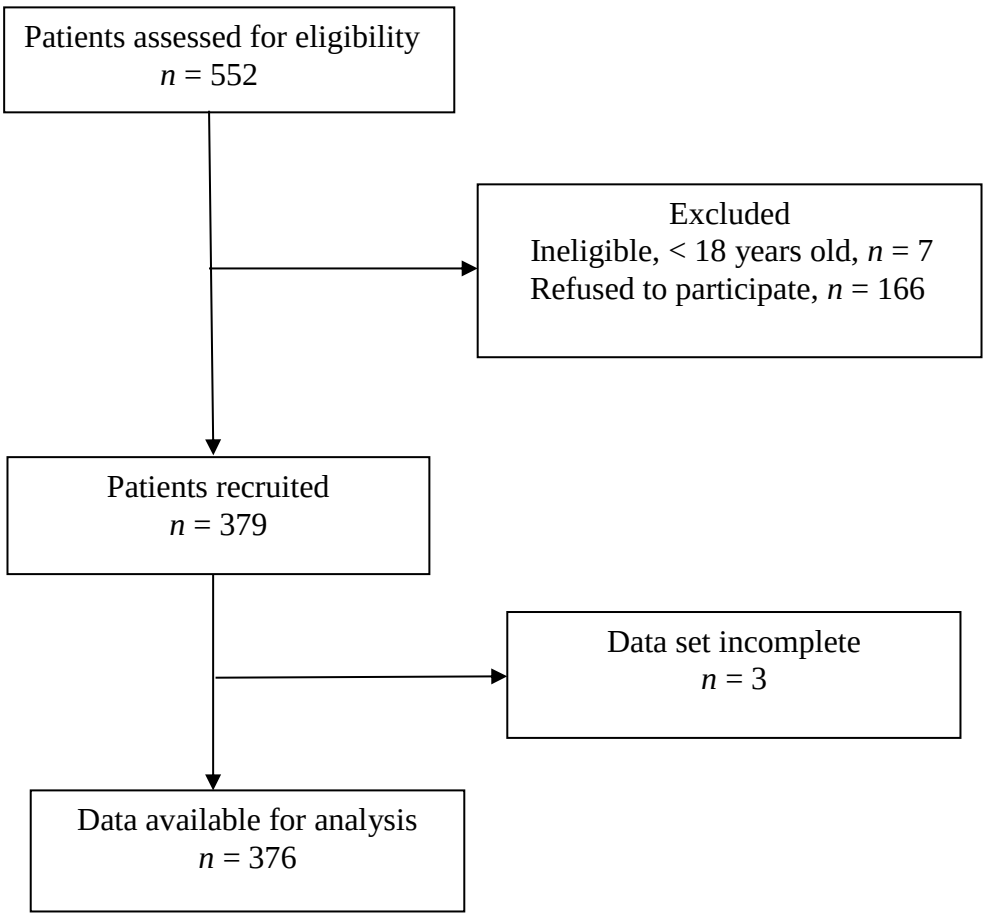


Figure 4.1 Participant recruitment and flow diagram.

Table 4.1

Age and Gender of Patients Assessed for Eligibility (N = 552)

Admitting service	Assessed for eligibility	Age *M* (SD)	Male *n* (%)	Female *n* (%)
Internal Medicine	216	68.2 (17.2)	100 (46.3)	116 (53.7)
Surgical	214	55.5 (19.4)	140 (65.4)	74 (34.6)
Cancer Care	67	61.3 (17.8)	39 (68.2)	28 (41.8)
Critical Care	40	48.8 (19.3)	19 (47.5)	21 (52.5)
Women's & Newborns[a]	15	50.4 (18.4)	0 (0)	15 (100)
Total	552	56.8 (22.7)	298	254

[a]Only adults were evaluated from this admitting service.

Prevalence of Incontinence

The prevalence of incontinence was 24% (n = 91). Double incontinence (urinary and faecal) was most common (12%, n = 45), followed by faecal incontinence (8%, n = 31), with the prevalence of urinary incontinence only 3.5% (n = 13). Urinary catheters were present in 13% (n = 49) of patients. Faecal incontinence was more prevalent in females (11%, n = 42) than males (9%, n = 35). Urinary incontinence was significantly more prevalent in females (10%, n = 38) than males (6%, n = 23), $\chi^2(1, N = 376) = 4.458$, $p = .035$; however, the reason for urinary catheter placement was not determined by this study, so the prevalence of urinary incontinence may be underestimated. Direct logistic regression was performed to assess the impact of a number of factors on incontinence. The model contained three independent variables (age, gender, and admitting service). The full model containing all predictors was statistically significant, χ^2 (6, N = 376) = 31.48, $p <$ 0.001. Gender made no difference to the odds of having incontinence (OR = 0.85, p = .516) (see Table 4.3). Older patients had a greater likelihood of having incontinence compared to younger patients (OR = 1.03, $p < .001$). Patients in the surgical service were less likely to have incontinence, compared to patients in the internal medicine service (OR = 0.51, p = .029). Internal medicine and other admitting services showed no difference in the likelihood of patients having incontinence ($p > .05$) (see Table 4.3).

Table 4.2

Sample (N = 376) Characteristics for Patients with Incontinence (n = 91) and IAD (n = 38)

	Sample *n* (%)	Incontinent *n* (%)	IAD *n* (%)
Gender			
Male	194 (51.6)	41 (45)	13 (34.2)
Female	182 (48.4)	50 (54.9)	25 (65.8)
Indwelling urinary catheter	49 (13)	23 (25.3)	9 (23.7)
Admitting service			
Internal medicine	167 (44.4)	55 (60.4)	23 (60.5)
Surgical	146 (38.8)	21 (23.1)	8 (1.1)
Critical care	21 (7.7)	6 (6.6)	3 (7.9)
Cancer care	29 (7.7)	6 (6.6)	2 (5.3)
Women's & newborns[a]	13 (3.5)	3 (3.3)	2 (5.3)

[a]Only adults were evaluated from this admitting service.

Table 4.3

Predictors of Incontinence (N = 376)

Characteristics & intercept	β	*SE*	χ^2	*p*	OR	95% CI
Intercept	-2.750	.617	19.226	<.001	.067	
Gender (Ref: Female)						
Male	-.168	.259	.421	.516	0.85	(0.51, 1.4)
Age	.029	.008	13.610	<.001	1.03	(1.01, 1.05)
Admitting service (Ref: Internal medicine)						
Critical care	.272	.537	.257	.612	1.31	(0.46, .76)
Surgery	-.670	.308	4.745	.029	0.51	(0.28, .94)
Cancer care	-.508	.496	1.048	.306	0.60	(0.23, .59)
Women & newborns[a]	-.189	.712	.070	.791	0.83	(0.2, 3.34)

Note. SE = standard error, OR= odds ratio, CI = confidence interval.

[a]Only adults were evaluated from this admitting service.

Prevalence of Incontinence-Associated Dermatitis

IAD was present in 10% (n = 38) of the sample and the prevalence of IAD in those who were incontinent was 42% (n = 38) (see Table 4.2). Among incontinent patients, chi-square analysis showed that there was a significant association between type of incontinence (urinary verses faecal) and IAD, $\chi^2(1, N = 91) = 7.237$, $p = .007$. Among patients with IAD, chi-square analysis showed that patients with semi-formed or liquid stool were more likely to have IAD than those patients with formed stool, $\chi^2(1, N = 38) = 5.520$, $p = .027$. Faecal frequency and IAD were not significantly associated, $\chi^2(1, N = 38) = 3.536$, $p = .116$ (see Table 4.4). Mild skin

Table 4.4

Clinical Characteristics of Patients with Incontinence (n = 91) and IAD (n = 38)

Characteristic	Incontinent *n* (%)	IAD *n* (%)
Urinary incontinence		
Male	6 (6.6)	1 (2.6)
Female	7 (7.8)	0 (0)
Faecal incontinence		
Male	18 (19.8)	5 (13.1)
Female	14 (15.4)	10 (26.3)
Double (urine and faecal) incontinence		
Male	17 (18.7)	7 (18.4)
Female	29 (31.9)[a]	15 (39.5)[a]
Faecal quality		
Formed	5 (5.5)	0 (0)
Semi-formed or liquid	36 (39.6)	19 (50)
Missing	50 (54.9)	19 (50)
Faecal frequency		
< 3 day	13 (14.3)	5 (13.2)
3 or more per day	28 (30.8)	17 (44.7)
Missing	50 (54.9)	16 (42.1)

[a]Percentages may not add up to 100 due to rounding.

redness was present in 84% (n = 32) of patients with IAD, a small area of skin breakdown occurred in 32% (n = 12), mild erosion was present in 32% (n = 12) of patients, while 50% (n = 19) of patients had no erosion. The most common anatomical locations for skin injury were buttocks (42%, n = 16), followed by the rectal area (34%, n = 13). The SAT severity score showed 82% (n = 31) were suffering from mild IAD, 13% (n = 5) were suffering from moderate IAD, 6% (n = 2) were suffering from severe IAD, and no patients suffering from extreme IAD (see Table 4.5).

Table 4.5

Characteristics, Location, and Severity of IAD (n = 38)

	n	%
Skin redness		
Mild	32	84.2
Moderate	4	10.5
Severe	2	5.3
Area of skin breakdown		
None	19	50.0
Small	13	34.2
Moderate	2	5.3
Large	4	10.5
Skin erosion		
None	19	50.0
Mild	18	47.4
Moderate	1	2.6
Severe	0	0
Extreme	0	0
Area affected[a]		
Buttocks	16	42.1
Coccyx	5	13.2
Gluteal cleft	4	10.5
Groins	6	15.8
Lower abdomen	3	7.9
Rectal area	13	34.2
Scrotum/labia	7	18.4
Upper thighs	2	5.3
IAD severity score		
1-3 Mild IAD	31	81.6
4-6 Moderate IAD	5	13.1
7-9 Severe IAD	2	5.3
> 9 Extreme IAD	0	0
Pressure injury	8	21.1
Clinical indication of fungal infection	12	31.6

[a]Total > 100% as patients may have more than one area affected.

Clinical indication of fungal infection was present in 32% (*n* = 12) of patients with IAD. However, presence of fungal infection may have been over or underestimated, as no microbiological testing to confirm the diagnosis of fungal

infection was undertaken in this study. Pressure injuries were present in 6% (*n* = 22) patients, with 21% (*n* = 38) patients with IAD having a pressure injury (see Table 4.5).

Products worn to manage incontinence and products used to provide perineal skin care.

Wrap-around incontinent briefs or pads (that is, those aids worn as an alternative to underwear) were worn by 77% (*n* = 70) of incontinent patients at the time of evaluation (see Table 4.6). Soap/water and disposable washcloths were the

Table 4.6

Products Worn to Manage Incontinence and Products Used to Provide Perineal Skin Care (n = 91)

Variable	*n*	%
Incontinence aid for urinary incontinence		
None	2	2.2
Wrap around pad	4	4.4
Pull up pad	5	5.5
Insert pad	1	1.1
Incontinence aid for faecal incontinence		
None	11	12.1
Wrap around pad	10	11.0
Pull up pad	8	8.8
Insert pad	1	1.1
Incontinence aid for double incontinence		
None	1	1.1
Wrap around pad	21	23.1
Pull up pad	22	24.2
Insert pad	1	1.1
Incontinent aid - missing	4	4.4[a]
Incontinence clean-up		
Soap/water and disposable cloth	55	60.4
Missing	36	39.6
Moisturiser		
Yes	31	34.1
No	22	24.2
Missing	38	41.7
Skin protection products		
Yes	52	57.1
Missing	39	42.8[a]

[a]Percentages may not add up to 100 due to rounding.

most common incontinence clean-up products at the bedside for incontinent patients (60%, *n* = 55). Moisturising agents were present at the bedside in 34% (*n* =

31) of incontinent patients. Skin protection products were present at the bedside in 57% (*n* = 52) patients. Examples of these products are 3M™ Cavilon™ No Sting Barrier Film (3M, Saint Paul, MN) and Skin Basics™ Zinc and Castor Oil Cream (Biotech Pharmaceuticals, Victoria, Australia).

Discussion

Incontinence occurred in one in four patients hospitalised in a major acute care setting in Australia, indicating it is a frequent and serious problem. IAD occurred in 42% of those who were incontinent, demonstrating that IAD is a prevalent and under-appreciated skin injury in hospitalised patients. The most common incontinence aid worn was an incontinent brief (80%), with soap/water and disposable cloths the most common incontinence clean-up present at the bedside (60%). This is the first Australian study to report both the prevalence of incontinence and IAD in the acute care setting and to differentiate IAD from pressure injury and fungal infection.

Incontinence-associated dermatitis

Acute care patients are subjected to treatment regimes that may result in IAD, for example, antibiotics, changes in dietary intake and enteral feeds. Thus, acute care patients are a unique population that are at increased risk. IAD has been under-appreciated, as is not the primary reason for admission. Anecdotal evidence suggests it is not only accepted, but actually expected that older patients will be incontinent.

IAD prevalence data for the general acute care setting is limited. The majority of published data are drawn from specialised settings such as critical care or the aged care setting. A study in three urban hospital critical care units found an IAD prevalence of 36% (Bliss et al., 2011) and prevalence in a long-term acute care setting was 23%, (Arnold-Long et al., 2011). Prevalence of IAD ranges in aged care from 6%-22% (Beeckman et al., 2010; Bliss et al., 2006).

An important finding to emerge from our study is that liquid and semi-formed stool was associated with IAD compared to formed stool. No other published studies examined the association between stool quality and IAD. Congruent with our finding, the extensive review by Gray and colleagues (2012) identified that stool is implicated as an aetiological factor in IAD; with clinical experience strongly suggesting that liquid stool is more irritating than solid or formed stool. Further

research is warranted to determine if stool quality, particularly semi-formed/liquid stool, promotes the development of IAD.

Most (82%) IAD severity in our study was mild. Junkin and Selekof (2007) classified IAD as red and dry, red and weepy, or having blisters in the areas likely to be exposed to urine or faeces. Of the patients with IAD, 75% had red and dry skin, with 25% having red and weepy skin. Both of these categories could be interpreted as being at the less severe end of a severity continuum, which correlates with the severity of IAD in our study. The natural history of IAD is poorly understood (Gray et al., 2007), but progression from 'mild' through to 'severe' IAD is inevitable in the presence of persisting incontinence, inadequate management of incontinence and inadequate or inappropriate incontinence clean-up, skin protection, and treatment of any cutaneous infections. Early recognition and treatment thus is optimum.

IAD needs to be differentiated from other skin lesions, especially in the pelvic girdle. Pressure injuries historically have been confused with IAD. The NPUAP and the European Pressure Ulcer Advisory Panel (EPUAP) have specifically stated that IAD is not a pressure injury (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009). A strength of this study is that both IAD and pressure injury were identified, so accurate prevalence of each could be determined. Future pressure injury prevalence studies would benefit from also measuring incontinence and IAD.

Presence of urine and faeces on denuded skin creates a favourable environment for development of fungal infection, with fungal infection frequently reported as a potential complication of IAD (Gray et al., 2007; Gray et al., 2011; Zulkowski, 2012). The presence of a fungal infection needs to be differentiated from IAD. Presence of fungal infection for our study was determined based on clinical presentation of a central maculopapular rash with characteristic satellite lesions (Black et al., 2011). No quantitative microbiological testing was undertaken. According to Professor Jack Sobel (J. Sobel, personal email, 3 April, 2014) the fungal rash may also present as non-specific, confluent and papular, creating some difficulty in clinical diagnosis. The presence of a fungal infection would require treatment, but it is desirable to obtain a microbiological culture prior to commencing anti-mycotic therapy (Maertens, 2007; Richardson, 2012; Vazquez & Sobel, 2002). Accordingly, the presence of a fungal infection may have been under or

overestimated in our study. Our data showed 32% of patients with IAD demonstrated clinical evidence of a fungal infection. This is higher than the United States data from Junkin and Selekof (2007) that showed 10% of incontinent patients had a fungal rash (based on clinical examination). The higher prevalence of suspected fungal infection in our study may be associated with the higher IAD prevalence rate. These infections are a serious threat to patient outcomes because of the possibility of under-diagnosis or missed diagnosis, and the potential for delay in treatment. It is not clear whether a fungal infection may have an aetiological role in IAD, rather than being a secondary infection.

Pressure injuries were present in 6% of our entire sample, with 12% of incontinent patients having a pressure injury. This prevalence is lower than that reported by Junkin and Selekof (2007), where 22% of incontinent patients had a PI. In part, our lower PI rate may reflect the increased emphasis on PI prevention in recent years.

One of the issues in the literature continues to be the lack of a universal definition for IAD prevalence. That is to say, should the denominator be the entire sample, or only those with incontinence? Since IAD cannot occur without incontinence (that is, skin exposure to urine and or faeces) (Gray et al., 2007), the number of incontinent patients logically would be the denominator. Most studies report IAD prevalence with the denominator being the number of incontinent patients (Beeckman, Verhaeghe, et al., 2011; Driver, 2007; Junkin & Selekof, 2007), but a consistent standard needs to be established. However, we recommend that until a standard definition is accepted, that researchers present the IAD rate for the entire sample and for those who are incontinent to ensure clarity and accuracy. We have used that approach in this paper.

Incontinence

The definition of incontinence for an IAD prevalence study needs further clarification, specifically, how to categorise patients who have a urinary catheter. The presence of a urinary catheter prevents skin exposure to urine – a known cause of IAD. Previous studies have categorised patients with urinary catheters as continent (Halfens et al., 2013; Junkin & Selekof, 2007). However, it should be acknowledged that categorising patients with a urinary catheter as continent can result in an underestimation of incontinence prevalence. In the acute care setting, patients can be

catheterised for a multitude of reasons, including incontinence. For example, in this study, 11 of 15 patients surveyed in ICU had a urinary catheter. The use of a urinary catheter in ICU is to monitor kidney function, fluid balance in the critically ill.

Our data showed a significant association between increasing age and incontinence. Junkin and Selekof (2007) found the odds of older patients having incontinence were greater (OR = 4.979, 95% CI = 1.015-22.427). Incontinence is recognised as one of the geriatric syndromes (Inouye et al., 2007; Lakhan et al., 2011), and has been associated with longer length of hospital stay and greater risk of being discharged to a residential care setting (Chiarelli et al., 2005; Fonda, Nickless, & Roth, 1988; Green, Smoker, Ho, & Moore, 2003). Ageing of the global population (Kinsella, 2009) coupled with the rising cost of healthcare (Australian Institute of Health and Welfare, 2012b; Kinsella, 2009; Rak & Coffin, 2013), means that managing incontinence in the acute care setting is an ever-increasing challenge.

The limited prospective prevalence data for incontinence in the acute care setting in Australia is noteworthy, since incontinence is associated with significant morbidity and decreased quality of life for individuals (Inouye et al., 2007). Healthcare providers require an understanding of the magnitude of this condition to provide appropriate care. We are not certain why the probability of incontinence is lower in the Surgical admitting service than the Internal Medicine admitting service, although there is some evidence supporting increased prevalence of geriatric syndromes (including incontinence) in older medical patients in the acute care setting (Lakhan et al., 2011). Our study adds important results that assist in understanding the burden of incontinence in the Australian acute care setting.

Products worn to manage incontinence and products used to provide perineal skin care

Our study showed disposable incontinence briefs were the most common incontinence aids worn (77%), soap/water and disposable washcloths the most common clean-up products at the bedside (60%), and skin barrier protection available at the bedside of 57% of patients. A consistent, structured approach to prevention and treatment of IAD is required (Black et al., 2011; Gray et al., 2007). Having supplies at the bedside provides an efficient approach and ensures that a consistent strategy is used. Three steps are recommended: (i) gentle cleansing, using a soft disposable washcloth and cleansers without perfumes or irritants and close to

skin pH (a no rinse formulation is suggested); (ii) moisturisation to preserve the lipid barrier (Black et al., 2011), and (iii) application of a skin barrier product is required to protect the stratum corneum from moisture and irritants (Black et al., 2011; Gray, 2007). Lack of bedside supplies suggests there is a gap between available products/recommendations and care. Further research is needed to identify how products are used, as well as their effectiveness in preventing and treating IAD.

Limitations

Several limitations need to be noted. This is a cross-sectional study and no cause and effect can be inferred. Every effort was made to recruit eligible participants; however, direct clinical examination of patients in this type of study can be intrusive and may have limited enrolment, (in our study, this was 69%). Data was not recorded as to why patients refused to participate. This study did not have ethical approval to collect data from those patients who did not consent. The IAD Severity Assessment tool was chosen in this study to classify severity of the condition. However, this scale does not include a measure of patient pain. IAD and faecal quality analysis was conducted at a bivariate level as the amount of missing data in these variables made adjusting for confounders and logistic regression analysis unfeasible. Clinical inspection was used to determine the presence of fungal infection in this study. The prevalence of fungal infection may have been over or underestimated as no quantitative laboratory measure was used to confirm the diagnosis. Future research needs to use appropriate quantitative measures to confirm the presence of fungal infection.

Conclusion

This is the first Australian study to report both the prevalence of incontinence and IAD in the acute care setting and to differentiate IAD from pressure injury and fungal infection. Almost one quarter of hospitalised adults were incontinent, and of the incontinent patients in the study, more than 40% developed IAD. Faecal incontinence occurred more frequently than urinary incontinence. Liquid and semi-formed stool was significantly associated with IAD compared to formed stool. In addition, our data confirmed that the likelihood of incontinence increases with age, especially in those >80. Products for incontinence containment, clean up, and skin protection need to be available at the bedside to facilitate incontinence management. Further, prospective observational prevalence studies are essential to confirm these

data in hospitalised Australian adults. The availability of results informing the prevalence of both incontinence and IAD is essential to measure the scope of the problem. More research addressing the effectiveness of treatment of incontinence and IAD in the acute care setting is needed. Additional research examining the aetiology of IAD and the role of fungal infections is warranted.

Acknowledgements

The principal investigator is the recipient of a Royal Brisbane and Women's Hospital Research Postgraduate scholarship, which in part supported preparation of this manuscript.

We thank the patients who participated in this study and the RAs who collected data. We also thank the Director of the RBWH Quality and Safety Unit - Therese Lee, as well as Michelle Holland, Kelly McDonough, and Katrina Rooke for the 'in kind' and logistical support of this project. We acknowledge the valuable contribution of Nurse Practitioner Complex Wound Management, Kerrie Coleman and Clinical Nurse Skin Integrity, Kathleen Hocking for their clinical expertise and review of the instrument. Finally, we would like to thank Emeritus Professor Nancy Stotts for reviewing this paper.

References

Abrams, P., Blaivas, J. G., Stanton, S. L., & Andersen, J. T. (1988). Standardisation of terminology of lower urinary tract function. *Neurourology and Urodynamics, 7*(5), 403-427.

Arnold-Long, M., Reed, L., Dunning, K., & Ying, J. (2011). Incontinence-associated dermatitis (IAD) in a long-term acute care (LTAC) facility: Findings from a 12 week prospective study. *Journal of Wound Ostomy & Continence Nursing, 38*(3S), S7-S7.

Australian Institute of Health and Welfare. (2012). Health expenditure Australia 2010-11. *Health and welfare expenditure series no. 47.* Retrieved from http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737423003

Australian Wound Management Association. (2001). *Clinical Practice Guidelines for the prediction and prevention of pressure ulcers.* (1st ed.). West Leederville: Cambridge Publishing.

Beeckman, D., Schoonhoven, L., Boucque, H., Van Maele, G., & Defloor, T. (2008). Pressure ulcers: E-learning to improve classification by nurses and nursing students. *Journal of Clinical Nursing, 17*(13), 1697-1707.

Beeckman, D., Schoonhoven, L., Fletcher, J., Furtado, K., Gunningberg, L., Heyman, H., . . . & Defloor, T. (2007). EPUAP classification system for pressure ulcers: European reliability study. *Journal of Advanced Nursing, 60*(6), 682-691.

Beeckman, D., Schoonhoven, L., Verhaeghe, S., Heyneman, A., & Defloor, T. (2009). Prevention and treatment of incontinence-associated dermatitis: Literature review. *Journal of Advanced Nursing, 65*(6), 1141-1154.

Beeckman, D., Vanderwee, K., Demarre, L., Paquay, L., Van Hecke, A., & Defloor, T. (2010). Pressure ulcer prevention: development and psychometric validation of a knowledge assessment instrument. *International Journal of Nursing Studies, 47*(4), 399-410.

Beeckman, D., Verhaeghe, S., Defloor, T., Schoonhoven, L., & Vanderwee, K. (2011). A 3-in-1 perineal care washcloth impregnated with dimethicone 3% versus water and pH neutral soap to prevent and treat incontinence-associated dermatitis: A randomised, controlled clinical trial. *Journal of Wound Ostomy & Continence Nursing, 38*(6), 627-634.

Beitz, J. (2006). Fecal incontinence in acutely and critically ill patients: options in management. *Ostomy Wound Management, 52*(12), 56-58, 60, 62-56.

Black, J., Gray, M., Bliss, D., Kennedy-Evans, K., Logan, S., Baharestani, M., . . . & Ratliff, C. (2011). MASD part 2: Incontinence-associated dermatitis and intertriginous dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 38*(4), 359-370.

Bliss, D., Johnson, S., Savik, K., Clabots, C., & Gerding, D. (2000). Fecal incontinence in hospitalized patients who are acutely ill. *Nursing Research, 49*(2), 101-108.

Bliss, D., & Powers, J. (2011). Faecal incontinence and its associated problems in hospitalised patients: The need for nursing management. *World Council of Enterostomal Therapists Journal, 31*(2), 35-39.

Bliss, D. Z., Johnson, S., Savik, K., Clabots, C. R., & Gerding, D. N. (2000). Fecal incontinence in hospitalized patients who are acutely ill. *Nursing Research, 49*(2), 101-108.

Bliss, D. Z., Savik, K., Harms, S., Fan, Q., & Wyman, J. F. (2006). Prevalence and correlates of perineal dermatitis in nursing home residents. *Nursing Research, 55*(4), 243-251.

Bliss, D. Z., Savik, K., Thorson, M. A. L., Ehman, S. J., Lebak, K., & Beilman, G. (2011). Incontinence-associated dermatitis in critically ill adults: time to development, severity, and risk factors. *Journal of Wound Ostomy & Continence Nursing, 38*(4), 433-445.

Chiarelli, P., Bower, W., Wilson, A., Attia, J., & Sibbritt, D. (2005). Estimating the prevalence of urinary and faecal incontinence in Australia: Systematic review. *Australasian Journal on Ageing, 24*(1), 19-27

Defloor, T., & Schoonhoven, L. (2004). Inter-rater reliability of the EPUAP pressure ulcer classification system using photographs. *Journal of Clinical Nursing, 13*(8), 952-959.

Doughty, D., Junkin, J., Kurz, P., Selekof, J., Gray, M., Fader, M., . . . & Logan, S. (2012). Incontinence-associated dermatitis: Consensus statements, evidence-based guidelines for prevention and treatment, and current challenges. *Journal of Wound Ostomy & Continence Nursing, 39*(3), 303-315.

Driver, D. S. (2007). Perineal dermatitis in critical care patients. *Critical Care Nurse, 27*(4), 42-46.

Farage, M. A., Miller, K. W., Elsner, P., & Maibach, H. I. (2007). Structural characteristics of the aging skin: A review. *Cutaneous Ocular Toxicology, 26*(4), 343-357.

Fonda, D., Nickless, R., & Roth, R. (1988). A prospective study of the incidence of urinary incontinence in an acute care teaching hospital and its implications on future service development. *Australian Clinical Review/Australian Medical Association [and] the Australian Council on Hospital Standards, 8*(30), 102-107.

Gray, M. (2007). Incontinence-related skin damage: Essential knowledge. *Ostomy Wound Management, 53*(12), 28-32.

Gray, M. (2011). Optimal management of incontinence-associated dermatitis in the elderly. *Journal of Wound Ostomy & Continence Nursing*(4S), S29-S29.

Gray, M., Beeckman, D., Bliss, D. Z., Fader, M., Logan, S., Junkin, J., . . . & Kurz, P. (2012). Incontinence-associated dermatitis: A comprehensive review and update. *Journal of Wound Ostomy & Continence Nursing, 39*(1), 61-74.

Gray, M., Black, J., Baharestani, M., Bliss, D., Colwell, J., Goldberg, M., . . . & Ratliff, C. (2011). Moisture-associated skin damage: Overview and pathophysiology. *Journal of Wound Ostomy & Continence Nursing, 38*(3), 233-241.

Gray, M., Bliss, D., Doughty, D., Ermer-Seltun, J., Kennedy-Evans, K., & Palmer, M. (2007). Incontinence-associated dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 34*(1), 45-56.

Green, J. P., Smoker, I., Ho, M. T., & Moore, K. H. (2003). Urinary incontinence in subacute care--a retrospective analysis of clinical outcomes and costs. *Medical Journal of Australia, 178*(11), 550-553.

Halfens, R. J. G., Meesterberends, E., van Nie-Visser, N. C., Lohrmann, C., Schönherr, S., Meijers, J. M. M., . . . & Schols, J. M. G. A. (2013). International prevalence measurement of care problems: results. *Journal of Advanced Nursing, 69*(9), e5-e17.

Halland, M., & Talley, N. J. (2012). Fecal incontinence: Mechanisms and management. *Current Opinion in Gastroenterology, 28*(1), 57-62.

Inouye, S. K., Studenski, S., Tinetti, M. E., & Kuchel, G. A. (2007). Geriatric syndromes: Clinical, research, and policy implications of a core geriatric concept. *Journal of the American Geriatrics Society, 55*(5), 780-791.

Junkin, J., & Selekof, J. (2007). Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of Wound Ostomy & Continence Nursing, 34*(3), 260-269.

Junkin, J., & Selekof, J. (2008). Beyond 'diaper rash': Incontinence-associated dermatitis: does it have you seeing red? *Nursing, 38*(11 Suppl), 56hn51.

Kennedy, K., & Lutz J. (4th October 1996). *Comparison of the efficacy and cost effectiveness of three skin protectants in the management of incontinent dermatitis.* Paper presented at the European Conference on Advances in Wound Management, Amsterdam, Netherlands.

Kinsella, K., & He, W. (2009). *An Aging World: 2008, International Population Reports,* US Census Bureau, 2009 Contract No P95/09-1.

Lakhan, P., Jones, M., Wilson, A., Courtney, M., Hirdes, J., & Gray, L. (2011). A prospective cohort study of geriatric syndromes among older medical patients admitted to acute care hospitals. *Journal of the American Geriatrics Society, 59*(11), 2001-2008.

Lewis, S. J., & Heaton, K. W. (1997). Stool form scale as a useful guide to intestinal transit time. *Scandinavian Journal of Gastroenterology, 32*(9), 920-924.

Maertens, J., & Marr, K. A. (Eds.). (2007). *Diagnosis of fungal infections*. CRC Press. New York: Informa Healthcare.

National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. (2009). *Prevention and treatment of pressure ulcers: Clinical practice guideline.* Washington DC: National Pressure Ulcer Advisory Panel.

Ostaszkiewicz, J., O'Connell, B., & Millar, L. (2008). Incontinence: Managed or mismanaged in hospital settings? *International Journal of Nursing Practice, 14*(6), 495-502.

Rak, S., & Coffin, J. (2013). Affordable care act. *The Journal of Medical Practice Management: 28*(5), 317-319.

Richardson, M. D & Warnock, D.,W. (2012). *Fungal infection diagnosis and management.* John Wiley& Sons:West Sussex.

Royal Brisbane and Women's Hospital Marketing and Communications. (2013). *2011-2012 RBWH year in review*. Brisbane: Metro North Hospital and Health Service, Royal Brisbane and Women's Hospital.

Vazquez, J. A., & Sobel, J. D. (2002). Mucosal candidiasis. *Infectious Disease Clinics of North America, 16*(4), 793-820

Zulkowski, K. (2012). Diagnosing and treating moisture-associated skin damage. *Advances in Skin & Wound Care, 25*(5), 231-236;

4.3 CHAPTER SUMMARY

Study 1 shed light on the prevalence of both incontinence and IAD in an Australian acute care setting. This study, the first of its kind in Australia, found a high prevalence of incontinence of nearly one quarter of participants (24%), with 42% of these found to have IAD (Campbell et al., 2014). These findings highlight that incontinence and IAD pose a considerable threat to skin integrity in these patients. Consistent with other studies, Study 1 found an association with older age and incontinence (Furlanetto & Emond, 2014; Inouye et al., 2007; Lakhan et al., 2011; Ostaszkiewicz et al., 2008).

This study provides evidence to support the inclusion of several constructs in the Skin Safety Model (SSM). It provided data on the prevalence of incontinence (24%) and IAD (42%) in the acute care setting. In addition, the study reported that disposable incontinent briefs were the most common incontinence containment device used in the hospital (77%), soap/water and disposable washcloths the most common incontinence clean-up products at the bedside (60%), and skin protection products present at the bedside in just over half of patients (57%). As discussed in Chapter 2, (Section 2.2.1), effective clinical governance is a critical determinant of patient safety and quality outcomes. Underpinning effective clinical governance is the requirement for accurate and valid data, which informs decision-making, planning resource allocation and continuous quality improvement. In the domain of maintaining skin integrity, PI prevalence data is traditionally the most common metric informing clinical governance. Clinical governance is included as an element in the first construct of the SSM, because, without robust clinical governance regarding the maintenance of skin integrity, skin injury is likely to ensue. This study provides prevalence data that can guide skin safety protocols and procedures at the level of clinical governance. Given the responsibility that clinical governance has in responding to and managing prevalence data, the serious prevalence results revealed by Study 1 indirectly support the validity of including the construct of clinical governance in the SSM.

Another systems factor proposed in the in the first construct of the SSM is skin assessment. While skin assessment was not a variable investigated in the study, accurate skin assessment was crucial for inter-rater reliability and data validity in

terms of accurately identifying and classifying injuries such as IAD, PI or fungal infection in this study. Further, to assure inter-rater reliability, skin injuries reported during the survey were reinspected on the same day by nurses with expertise in assessing skin integrity. This supports the validity of the inclusion of skin assessment as a systems factor in the first construct of the SSM.

Study 1 demonstrated a significant association between the variables older age and incontinence (OR = 1.03, $p < .001$). These variables are identified in the first construct of the model as potential contributing factors. All participants in the study by virtue of their hospital admission were subject to an acute situational stressor, either acute illness, exacerbation of a chronic condition, surgery, trauma or psychosocial stressors, or a combination of these factors. The second model construct identifies a range of exacerbating elements that contribute to skin injury. Study 1 investigated the exacerbating elements of skin irritants, in this case, urine and/or faeces as a result of incontinence. Of the incontinent patients in the sample, 42% suffered from IAD. This result provides evidence that there is an association between incontinence, resultant exposure to urine and faeces and the development of IAD as proposed in the SSM. In addition, the study found a significant association between IAD and semi-formed or liquid stool. The final construct of the model addresses potential outcomes of skin injury. The study found that 32% of patients with IAD presented with clinical evidence of a fungal infection. This adds empirical evidence to the scant data available demonstrating infection as a possible outcome of IAD.

With the global trend towards population ageing, it is likely that the prevalence of incontinence and associated IAD will continue to increase, placing further burdens on already strained heath care systems and placing patients at risk of adverse outcomes. This data has made a significant contribution to the understanding of the prevalence of IAD in the Australian acute care setting.

4.4 RATIONALE FOR STUDY 2

The results of Study 1 highlighted the significant magnitude of incontinence and IAD within the research facility. The imperative to understand the prevalence of IAD and to prevent nosocomial skin injury has been presented in the previous chapters. In response to the significant implications of this data for skin integrity outcomes, the facility's pressure injury prevention committee made the important

decision that the ongoing gathering of this data was warranted. Subsequently, the committee adopted (with some minor adaptations) the combined PI and IAD prevalence survey protocol for future facility-wide surveys. The unique, combined pressure injury and IAD prevalence survey protocol (used in Study 1) and pressure injury data are presented in Publication 3 outlined in Chapter 5.

A key finding from Study 1 highlighted the presence of a fungal infection in 32% of patients with IAD. However, this finding was based on clinical judgement, and not validated with microbiological testing. Further research was warranted into the association between *Candida* infection and IAD, as demonstrated by the significant prevalence of this condition found in Study1. The results of Study 1 provide rationale for Sudy 2.

Chapter 5: COMBINING PRESSURE INJURY AND INCONTINENCE-ASSOCIATED DERMATITIS PREVALENCE SURVEYS

5.1 INTRODUCTION

This chapter presents Publication 3 of the thesis:

Campbell, J., Gosley, S., Coleman, K., & Coyer, F. Combining pressure injury and incontinence-associated dermatitis prevalence surveys: An effective protocol? This manuscript has been accepted for publication with minor revisions by *Wound Practice and Research.*

The objectives of the publication were to:

1. Review the PI prevalence before and after the commencement of the protocol of combining the PI and IAD surveys
2. Review the utility of combining the PI and IAD prevalence survey protocols in an Australian metropolitan hospital.

The research facility has conducted annual pressure injury prevalence surveys for the last decade. However, the impetus to adopt the combined prevalence survey protocol was underpinned by several drivers. The key driver resulted from Study 1, with the revelation of the significant scope of the problem of IAD within the facility, a previously under-appreciated problem. In Queensland, a system of financial penalties for hospitals applies for stage III or IV for hospital-acquired PIs, with a stage III injury incurring a penalty of $30,000, and a stage IV incurring a penalty of $50,000 (Department of Health, 2013). Coupled with the understanding that IAD and pressure injuries are frequently misclassified (Beeckman et al., 2008; Doughty, 2012; D.Voegeli, 2011), which subsequently results in inappropriate prevention and management of both lesions, the combined survey protocol was adopted as a strategy to improve patient outcomes and data accuracy.

The Skin Safety Model (SSM) (see Chapter 2, Publication 1), guided the understanding of the complex and inter-related antecedents of skin injury in vulnerable patients in the acute care setting. The conduct of the combined PI and

IAD prevalence surveys represented a pragmatic clinical application of the concepts set forth in the Skin Safety Model. Appreciation of the requirement to understand the prevalence of several inter-related skin injuries, as well as the extent of the patients at risk for these inter-related skin injuries reflected the move towards a holistic approach to managing skin integrity, and a move away from the delivery of siloed, narrow, injury-focused skin integrity care.

The following publication is a collaboration between the researcher, the research facility's quality and safety unit, and the Nurse Practitioner Complex Wound Care, and was presented as an oral presentation at the Australian Wound Management Association's 10th national conference in 2014.

5.2 PUBLICATION 3

Combining Pressure Injury and Incontinence-Associated Dermatitis Prevalence Surveys: An Effective Protocol?

Abstract

Incontinence-associated dermatitis (IAD) is a largely preventable skin injury that can occur following chronic skin exposure to urine and faeces as a result of incontinence. Limited data is available regarding the prevalence of IAD in the Australian acute care setting. In 2011, the facility combined the annual pressure injury (PI) prevalence survey with a survey to determine the prevalence of IAD. This paper examines the PI and IAD prevalence results from surveys before and after the introduction of the combined survey protocol. The surveys were conducted in a major acute care Australian hospital between 2009 and 2013, with the combined PI and IAD surveys undertaken from 2011-2013. Overall, PI point prevalence decreased from 12.8% (*n* = 64) in 2009 to 6.3% (*n* = 28) in 2013. IAD prevalence was first reported in the 2011 survey. IAD prevalence decreased from 10% (*n* = 38) in 2011, to 2.7% (*n* = 12) in 2013. Combining the PI and IAD survey protocols provided valuable and previously unknown IAD data. In addition, combining the surveys was accomplished without increased financial or staff resources, nor increased survey participation burden for patients. Key aspects of the combined protocol have subsequently been adopted by the facility as standard procedures for ongoing PI prevalence surveys.

Key words: Incontinence-associated dermatitis, incontinence, pressure injury, prevalence.

Introduction

Pressure injuries (PIs) are localised injuries to the skin and /or underlying tissue, usually over a bony prominence resulting from sustained pressure (including pressure with shear). Largely preventable, PIs, if sustained while in hospital care are considered to be nosocomial skin injuries (National Pressure Ulcer Advisory, European Pressure Ulcer Advisory, & Pan Pacific Pressure Injury, 2014). Prevalence

surveys are a common and well-established method for determining the number of existing PIs in the acute care setting (Baharestani et al., 2009a). Prevalence data provides a snapshot of the burden of a condition at the time of the survey, and can provide data to assist in evaluating clinical and preventative practices, benchmarking, and resource allocation (Amlung, Miller, & Bosley, 2001; Baharestani et al., 2009a; Baumgarten, 1998; Beeckman et al., 2007). Incontinence-associated dermatitis (IAD) is skin injury that can occur following chronic skin exposure to urine and faeces as a Therefore, the primary risk factor for IAD is incontinence (Beeckman et al., 2015). Moreover, IAD can predispose patients to serious complications, such as superficial PI and/or superimposed infections (Beeckman et al., 2015; Doughty et al., 2012; Furlanetto & Emond, 2014; Gefen, 2014; Gray et al., 2007; Junkin & Selekof, 2007). Like PIs, IAD is largely preventable. IAD and PIs commonly co-exist, are often co-located, and are frequently misclassified by clinicians (Beeckman et al., 2015; Voegeli, 2011). If misclassification occurs within the context of a PI prevalence survey, it is possible that IAD may be classified as a stage I or II PI, thereby erroneously increasing PI prevalence (Baharestani et al., 2009a; Beeckman et al., 2015). Patients at risk of skin injury due to pressure and shear are also likely to be vulnerable to injury from moisture, friction, and irritants found in urine and /or faeces (Doughty, 2012; Gefen, 2014; Voegeli, 2011). Unlike the extensive understanding of PI prevalence in the acute care setting, there is a gap in the understanding of IAD prevalence in this setting. Furthermore, established protocols or agreement on the ideal methods to conduct prevalence surveys are lacking (Beeckman et al., 2015). Given the potentially serious complications of IAD, understanding the scope of this condition in the acute care setting is imperative for maintaining skin integrity, and the broader mandate of patient safety (Campbell, Coyer & Osborne, 2015).

In Australia, there is evidence that the prevalence of PIs in the acute care setting has been decreasing steadily over the last decade. For example, in Ballarat Victoria, PI prevalence decreased from 11% in 2009, to 2.5% in 2012 (Antonio & Conrad, 2013), at a large metropolitan hospital in Brisbane Queensland hospital-acquired PI prevalence fell from 14% in 2002 to 4.0% 2012 (Miles, et al., 2013), and statewide hospital PI prevalence audits conducted in Victoria found that PI prevalence decreased from 26.5% in 2003 to 17.6% in 2006 (Victorian Quality

Council, 2008). Internationally, PI prevalence has also declined over the last decade. Prevalence in the United States ranged from 13% in 2003 to 11% in 2009 (Vangilder, Amlung, Harrison, & Meyer, 2009). An appreciation of incontinence is required to understand IAD (Campbell, Coyer & Osborne, 2014), with the prevalence of incontinence providing a guide as to the proportion of patients at risk of IAD (Ersser, Getliffe, Voegeli, & Regan, 2005). The prevalence of IAD in the acute care setting is reported to range between 20-42% (Bliss et al., 2011; Campbell et al., 2014; Junkin & Selekof, 2007). A 2014 Australian study (Campbell et al., 2014), found the prevalence of incontinence to be 24%, with 42% of those incontinent patients having IAD, reflecting the significant extent of the condition in this setting.

Awareness of the importance of IAD as a significant skin injury has been growing over the last decade (Beeckman, 2016; Voegeli, 2016). One of the challenges that persists in regard to IAD is the difficulty clinicians face in accurately differentiating between IAD and PI (Beeckman et al., 2007; Defloor, Schoonhoven, Vanderwee, Weststrate, & Myny, 2006; Mahoney, Rozenboom, Doughty, & Smith, 2011; Voegeli, 2011). Several factors may contribute to this difficulty. Firstly, while there is an agreed categorisation system for PIs (National Pressure Ulcer Advisory et al., 2014), at the time of the study, there was no internationally agreed categorisation system for IAD. PIs are classified or staged according to a classification system that includes stage I-IV injuries, as well as unstageable and suspected deep tissue injury categories (National Pressure Ulcer Advisory et al., 2014). While several IAD severity categorisation systems have been proposed, (Beeckman et al., Borchert, Bliss, Savik, & Radosevich, 2010 2015; Junkin, 2008, Kennedy & Lutz, 1996), use of these categorisation systems in clinical practice is limited. This may in part, be due to the lack of evidence regarding improvements to clinical decision-making and care when these systems are used (Beeckman et al., 2015). Secondly, accurate classification is complicated by similarities in clinical presentation and location of PIs and IAD (see Table 5.1) with particular challenges found in differentiating IAD from Category/stage I and II PI (Beeckman et al., 2015) (see Appendix G).

In 2011, as a result of a growing appreciation of the significance of IAD as nosocomial skin injury, the role of IAD and incontinence as risk factors for PI, and the imperative for accurate and reliable PI data, the facility conducted a combined PI and IAD prevalence survey. This combined prevalence survey was a facility wide

quality improvement activity, and also formed a component of the first author's higher research degree, (results of the research have been published elsewhere, Campbell et al., 2014). Combining PI and IAD prevalence surveys into a single protocol is not routine clinical practice.

Table 5.1

IAD and PI Differentiation

Parameter	IAD	PI
History	Urinary and/or faecal incontinence	Exposure to pressure/shear
Symptoms	Pain, itching, burning, tingling	Pain
Location	Affects perineum, perigenital area; buttocks; gluteal fold; medial and posterior aspects of upper thighs; lower back; may extend over bony prominence	Usually over bony prominence or associated with location of a medical device
Shape/edges	Affected area is diffuse with poorly-defined edges/may be blotchy	Distinct edges or margins
Presentation/depth	Intact skin with erythema (blanchable or non-blanchable), with/without superficial, partial thickness skin loss	Presentation varies from intact skin with non-blanchable erythema to full-thickness skin loss. Base of wound may contain non-viable tissue
Other	Secondary superficial skin infection (for example *Candida*) may be present	Secondary soft tissue infection may be present

Note. IAD = Incontinence-associated dermatitis, PI = pressure injury. Adapted with permission from Beeckman, D., Campbell, J., Campbell, K., Chimentao, D., Coyer, F., Domansky, R., …Wang, L. (2015). Proceedings of the Global IAD expert panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International*. Retrieved from www.woundsinternational.com (see Appendix G).

Potential benefits of combining PI and IAD surveys may include; improved PI data accuracy as a result of improved surveyor education, access to new and valuable IAD and incontinence data, allowing for a more comprehensive understanding of skin integrity risks and injuries within the facility and importantly, and value adding to costly PI surveys by means of simultaneously capturing IAD and PI data at minimal or no extra cost to the facility.

Poor understanding of the prevalence of both PIs and IAD, as well as lesion misclassification can have implications for patient outcomes, delivery of quality care, resource allocation, PI prevalence data accuracy and skin integrity benchmarking (Baharestani et al., 2009a; Beeckman et al., 2015; Beeckman, 2016; National Pressure Ulcer Advisory et al., 2014). An opportunity exists to improve the understanding of these skin injuries in the acute care setting, by way of combining PI and IAD prevalence surveys and simultaneously obtaining valuable PI and IAD prevalence data.

Objective

The objectives of this paper were to review PI prevalence before (2009-2010) and after (2011-2013) the commencement of the protocol combining PI and IAD surveys, and to review IAD prevalence data after the commencement of the protocol combining PI and IAD surveys (2011-2013).

Methods

Design

PI prevalence results from surveys conducted between 2009 and 2013 were examined. IAD prevalence results from surveys conducted between 2011-2013 were examined.

Setting and sample

This study was conducted at a 929-bed major acute care teaching hospital in Australia. Hospitalised adults aged 18 aged years or older admitted to the facility on the days of the surveys were eligible for inclusion. Patients were surveyed from Internal Medicine, Surgery, Critical Care, Cancer Care, and Women's and Newborn services (only non-obstetric patients were included from Women's and Newborn service). Patients from the Mental Health service were excluded from the surveys.

Pressure injury and incontinence-associated dermatitis prevalence formulae

PI prevalence was calculated as the total number of participants with one or more PIs detected on skin inspection on the survey days, divided by the total number of participants. In 2011, the prevalence of IAD amongst incontinent patients was calculated as the total number of IAD cases in the sample divided by the total number of incontinent participants (see Figure1) (Campbell et al., 2014). In 2012 and 2013, incontinence prevalence was not calculated, as the prevalence of incontinence was not recorded in these surveys. The change in formula would have impacted on the ability to benchmark effectively. Therefore, for these years, the prevalence of IAD was calculated by the total number of IAD cases in the sample, divided by the total number of participants in the sample.

Measures

Pressure injury classification: All PIs were staged according to the PI staging guidelines accepted for use in Australia at the time of each survey (Australian Wound Management Association, 2012; National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009).

Incontinence-associated dermatitis classification: IAD was classified in 2011 according the Skin Assessment Tool (Kennedy & Lutz, 1996). This tool was designed to provide a cumulative IAD severity score and was used for the research component of the project. In the 2012 and 2013 surveys no IAD severity instrument was used, IAD was reported as present or absent. The presence of superimposed fungal infection was not recorded in the 2012-2013 surveys.

Procedures

PI prevalence survey methodology used by Queensland Health for the surveys 2009-2013, was based on methodology developed by Prentice, Stacey and Lewin in 2003. IAD prevalence survey methodology followed best practice guidelines available at the time (Beeckman, Woodward, Rajpaul, & Vanderwee, 2011; Defloor et al., 2006; Junkin & Selekof, 2007; Prentice et al., 2003).

Prior to data collection for all surveys, surveyors (registered nurses, occupational therapists, physiotherapists and medical practitioners seconded from the facility) were trained in the use of the survey instruments, skin inspection procedures and assessment and classification of PIs. In the 2011-2013 surveys, surveyor education was expanded to include accurate differentiation between IAD, clinical presentation of fungal infections as well as identification and staging of PIs. Inter-

rater reliability was established at the conclusion of all education sessions by scores on written multiple-choice tests, and tests using clinical photographs. The surveys conducted between 2009-2010 included photographs of a variety PIs. The surveys conducted between 2011-2013, included clinical photographs of IAD, fungal infections as well as a variety of PIs. The tests required participants to accurately identify and stage PIs (for the tests conducted for the 2009-2010 surveys), and differentiate between IAD, clinical evidence of fungal infection and PI, as well as accurately stage PIs (for surveys conducted in 2011-2013). In all years, surveyors were required to achieve a score of 85% to participate in the survey. The use of photographs to test inter-rater reliability has been used previously (Beeckman, Schoonhoven, Boucque, Van Maele, & Defloor, 2008; Beeckman et al., 2007; Defloor & Schoonhoven, 2004).

The surveys were conducted over two days. Teams of two surveyors conducted skin inspections on all eligible, consenting patients. Any loss of skin integrity in the pelvic region was classified as either, IAD, PI or fungal infection. PI risk assessment, skin integrity documentation in medical records, the use of pressure redistributing equipment and demographic data were collected for all participants. In addition, in 2011 (as a component of the first author's research), data were collected on continence status, stool frequency and quality, and IAD severity. When patients were off the ward at the time of data collection, the surveyors returned later to include those patients where possible. To ensure accuracy, expert skin integrity nurses conducted independent skin inspections on the same day, on all patients reported by the surveyors to have a PI, IAD or clinical evidence of a fungal infection.

Results

Between 2009 and 2013, 2126 patients participated in the facility wide PI prevalence surveys (see Table 5.2). Overall, PI point prevalence decreased from 12.8% in September 2009 to 6.3% in October 2013 (see Figure 5.1). Hospital-acquired PI point prevalence decreased from 12.7% in June 2010 to 4.0% in October 2013, with the community-acquired PI point prevalence ranging from 3% - 2.2% over the period (see Table 5.2 and Figure 5.1).

No IAD or incontinence data were recorded in 2009 and 2010. The research component of the project was conducted in 2011, with fewer patients consenting to participate in the research than participated in the PI prevalence survey. This explains

the difference in the denominator between the IAD data (*N* = 376) and the PI data (*N* = 459) for 2011 (see Table 2). In 2011, the prevalence of incontinence was 24% (*n*= 91) and the prevalence of IAD for the entire sample (*N* = 376) was 10% (*n* = 38),

Table 5.2

Pressure Injury Prevalence Survey Data Summary, 2009-2013

	September 2009 (*N* = 500) *n* (%)	June 2010 (*N* = 50) *n* (%)	November 2011 (*N* = 459) *n* (%)	November 2012 (*N* = 273) *n* (%)	October 2013 (*N* = 444) *n* (%)
One or more PIs	64 (12.8)	68 (15.1)	43 (9.4)	23 (8.4)	28 (6.3)
One or more hospital-acquired PIs	50 (10)	57 (12.7)	30 (6.5)	15 (5.5)	18 (4.0)
One or more community-acquired PIs	15 (3.0)	12 (2.6)	15 (3.3)	8 (2.9)	10 (2.2)

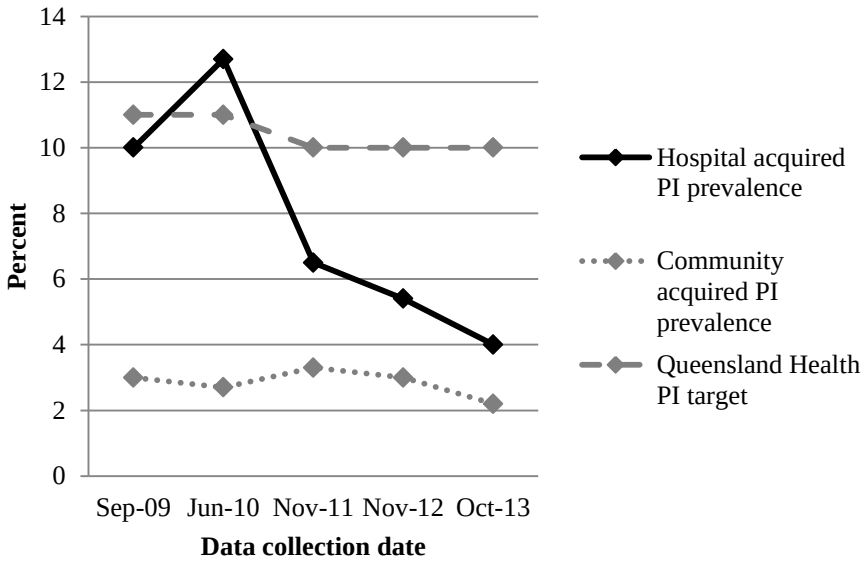


Figure 5.1 Pressure injury prevalence from September 2009 to October 2013

with the prevalence of IAD for incontinent patients (*n* =91) being 42% (*n* = 38), (Campbell et al., 2014). The prevalence of IAD (*N* = 273) in 2012 was 3.6% (*n* = 10) and in 2013 (*N* = 444), 2.7% (*n* =12).

Discussion

The requirement for accurate, valid and reliable skin integrity prevalence data within the acute care setting is essential for understanding the scope of a problem (Coggon, Barker, & Rose, 2003), for evaluation of skin injury prevention protocols, and increasingly prevalence data is being used as an indicator of quality care (Baharestani et al., 2009). The survey data demonstrate a sustained decrease in PI prevalence from the 2010 survey through to 2013 inclusive of the 2011survey, where the PI and IAD prevalence surveys were combined into a single procedure. The facility PI prevalence is consistent with national and international downward trends, including hospital acquired PI prevalence (Miles et al.2013; Mulligan et al., 2011; Stotts, Brown, Donaldson, Aydin, & Fridman, 2013; Vanderwee, Clark, Dealey, Gunningberg, & Defloor, 2007; Vanderwee et al., 2011; Vangilder et al., 2009; Victorian Quality Council, 2008). Survey data also demonstrated a sustained decrease in IAD prevalence. The downward PI prevalence trend from 2011 may be explained in part by improved differentiation of PI and IAD as a result of more comprehensive surveyor education, which may ultimately improve prevalence data accuracy, and result in lower PI prevalence. However, the effect of the combined survey protocols on PI prevalence cannot be quantified. Other factors that may have contributed to the downward PI prevalence trend during that period include, ongoing clinician PI education programs, ongoing utilisation of PI prevention champions in clinical areas, and the introduction of a system whereby financial penalty was applied to Queensland hospitals by the Queensland Department of Health if a patient developed a preventable stage III or IV hospital acquired PI (Queensland Government, 2013). Improved surveyor education, effective collection of data without the need to increase personnel, material or financial resources and importantly no increased survey participation burden experienced by patients demonstrated the utility of combining PI and IAD surveys.

Overall, the unique surveys provided important data on both PI and IAD prevalence. Subsequently, key aspects of the combined protocol, that is, improved surveyor education and recording the presence of IAD as a component of data collection was adopted as standard practice for ongoing PI prevalence surveys within the facility.

PI and IAD prevalence

The sustained decrease in the facility's PI prevalence demonstrated in the surveys is consistent with downward national and international PI prevalence trends. Wound prevalence surveys conducted in Western Australian public hospitals between 2007-2011 (Mulligan et al., 2011), found PI prevalence ranged between 12% - 9%, with hospital acquired PI prevalence ranging between 7% - 9%. In Victoria, Australia, state-wide PI prevalence surveys conducted in 2003, 2004 and 2006 found the prevalence of PIs ranged between 26%-18% respectively, with approximately two thirds of PIs sustained in hospital in all three surveys (Victorian Quality Council, 2008). Surveys conducted at a metropolitan hospital in Queensland (Miles et al., 2013) reported hospital acquired PI prevalence rates ranging from 8% in 2009, 4% in 2012, with overall PI prevalence ranging from 12 % in 2009 to 6% in 2012.

Internationally, a large American study, conducted over eight years (Stotts et. al., 2013) reported PI prevalence data from 78 acute care hospitals (nearly 260 000 patients). This study found the hospital acquired PI rate decreased from 10% in 2003 to 2% in 2010. Another large study (Vangilder et al., 2009) in the United States found PI prevalence in acute care hospitals in 2008 -2009 to be 13% and 12% respectively, with the hospital acquired prevalence being 6% and 5% respectively. A Belgian study (Vanderwee et al., 2011), found a PI prevalence of 12% in 143 hospitals. Consistent with the national and international downward PI prevalence trends, the facility data demonstrates continuing reductions in PI and hospital acquired PI prevalence.

It can be speculated that a portion of the PI prevalence reduction between 2011 and 2013 may be attributed to improved surveyor accuracy regarding differentiation of PIs and IAD as a result of the more comprehensive surveyor education provided prior to participation in these surveys. Traditionally, PI surveys focused on establishing inter-rater reliability with regard to accurate identification and staging of PIs only. While difficulty with differentiating PI and IAD is recognised (Beeckman et al., 2008; Beeckman et al., 2007; Defloor & Schoonhoven, 2004), the impact of misclassified lesions on PI prevalence data has not been reported in the literature, nor quantified in the facility.

The majority of published IAD data comes from the aged care or critical care environment. The IAD prevalence in critical care is reported to be 36% (Bliss et al., 2011), with the prevalence of IAD ranging between 6% and 22% in aged care (Beeckman et al., 2010; Bliss, Savik, Harms, Fan, & Wyman, 2006). The 2011 IAD survey (see Campbell et al., 2014) found that 24% of participants were incontinent and of those who were incontinent, 42% had IAD (Campbell et al., 2014). A 2007 study conducted in the acute care setting in the United States reported the prevalence of incontinence to be 19%, with IAD present in 20% of those who were incontinent. IAD trend data is not available nationally or internationally to enable comparison with the facility IAD data. The facility downward IAD prevalence trend between 2011-2013 may be due to the comprehensive surveyor education requiring accuracy in differentiation between PI, IAD and fungal infections as well as facility wide ongoing education for clinicians regarding IAD. Similar to PI prevalence data, prospective IAD data is necessary for benchmarking and tracking quality care over time.

Drivers for combining surveys

The impetus for combining the PI and IAD prevalence surveys into a single procedure in 2011 was based on the facility's need to understand the prevalence of incontinence and IAD in its population. Parallels between PI and IAD survey procedures such as common patient populations, the requirement for comparable surveyor education, establishment of inter-rater reliability, and the requirement for participants to undergo a pelvic skin inspection (Arnold-Long, Reed, Dunning, & Ying, 2011; Campbell et al., 2014; Junkin & Selekof, 2007; National Pressure Ulcer Advisory et al., 2014), meant that combining the survey protocols was straightforward. In addition, the practical and logistical requirements for an IAD prevalence survey are almost identical to the requirements for the routine PI survey conducted each year in the facility.

It is accepted that direct skin inspection is the gold standard for obtaining PI prevalence data, with the caveat that surveyors have adequate skill in classifying PIs and differentiating them from other lesions such as IAD (Baharestani et al., 2009; Black & Langemo, 2012; Defloor et al., 2005). The rationale for the recommendation of skin inspection as the primary data source is based on the understanding that documentation in regard to PI is often inadequate (Baharestani et al., 2009a). It

would therefore be consistent then, that data obtained from direct skin inspection would also be the gold standard practice for IAD prevalence survey methodology. In light of the fact that a thorough pelvic skin inspection is required for both PI and IAD prevalence data collection, combining the survey protocols does not result in any further survey participation burden for the patient.

It is well recognised that clinicians face difficulties when differentiating between PIs and IAD (Defloor et al., 2006; Mahoney et al., 2011). These lesions have different aetiologies and as such require different prevention and management strategies. Subsequently, misclassification can have a significant impact on patient outcomes, data accuracy, benchmarking, and resource allocation (Beeckman et al., 2015; Defloor et al., 2006; Mahoney et al., 2011; Voegeli, 2011). In 2007, the NPUAP (Black et al., 2007) issued a statement with the description of stage II PI, stating that this category should not be used to describe 'skin tears, tape burns, perineal dermatitis, maceration or excoriation' (p. 40). This raised awareness of the fact that until that time most superficial pelvic lesions were classified as a stage II PI (Doughty, 2012). In Queensland, a funding penalty is applied by the Queensland Department of Health to a hospital, if a patient develops a stage III or IV hospital-acquired pressure injury. This disincentive means that a stage III hospital-acquired PI will incur a funding penalty for the care provider of $30,000, and a stage IV hospital-acquired PI will incur a funding penalty of $50,000 (Queensland Government, 2013). Accordingly, a misclassified pelvic lesion (for example IAD erroneously classified as a stage III PI) has the potential to attract a penalty of $30,000 for the healthcare provider. Accurate differentiation of PIs and IAD is therefore of utmost importance for patients and healthcare providers alike.

The utility of combining the PI and IAD surveys was persuasive. The combined survey utilised the same number of surveyors and support staff, meaning no increase in personnel or financial resources was necessary. In addition, the data collection was completed in the same time as the previous annual PI surveys that is, over two days. Therefore, combining the PI and IAD protocols maximised value from the costly and resource intensive annual PI prevalence survey. While a cost-effectiveness analysis was not undertaken in the 2011-2013 surveys, any minor cost increase as a result of extra time taken recording IAD data would have been offset by the benefits of having access to the additional data. An additional positive outcome is

that anecdotally, IAD awareness is improved for staff that participate as surveyors, and subsequently champion IAD awareness in their respective clinical areas. Extra time was required to develop resources for the combined survey including educational materials and data extraction forms. However, this was seamlessly integrated into the routine planning for the annual PI prevalence survey. As a result, valuable data regarding the burden of IAD and incontinence became available to the facility enabling comprehensive understanding of the burden of these conditions.

Prevalence studies are difficult and costly to perform, and require a significant number of adequately trained personnel. In view of the high cost of conducting these studies, and the financial and clinical imperative that resultant data are accurate, it is logical to combine the PI and IAD surveys into a single protocol. Further, documenting and reporting of these valuable metrics is crucial given the appreciation of the association between incontinence and IAD as risk factors for PI development. Utilising protocols that aid in the understanding of the burden of incontinence and IAD in patients vulnerable to PI is surely the next logical step in quality improvement.

Limitations

As discussed, no international agreement exists as to an IAD prevalence survey methodology, or methodology combining PI and IAD surveys, which leads to study limitations. An IAD severity instrument was not utilised for the 2012 and 2013 surveys, rather, the presence or absence of IAD was reported. PI data were reported in all surveys by stage and location as collective totals. Therefore, it was not possible to report the prevalence of stage 1 or II pelvic PIs, or to investigate the prevalence of these PIs when IAD was included in data collection. An appreciation of incontinence is essential for the understanding of the epidemiology of IAD. The 2012 and 2013 surveys did not collect incontinence data; therefore IAD is reported as a percentage of the entire sample rather than a percentage of incontinent participants. Opportunities exist to improve collection and reporting of survey data, as well as reaching agreement in regards to survey protocols, particularly formulae for calculating the prevalence of IAD.

Conclusion

This paper has proposed a unique protocol for conducting combined pressure injury and incontinence-associated dermatitis prevalence surveys. The data from the

combined surveys reveals downward trends in both PI and IAD prevalence. In addition, the combined protocol has been shown to be effective, practicable and achievable, without incurring additional costs to the facility, or placing additional burdens on patients to participate. The resultant IAD data is the first of its kind in Australia, and provides previously unknown IAD trend data for the acute care setting.

PIs and IAD are both largely preventable skin injuries. During the last decade, there is a wider appreciation of the potentially serious complications of IAD, particularly IAD as a risk factor for superficial PI (Gefen, 2014).Therefore from a patient safety perspective, understanding the prevalence of IAD and incontinence constitutes a vital component of maintaining skin integrity (Campbell et al., 2015). Prevalence studies are difficult and costly to perform and require a significant number of adequately trained personnel. In view of the financial burden to the facility in conducting these studies, and the financial as well as clinical imperative that resultant data are accurate, combining PI and IAD surveys into a single protocol has multiple benefits. While this research could not quantify the extent of the influence of the combined protocol on PI prevalence data a sustained downward trend in PI prevalence was demonstrated. It is feasible therefore, to attribute a portion of the reduction in PI prevalence to improved accuracy in the classification of pelvic lesions. Recommendations for future surveys include determining agreement as to the definition of incontinence for IAD surveys, agreement as to the minimum data set required for a combined PI and IAD survey protocol, formulae for calculating and reporting IAD prevalence and finally, agreement as to an IAD severity classification instrument. Further research is required to evaluate PI and IAD prevention programs within the facility. In the future, PI prevalence surveys may evolve into broader, comprehensive skin integrity prevalence surveys, providing a rich source of data that will ultimately inform and guide skin integrity care and outcomes in acute care patients.

References

Amlung, S., Miller, W., & Bosley, L. (2001). The 1999 National Pressure Ulcer Prevalence Survey: A benchmarking approach. *Advances in Skin & Wound Care, 14*(6 297-301.

Antonio, T., & Conrad, K. (2013). Clinical and economic improvements in pressure injury care at Ballarat Health Services. *Wound Practice and Research 21*(1); 4-10

Arnold-Long, M., Reed, L., Dunning, K., & Ying, J. (2011). Incontinence- associated dermatitis in a long-term acute care facility: Findings from a 12 week prospective study. *Journal of Wound Ostomy & Continence Nursing, 38*(3S), S7-S7.

Australian Wound Management Association. (2012). *Pan Pacific clinical practice guideline for the prevention and management of pressure injury*. Cambridge Publishing, Osborne Park, Western Australia.

Baharestani, M., Black, J., Carville, K., Clark, M., Cuddigan, J., Dealey, C., . . . & Sanada, H. (2009a). Dilemmas in measuring and using pressure ulcer prevalence and incidence: An international consensus. *International Wound Journal, 6*(2), 97-104.

Baumgarten, M. (1998). Methodology. Designing prevalence and incidence studies. *Advances in Wound Care, 11*(6), 287-293.

Beeckman, D. (2016) A decade of research on incontinence-associated dermatitis (IAD): Evidence, knowledge gaps and next steps. *Journal of Tissue Viability*. doi:http://dx.doi.org/10.1016/j.jtv.2016.02.004

Beeckman, D., Campbell, J., Campbell, K., Chimentao, D., Coyer, F., Domansky, R., … & Wang, L. (2015). Proceedings of the Global IAD Expert Panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International*. Retrieved fromhttp://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf

Beeckman, D., Schoonhoven, L., Boucque, H., Van Maele, G., & Defloor, T. (2008). Pressure ulcers: e-learning to improve classification by nurses and nursing students. *Journal of Clinical Nursing, 17*(13), 1697-

Beeckman, D., Schoonhoven, L., Fletcher, J., Furtado, K., Gunningberg, L., Heyman, H., . . . & Defloor, T. (2007). EPUAP classification system for pressure ulcers: European reliability study. *Journal of Advanced Nursing, 60*(6), 682-691.

Beeckman, D., Vanderwee, K., Demarre, L., Paquay, L., Van Hecke, A., & Defloor, T. (2010). Pressure ulcer prevention: Development and psychometric validation of a knowledge assessment instrument. *International Journal of Nursing Studies, 47*(4), 399-410.

Beeckman, D., Woodward, S., Rajpaul, K., & Vanderwee, K. (2011). Clinical challenges of preventing incontinence-associated dermatitis. *British Journal of Nursing 20*(13), 784-790.

Black, J., Baharestani, M., Cuddigan, J., Dorner, B., Edsberg, L., Langemo, D., . . . & Taler, G. (2007). National Pressure Ulcer Advisory Panel's updated pressure ulcer staging system. *Advances in Skin & Wound Care, 20*(5), 269-274.

Black J., & Langemo D (2012). Chapter 2, Pressure ulcer staging/categorisation. In Pieper B (Ed.), *National Pressure Ulcer Advisory Panel. Pressure ulcers: Prevalence, incidence, and implications for the future* (pp. 5-8), Washington DC: NPUAP

Bliss, D., Savik, K., Harms, S., Fan, Q., & Wyman, J. (2006). Prevalence and correlates of perineal dermatitis in nursing home residents. *Nursing Research, 55*(4), 243-251.

Bliss, D., Savik, K., Thorson, M., Ehman, S., Lebak, K., & Beilman, G. (2011). Incontinence-associated dermatitis in critically ill adults: Time to development, severity, and risk factors. *Journal of Wound Ostomy & Continence Nursing 38*(4), 433-445.

Borchert, K., Bliss, D. Z., Savik, K., & Radosevich, D. M. (2010). The incontinence-associated dermatitis and its severity instrument: Development and validation. *Journal of Wound Ostomy & Continence Nursing, 37*(5), 527-535.

Campbell, J., Coyer, F., & Osborne, S. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting. *International Wound Journal*. doi:1111/iwj.12322

Campbell, J., Coyer, F., & Osborne, S. (2015). The Skin Safety Model: Reconceptualizing skin vulnerability in older patients. *Journal of Nursing Scholarship,48*(1), 14-22.

Defloor, T., Clark, M., Witherow, A., Colin, D., Lindholm, C., Schoonhoven, L., & Moore, Z. (2005). EPUAP statement on prevalence and incidence monitoring of pressure ulcer occurrence in 2005. *European Pressure Ulcer Advisory Panel, 6*(3), 74-80.

Defloor, T., & Schoonhoven, L. (2004). Inter-rater reliability of the EPUAP pressure ulcer classification system using photographs. *Journal of Clinical Nursing,13*(8), 952-959.

Defloor, T., Schoonhoven, L., Vanderwee, K.,Weststrate, J., & Myny, D. (2006). Reliability of the European Pressure Ulcer Advisory Panel classification system. *Journal of Advanced Nursing, 54*(2), 189-198.

Department of Health, Q. G. (2013). *Health funding principles and guidelines 2013-14*. Retrieved from https://publications.qld.gov.au/.../health-fund-pples-n-guidelines-13-14.pdf

Doughty, D. (2012). Differential assessment of trunk wounds: Pressure ulceration versus incontinence-associated dermatitis versus intertriginous dermatitis. *Ostomy & Wound Management, 58*(4), 20.

Doughty, D., Junkin, J., Kurz, P., Selekof, J., Gray, M., Fader, M., . . . & Logan, S. (2012). Incontinence-associated dermatitis: Consensus statements, evidence-based guidelines for prevention and treatment, and current challenges. *Journal of Wound Ostomy & Continence Nursing, 39*(3), 303-315.

Ersser, S., Getliffe, K., D.Voegeli, D., & Regan, S. (2005). A critical review of the inter-relationship between skin vulnerability and urinary incontinence and related nursing intervention. *International Journal of Nursing Studies, 42*(7), 823-835.

Furlanetto, K., & Emond, K. (2014). 'Will I come home incontinent?' A retrospective file review: Incidence of development of incontinence and correlation with length of stay in acute settings for people with dementia or cognitive impairment aged 65 years and over. *Collegian*. *23*(1), 79-86.

Gefen, A. (2014). From incontinence associated dermatitis to pressure ulcers. *Journal of Wound Care, 23*(7), 345.

Gray, M., Black, J., Baharestani, M., Bliss, D., Colwell, J., Goldberg, M., . . . & Ratliff, C. (2011). Moisture-associated skin damage: overview and pathophysiology. *Journal of Wound Ostomy & Continence Nursing, 38*(3), 233-241.

Gray, M., Bliss, D., Doughty, D., Ermer-Seltun, J., Kennedy-Evans, K., & Palmer, M. (2007). Incontinence-associated dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 34*(1), 45-56.

Junkin, J. (2008). Incontinence-Associated Dermatitis Intervention Tool (IADIT). Retrieved from http://ltctoolkit.rnao.ca/sites/ltc/files/resources/continence/Continence_EducationResources/IADIT.pdf

Junkin, J., & Selekof, J. (2007). Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of Wound Ostomy & Continence Nursing, 34*(3), 260-269

Junkin, J., & Selekof, J. (2008). Beyond 'diaper rash': Incontinence-associated dermatitis: Does it have you seeing red? *Nursing, 38*(11 Suppl), 56hn51.

Kennedy, K., & Lutz, L. (October 4 1996). *Comparison of the efficacy and cost-effectiveness of three skin protectants in the management of incontinent dermatitis.* Paper presented at the Proceedings of the European Conference on Advances in Wound Management. Amsterdam, Netherlands.

Mahoney, M., Rozenboom, B., Doughty, D., & Smith, H. (2011). Issues related to accurate classification of buttocks wounds. *Journal of Wound Ostomy & Continence Nursing, 38*(6), 635-642.

Miles, S., Fulbrook, P., Nowicki, T., & Franks, C. (2013) Decreasing pressure injury prevalence in an Australian general hospital: A 10-year review. *Wound Practice and Research, 21*(4), 148-156.

Mulligan, S., Prentice, J., & Scott, L. (2011). WoundsWest Wound prevalence survey 2011 State-wide overview report. *Ambulatory Care Services, Perth,*

Western Australia: Department of Health. Retrieved from https://www.whia.com.au/whwp/wp-content/uploads/2015/05/WWWPS2011-State-wide-Report-Overview-Final.pdf

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance. (2014). *Prevention and treatment of pressure ulcers: Clinical practice guideline* (E. Haesler Ed.). Perth, Australia: Cambridge Media.

National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. (2009). *Prevention and treatment of pressure ulcers: clinical practice guideline.* Washington DC: National Pressure Ulcer Advisory Panel.

Prentice, J., Stacey, M., & Lewin, G. (2003). An Australian model for conducting pressure ulcer prevalence surveys. *Primary Intention, 11* (2):87-88, 90-91, 93-96,98-100,102-109

Queensland Government. (2013). *Health funding principles and guidelines 2013-14.* Retrieved from https://publications.qld.gov.au/storage/f/2014-06-06T04:24:00.515Z/health-fund-pples-n-guidelines-13-14.pdf

Stotts, N. A., Brown, D. S., Donaldson, N. E., Aydin, C., & Fridman, M. (2013). Eliminating hospital-acquired pressure ulcers: within our reach. *Advances in Skin & Wound Care, 26*(1), 13-18.

Vanderwee, K., Clark, M., Dealey, C., Gunningberg, L., & Defloor, T. (2007). Pressure ulcer prevalence in Europe: A pilot study. *Journal of Evaluation in Clinical Practice, 13*(2), 227-235.

Vanderwee, K., Defloor, T., Beeckman, D., Demarre, L., Verhaeghe, S., Van Durme, T., & Gobert, M. (2011). Assessing the adequacy of pressure ulcer prevention in hospitals: A nationwide prevalence survey. *British Medical Journal Quality & Safety, 20*(3), 260-267.

Vangilder, C., Amlung, S., Harrison, P., & Meyer, S. (2009). Results of the 2008-2009 International Pressure Ulcer Prevalence Survey and a 3-year, acute care, unit-specific analysis. *Ostomy& Wound Management, 55*(11), 39-45.

Victorian Quality Council. (2008). Pressure ulcer point prevalence surveys (PUPPS): state-wide PUPPS 3 report 2006. Retrieved from https://www2.health.vic.gov.au/about/publications/researchandreports/pressure-ulcer-prevalence-survey

Voegeli, D. (2011). Pressure ulcer or moisture lesion - what's the difference? *Nursing & Residential Care, 13*(5), 222-227.

Voegeli, D. (2016). Incontinence-associated dermatitis: New insights into an old problem. *British Journal of Nursing, 25*(5), 256-262.

Vogt, W. P. (2005). *Dictionary of statistics & methodology: A nontechnical guide for the social sciences*. Thousand Oaks, Calif: SAGE Publications, Inc.

5.3 CHAPTER SUMMARY

The results of Study 1 raised some important issues for the research facility in terms of the appreciation of the growing complexity of ageing patients who have multiple skin injury vulnerabilities. Traditional silo driven skin integrity care can result in an under-estimation of both the extent of skin integrity risks, and the extent of patients suffering a range of skin injuries within the facility.

Consensus is required on several aspects of the combined prevalence survey methodology, including testing of the IAD severity categorisation instrument published by Beeckman et al. (2015), formulae for calculating IAD prevalence, and also, agreement on the format for the reporting of IAD prevalence data. However, this review has taken the first step in evaluating the effect that the combined IAD and PI surveys have on resultant PI prevalence data, as well as reviewing the utility of conducting combined PI and IAD prevalence surveys. While further research is warranted regarding consensus for the combined methodology, the success of the combined protocol presented in this publication provides a sound basis for continuing with the combined survey protocol. This publication represents an immediate and significant outcome of this research program, by way of improving the validity and reliability of the PI data, as well as presenting a survey protocol that provides access to IAD and incontinence data, which was not previously available to the facility.

Following the combined PI and IAD prevalence study, the research facility adopted (following some minor adaptations) the survey procedures as part of the protocol for annual PI prevalence surveys. Further, in Queensland annual state-wide PI prevalence surveys are conducted by the Patient Safety and Quality Improvement Service Clinical Excellence Division and are known as the Queensland Bedside Audit (QBA). This group determines the minimum data set to be collected, preparation and distribution of educational materials, inter-rater reliability testing procedures, as well as data analyses and preparation of state-wide PI prevalence reports. From 2012, as a result of the combined IAD and pressure injury prevalence survey protocol adopted in the research facility, QBA developed and distributed new surveyor educational resources to facilitate improved inter-rater reliability for the state-wide PI surveys. In addition, the QBA data survey instrument was amended to include a category noting the presence of IAD (J. Whitmore, personal

communication, November 18, 2015). These procedural changes adopted by the research facility, and then by the Queensland Patient Safety and Quality Improvement Service represent the immediate and significant impacts of this research program.

The following chapter presents the methods for Study 2 of this thesis which continues the exploration of the phenomenon of IAD in the acute care setting by investigating the role of *Candida albicans* colonisation in the aetiology of IAD.

Chapter 6: METHODS

6.1 INTRODUCTION

This chapter describes the research design, study participants, rationale and justification for the selection and use of the study instruments, study procedure, timeline, data analyses, ethical considerations and study limitations adopted to achieve the aims and objectives of Study 2.

6.2 BACKGROUND

Study 1 of this research program revealed that almost one quarter of patients were incontinent, with a high prevalence (42%) of IAD among incontinent patients. These results demonstrate the considerable extent of both conditions in the acute care setting. In addition, Study 1 found that nearly one third of patients with IAD had clinical evidence of *Candida* infection.

A reported complication of IAD is *Candida* infection (Beeckman et al., 2015; Farage, Miller, Berardesca, et al., 2007; Gray et al., 2007; D.Voegeli, 2013). The diagnosis of *Candida* infection, however, is predominantly informed by a presumptive diagnosis based on the clinical presentation of the perineal skin. It is known that *Candida* spp. are the most common fungal human commensal organisms, with colonisation being a necessary antecedent to infection (Kumamoto, 2011; Moran et al., 2012; Odds et al., 2006). *Candida* colonisation is common in the gastrointestinal and genito-urinary systems, with faecal *Candida* colonisation equivalent to rectal colonisation levels (Odds, 1988). Furthermore, incontinence and the subsequent use of occlusive incontinence containment aids increases skin moisture, temperature, and skin pH, which in turn fosters ideal conditions for proliferation of certain skin microorganisms, particularly *Candida* spp (Ali & Yosipovitch, 2013; Aly et al., 1978; Baroni et al., 2012; Fidel, 1999; Honig, 1983; Tsai & Maibach, 1999; Zhai & Maibach, 2002).

In addition, it has been reported that certain factors predispose to *Candida* infection for example, age, gender, treatment with antibiotics, or the presence of diabetes. It is uncertain whether these factors influence *Candida* colonisation in acute care incontinent patients or those with IAD.

It is not clear whether there is an association between incontinence and *Candida* colonisation, that is, whether skin contact with urine and faeces, combined with the local skin environment resulting from wearing an incontinent pad influences the level of *Candida* colonisation. Alternatively, it is unclear if incontinence acts as a trigger for *Candida* to transform from commensal to pathogen, resulting in skin infection, specifically in incontinent patients or those with IAD, or those already colonised with *Candida.* Moreover, it is unclear if there are there factors that constitute risk factors for *Candida* colonisation in this sample.

There is a paucity of data that identifies *Candida* colonisation in incontinent compared to continent acute care patients, as well as those with IAD. The purpose of Study 2 was to compare the prevalence of *Candida* colonisation at the perianal and inguinal sites between continent compared to incontinent patients, as well as those with IAD, and to identify risk factors for *Candida* colonisation in these patients.

6.3 RESEARCH QUESTIONS

The primary research questions guiding this study were:

4. Is colonisation with *Candida albicans* more common at hospital admission in incontinent patients compared with continent patients?
5. In incontinent patients (urinary or urinary and faecal), is there an association between *Candida albicans* colonisation and the clinical presentation of IAD on admission to hospital.

The secondary research question was:

6. In acute care medical patients, are gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or body mass index (BMI) risk factors for *Candida* colonisation?

6.4 METHOD

6.4.1 Design

The research aims and questions in this study were best addressed using the empiricist paradigm, utilising a quantitative methodology. In many instances, it is not possible or ethical to manipulate the independent variable, thus, non-experimental

study designs must be used (Coggon, Barker & Rose, 2003). These designs are used to answer questions about groups, differences in one group or differences between more than one group (Coggon, Barker & Rose, 2003).

This study utilised cross-sectional, observational methods. Observational studies collect, record, and analyse data without any control of the exposure status or study conditions; the researcher simply compares existing groups (Oleckno, 2008). In this study method, there is no manipulation of the independent (or explanatory) variable; therefore, a causal relationship cannot be established. However, this study method can yield important information about the relationship between the variables of interest (Oleckno, 2008).

Further, in view of the scant data identifying *Candida* colonisation in this patient group, the present study was conducted as a pilot study. A pilot study is utilised to test methods and procedures to be used on a larger scale (Arain, Campbell, Cooper & Lancaster, 2010; Leon, Davis & Kraemer, 2010; Thabane et al., 2010) with respect to aspects of the research, such as recruitment, assessment procedures, and data collection tools. Alternatively, the pilot study may show that the proposed relationship between variables does not exist (Arain et al., 2010, Leon et al., 2010, Thabane et al., 2010).

6.4.2 Measurements

The data collection instrument was designed specifically for the study (see Appendix H). It included several instruments, including the Skin Assessment Tool (SAT) (Kennedy and Lutz, 1996) (see Appendix B), the Bristol Stool Form Chart (see Appendix G), the SGA (see Appendix H) and the mobility subscale of the Braden Scale for predicting pressure sore risk (see Appendix I).

Independent variables

The independent variables for this study were age, gender, length of hospital stay (LOHS), height and weight, primary admission diagnosis, co-morbid conditions regular medications, antibiotics, smoking status, continence status, stool frequency and quality, continence aid use, administration of enteral nutrition, nutrition and mobility status, and finally, presence and location of pressure injury.

These independent variables were measured as follows. Age was defined in years at the participants last birthday, with data extracted from the medical record.

Gender was defined as male or female. Length of hospital stay (LOHS) was recorded in days, with admission and discharge dates extracted from the medical record. Height and weight data were extracted from the medical record, which allowed for the calculation of BMI (height/weight^2 or kg/m2) The primary admission diagnosis and comorbid conditions were extracted from the medical record, and medication data, including antibiotics, route of antibiotic administration, excluding pro re nata (PRN) medication, were extracted from the medication chart. Smoking status was categorised as yes/no, as reported by the patient.

Continence status was categorised as continent, incontinent of urine only, incontinent of urine and faeces, indwelling urinary catheter in situ but continent of faeces, indwelling urinary catheter in situ, but incontinent of faeces. Continence status was determined as reported by the patient or bedside nurse, or extracted from the bedside medical record. The presence and type of a urinary or faecal stoma was recorded. Stool frequency was categorised as ≤ 1 per day, 2-3 per day, > than 3 per day, as reported by the patient or bedside nurse or extracted from the bedside medical records. Stool quality was categorised according to the Bristol Stool Form Scale, (Lewis & Heaton, 1997) (see Appendix D) and collapsed into the dichotomous categories of 'formed' or 'semi-formed/liquid'. This data was determined as reported by the patient or bedside nurse, or extracted from the medical record. Continence aid use was categorised as full brief or insert pad.

The administration of enteral nutrition was recorded as yes/no. Nutritional status was measured by administration of the Subjective Global Assessment (SGA) by the research nurse (Agarwal et al., 2012; Detsky et al., 1987) (see Appendix I), and categorised as SGA-A, SGA-B, and SGA-C. Mobility status was categorised as immobile, very limited, slightly limited, or limitation. The mobility subscale from the Braden Scale for predicting pressure sore risk (Benoit & Mion, 2012) was used to assess mobility (see Appendix J) (Benoit & Mion, 2012; Bergstrom, Braden, Laguzza, & Holman, 1987).

The presence of a PI was categorised as yes/no. If a PI was present, it was categorised according to the National Pressure Ulcer Advisory Panel pressure ulcer classification system of stage I - stage IV, unstageable or deep tissue injury (National Pressure Ulcer Advisory et al., 2014). The location of a PI was recorded as sacrum/coccyx, ischial tuberosity, or greater trochanter/hip.

Dependent Variables

The dependent variables were the presence of IAD, IAD severity, and semi-quantitative results of the microbiological cultures for *Candida albicans* or *Candida* spp.

These dependent variables were measured as follows. The presence of IAD was determined following a pelvic skin inspection and categorised as yes/no. IAD was deemed to be present if any skin redness was detected, with or without erosion. IAD severity was categorised according to the SAT (Kennedy & Lutz, 1996, used with permission, see Appendices A and B) in the categories of skin redness, area of skin breakdown, erosion, and region affected. Clinical evidence of fungal infection was derived from the skin inspection and categorised as yes/no. Semi-quantitative results of the microbiological cultures for *Candida albicans* or *Candida* spp. were reported as scant, 1+, 2+ or 3+ and recorded on the study instrument for each patient.

6.4.3 Instruments

The Skin Assessment Tool

The SAT (Kennedy and Lutz, 1996) was included as a component of the overall instrument to assess IAD severity, used with permission (see Appendices A & B). The SAT derives a cumulative IAD severity score, with a numerical score assigned according to severity within each of three categories: skin redness, area of skin breakdown (cm^2); and erosion. A cumulative severity score (maximum score = 10) is generated by adding scores in each category. A higher score indicates more severe IAD (Gray, 2007). The SAT was used by Beeckman and colleagues (2010) in a randomised controlled trial to investigate the effect of a specialised cloth compared to standard care in the prevention of IAD. The overall inter-observer reliability regarding skin observation using the SAT was κ =0.81 (95% CI, 0.69 - 0.87) (Beeckman et al., 2010). The SAT was also used in study one of this research program. Word descriptors were assigned in study one to correspond with IAD severity categories (that is, mild, moderate, severe, or extreme) in the SAT (Campbell et al., 2014) (see Chapter 4, *Measures*)

Stool Quality Assessment

This study collected data on stool form based on the Bristol Stool Form Scale (see Appendix D). The Bristol Stool Form Scale was devised as a means to describe

stool consistency in seven categories or types, ranging from Type 1-separate hard lumps, like nuts (hard to pass), to type 4-like a sausage or snake, smooth and soft, through to type 7-watery, no solid pieces, entirely liquid. Each category is accompanied by a representational diagram (Lewis & Heaton, 1997). Types 1 and 2 equate to constipation, types 3 and 4 equate to normal stool and types 5-7 equate to diarrhoea (Abrams et al., 2010). Stool quality was collected in dichotomous variables. Categories from the Bristol Stool Form Scale types 1 – 4 were collapsed to the formed category, and types 5-7 were collapsed to the semi-formed-liquid category for this study.

Subjective Global Assessment

The SGA is a commonly used malnutrition assessment tool (see Appendix I), although no gold standard exists (Steenson, Vivanti, & Isenring, 2013). This tool is valid and reliable and assesses nutritional status based on patient history and physical examination (Agarwal et al., 2012; Detsky et al., 1987). Patient history queries five categories, including weight change, dietary intake change (relative to normal), gastrointestinal symptoms, functional capacity, disease, and relation to nutritional intake (Detsky et al., 1987). The physical examination includes loss of subcutaneous fat (triceps, chest), muscle wasting (quadriceps, deltoids), ankle oedema, sacral oedema, and ascites. Each category is scored as either normal (0), mild (1+), moderate (2+), or severe (3+). Results of both of these assessments are combined to produce an overall global rating: well nourished (SGA-A), moderately malnourished or suspected of being malnourished (SGA-B), and severely malnourished (SGA-C) (Agarwal et al., 2012; Detsky et al., 1987).

A training session in use of the SGA was administered by a clinical dietitian and an assessment of several patients was then conducted together to ensure researcher competence with the use of the instrument.

Braden Scale for Predicting Pressure Sore Risk

The Braden Scale for Predicting Pressure Sore Risk (Benoit & Mion, 2012) is a validated tool widely used in a variety of healthcare settings (Kring, 2007). It contains six subscales, including mobility. The mobility categories are: completely immobile, very limited, slightly limited, and no limitations, with accompanying explanation for each category (Benoit & Mion, 2012). Convergent construct validity

has been reported for the mobility subscale of the instrument (Powers, Zentner, Nelson, & Bergstrom, 2004).

6.4.4 Sample size

There are no microbiological data reporting perianal and inguinal *Candida albicans* colonisation levels in the acute care patient population. Study 1 provided data on the prevalence of incontinence, IAD, and the presence of fungal infection (based on the clinical judgement of the research assistants). There was insufficient data available for a sample size calculation for this study, as computing a sample size would require guessing key equation elements, resulting in an invalid output.

It was anticipated that 80-85 patients would be recruited, with 27-28 patients in each group (that is, continent, incontinent of urine only, and incontinent of urine and/or faeces

Setting

This study was conducted in the Internal Medicine Service (IMS) wards of the Royal Brisbane and Women's Hospital (RBWH), Brisbane, Australia. Recruitment and enrolment took place between April and October 2014. The RBWH is a 929-bed, major teaching hospital in southeast Queensland, Australia, that provides care over a comprehensive range of specialities. It is the largest tertiary referral hospital in Queensland, providing care in 2012 to almost 94,000 inpatients, 520,000 outpatients and 72,000 emergency department presentations (Royal Brisbane and Women's Hospital Marketing and Communications, 2013a). The IMS has approximately 240 overnight beds and is comprised of over 16 specialty medical areas (Royal Brisbane and Women's Hospital Marketing and Communications, 2013a).

6.4.5 Participants

The study population was comprised of patients admitted to all acute care wards in the hospital's IMS who met the eligibility criteria over a consecutive seven-month period. The IMS comprised eight acute wards, with 174 patient beds, with average bed occupancy of 97%.

The findings of Study 1 informed the decision to select the IMS as the setting for Study 2, with the prevalence of incontinence (30%) and IAD (42% among incontinent patients) being higher in this admitting service than in the other admitting services.

Inclusion and Exclusion Criteria

The inclusion criteria were: consenting inpatients of the IMS wards aged 18 years and over; and expected admission time of three or more days.

The exclusion criteria were: expected short admission time, of less than three days, or where data could not be collected within 48 hours of admission; current treatment with systemic or topical antifungal agents; presence of a dermatological condition requiring topical or systemic treatment, which potentially disrupts the normal skin microbiota; current radiation treatment to the pelvic area; and pregnant or breastfeeding.

6.4.6 Procedure

The investigator approached the Executive Director (ED) and Director of Nursing (DON) of the IMS to negotiate access to the wards to collect the study data. Project implementation information sessions, written information, and posters were used to inform staff and patients about the study. The principal investigator was contactable to answer any questions of the staff or patients regarding the research.

The research nurses visited each medical ward from Monday to Friday, where the Nurse Manager or shift co-ordinator identified patients admitted within the last 48 hours. If the newly admitted patient met the study inclusion criteria (this was determined by the bedside nurse together with the research nurse) the patient was asked by the bedside nurse if they were willing to hear information about the study from the research nurse. The patient was then approached by a research nurse and invited to participate in the study. A written information sheet was provided and left with the patient or their representative to consider. Contact details of the researcher were available on the patient information form for any questions the patient may have had. Written consent was obtained from each participant or their substitute decision-maker (National Health Medical Research Council, 2000) (see Appendices K & L). The researchers liaised with the Nurse Manager or shift co-ordinator, as well as the bedside nurse to arrange a suitable time for screening. Every effort was made to align the data collection with routine care in an effort to minimise patient disruption. Data was collected within 48 hours of admission.

Skin Inspection

A skin inspection of the pelvic girdle (perianus, perineum, groins, buttocks labia/scrotum, and lower abdomen) was conducted to detect skin redness, skin erosion and severity, area and location of skin lesions, or the presence of fungal infection based on clinical appearance or the presence and category of pressure injuries. Findings of the skin inspection were recorded on the data collection instrument. The total time required for patients to participate in the study was 10-20 minutes. Patient dignity and privacy was maintained at all times.

Microbiological testing

Microbiological samples were collected from the perianal and inguinal sites of study participants. These anatomical regions were selected for microbiological sampling, as *Candida albicans* is known to be present in faeces and found as a commensal organism in the perianal region (Fidel, 1999). The moist environment of the inguinal region (particularly in the incontinent patients) also supports *Candida albicans* colonisation (Anaissie et al., 2003; Fidel, 1999).

Each patient had two microbiological specimens collected. A dry flocked swab (without transport medium) was pre-moistened in an ampoule of saline, with excess saline removed by pressing the swab to the side of the ampoule. The inguinal site was sampled rolling the swab from the proximal inguinal fold to a distance of approximately six centimetres. One swab was used for collection of both the right and left inguinal specimens. The perianal specimen was collected from the anal verge using a rolling action, with any faecal matter removed from the skin prior to specimen collection.

Pathology request forms were signed by the Director of Dermatology, RBWH. Specimens were transported to the laboratory as per the usual ward procedure. Specimens were cultured directly to Sabouraud's medium for yeasts and incubated at 37° Celsius (98.6° Fahrenheit) for 48-72 hours. Chloramphenicol and gentamycin were added to the medium to inhibit bacterial growth on the plate. A germ tube test was performed to identify *Candida albicans*. The specific ability of *Candida albicans* to form germ tubes or hyphal outgrowths from blastospores when incubated in serum for two hours at 37°C (98.6°F) is presumptive evidence of the organism, with the germ tube test being the traditional specific test for rapid identification of *Candida albicans* (Leyden & Kligman, 1978; Moran et al., 2012;

Odds, 1988). The results specified either *Candida albicans* or non-*albicans* species. The laboratory did not culture other organisms. The results of the microbiological cultures were reported by the laboratory as scant, 1+, 2+ or 3+.

The results of scant, 1+, 2+ and 3+ represent the density of *Candida albicans* present following specimen culture. The culture results should be considered in conjunction with a clinical assessment to diagnose the presence of a *Candida* infection (I. Robertson, personal communication, October 10, 2013). Results were entered into the hospital pathology reporting system, which enabled them to be accessed by the principal investigator.

6.4.7 Risk management

Incontinence skin care followed the standard protocol of the clinical area. This protocol included cleansing with a soft cloth and pH neutral soap-free cleanser or water, followed by application of skin barrier product containing either acrylate teropolymer, dimethicone, or zinc oxide. If a patient in the study developed IAD or *Candida* infection, they were managed according to hospital protocol and/or medical treatment orders.

Routine hospital reporting procedures were followed in the IMS for those patients identified with IAD or a *Candida albicans* infection. Record of enrolment into the study and microbiological sample collection was entered into the patient's chart. The bedside nurse and treating medical team were informed of any adverse findings.

6.4.8 Data management

Data were documented for each patient on a paper-based case report form, developed by the researcher. Data were de-identified for patient confidentiality by creating a master log of patients and unit record numbers, and assigning a sequential study number. The hospital number and ward were recorded. It was necessary to collect data in a potentially re-identifiable form to ensure microbiological data was recorded accurately for each participant. The identity of participants was not disclosed.

The master log was kept as a separate form in a separate location (electronic forms were password protected), thus ensuring the information on the data collection forms could not be linked to any specific patient (or hospital area). All data

collection forms and the master log were held by the principal investigator and did not include the patient name or bed number. At the completion of the data collection, the electronic master log identifying the observation form that corresponded with the patient record number was deleted. All data was consequently de-identified for both the investigators and supervisors.

6.4.9 Data analysis

All data were entered into the IBM SPSS Statistics for Windows (Version 22.0, Armonk, NY, USA). A random 10% of data were cross-checked for accuracy by the researcher. Incomplete data was coded as missing data. Descriptive statistics were used to describe sample characteristics (means and standard deviations for continuous variables; frequencies and percentages for categorical variables). Characteristics were compared between the three groups. Bivariate analyses using descriptive correlational statistics (χ^2 test for independence with Yates continuity correction and Fisher's exact test where expected cell counts were less than five for categorical variables, and one-way, between groups analysis of variance (ANOVA) with post-hoc analysis using the Tukey test for continuous variables). *Candida albicans* colonisation was compared between continent and incontinent participants, and between incontinent participants with and without IAD. The level of statistical significance was set at $p \leq 0.05$, to reduce the risk of Type I errors (Oleckno, 2008). Normality of the data distribution scores was tested using the Kolmogorov-Smirnov statistic.

6.4.10 Ethical considerations

Ethical approval for this study was granted by the RBWH Human Research Ethics Committee and the Queensland University of Technology. Human Research Ethics Committees (see Appendices M, N & O).

Informed consent

Participation in this study required written consent from the patient or their representative (National Health Medical Research Council, 2000) (See Appendices L, & M).

Written information was provided to each patient prior to obtaining consent. The principal investigator was available to answer any questions by the patient throughout the study. Patients or their representative were informed they were able to

withdraw from the study during or after data collection without comment, penalty or compromise to their current treatment

Patient dignity

Patient dignity and privacy was maintained at all times. Skin examination and specimen collection was conducted behind closed doors or drawn curtains. Negotiation with the patient and bedside nurse allowed for a suitable time for the skin inspection to be arranged. Every effort was made to integrate the skin examination and specimen collection with the routine care to minimise disruption. Any questions asked of patients were similar to those asked during routine patient care.

Confidentiality

A coding mechanism (previously detailed) ensured no individual could be identified. De-identified study participant forms were stored at the Queensland University of Technology, Royal Brisbane and Women's Hospital campus in a locked filing cabinet and locked office. Password control was used to access computer stored data and only the principal investigator had direct access to this information. The data enrolment log was shredded at the completion of the data collection.

6.5 CHAPTER SUMMARY

The conceptual framework presented in Chapter 2 and the results of Study 1 presented in Chapter 4 informed the development of Study 2. This chapter has presented the rationale for selection of the quantitative method for the study, while the study questions guided the study design. The study participants, study setting, procedure, and rationale for selecting the study instruments were explained. In addition, the study variables, statistical analysis, and ethical considerations were described for Study 2 of this research program. The following Chapters 7 and 8 present the results of the study, as well as Publications 4 and 5.

Chapter 7: *CANDIDA ALBICANS* COLONISATION, INCONTINENCE-ASSOCIATED DERMATITIS AND CONTINENCE STATUS IN THE ACUTE CARE SETTING: A PILOT STUDY

7.1 INTRODUCTION

This chapter comprises Study 2 and Publication 4 of this thesis.

The aim of this study was to compare *Candida* colonisation in incontinent and continent patients and those with IAD. In addition, this study aims to explore which variables in the Skin Safety Model (SSM) are supported by the findings of this study

This study addressed the following research questions

4. Is colonisation with *Candida albicans* more common at hospital admission in incontinent patients compared with continent patients?
5. In incontinent patients (urinary or urinary and faecal), is there an association between *Candida albicans* colonisation and clinical presentation of IAD at admission to hospital?

In view of the understanding of the role of endogenous *Candida* organisms in subsequent *Candida* infection, accurate data explaining the epidemiology of *Candida* colonisation that compares incontinent with continent patients, as well as those with IAD is likely to contribute to the understanding of IAD and incontinence-associated *Candida* infections

To date, the only data regarding the prevalence of *Candida albicans* infection related to IAD in the general adult acute care population are from Study 1 of this research program (Campbell et al., 2014), and a study conducted by Junkin and Selekof (2007). Data from both studies relied on the clinical judgement of research assistants who were specifically trained in study protocols to distinguish between different perineal lesions. However, it is unknown if there is agreement between clinical assessment and presumptive diagnosis and microbiologically proven

diagnosis of *Candida albicans* infections. There is limited quantitative evidence for the prevalence of *Candida albicans* colonisation or infection demonstrated by microbiological testing associated with either incontinence or IAD in the adult hospital population. A study in a long-term care facility of elderly inpatients with IAD found that 63% were colonised with *Candida* (Foureur et al., 2006). However, this study did not have a non-IAD comparison group.

Understanding the association between *Candida albicans* and IAD is important for several reasons. Firstly, baseline data are important to understand the potential pathogenic *Candida* reservoir in the adult inpatient population. Secondly, it is not known whether *Candida albicans* colonisation plays a role in the pathogenesis of IAD. Therefore, establishing baseline *Candida* colonisation data is a vital step in understanding the natural history of fungal infection related to IAD. Finally, IAD is a prevalent skin injury in incontinent individuals; therefore, understanding the pathogenesis of this condition is a critical component of the broader healthcare priority of maintaining skin integrity. Overall, *Candida* infection in patients with incontinence or IAD poses a serious threat to patient outcomes and merits further research.

The following manuscript represents Study 2 and Publication 4 of this thesis:

Campbell, J., Coyer, F., Mudge, A., Robertson, I., & Osborne, S. *Candida albicans* colonisation, incontinence-associated dermatitis and continence status in the acute care setting: A pilot study. This manuscript has been accepted for publication in the *International Wound Journal*.

7.2 PUBLICATION 4

Candida albicans Colonisation, Continence Status, and Incontinence-Associated Dermatitis in the Acute Care Setting: A Pilot Study

Abstract

Candida albicans is the most prevalent human fungal commensal organism, and is reported to be the most frequent aetiological organism responsible for infection associated with incontinence-associated dermatitis. However, it remains unclear whether incontinence predisposes a patient to increased *Candida* colonisation, or whether incontinence acts as a trigger for *Candida* infection in those already colonised. The purpose of this cross-sectional observational pilot study was to estimate colonisation rates of *Candida albicans* in continent compared to incontinent patients, and patients with incontinence-associated dermatitis. Data were collected on 81 inpatients of a major Australian hospital, and included a pelvic skin inspection and microbiological specimens to detect *Candida albicans* at hospital admission. The mean age of the sample was 76 years (*SD* = 12.22), with 53% being male. Incontinent participants (*n* = 53) had a non-significant trend towards greater *Candida* colonisation rates at the perianal site (43% versus 28%), $\chi^2(1, N = 81) = 4.453$, $p = .638$, and the inguinal site (24% versus 14%), $\chi^2(1, N = 81) = 6.868$, $p = .258$ than continent participants (*n* = 28), respectively. The incontinent subgroup with incontinence-associated dermatitis (*n* = 22) showed no significant difference in colonisation rates compared to those without incontinence–associated dermatitis $\chi^2(1, N = 53) = 000$, $p = 1.00$. Understanding the epidemiology of colonisation may have implications for prevention of *Candida* infection in these patients.

Key words: *Candida albicans*, colonisation, incontinence, incontinence-associated dermatitis, cross-sectional study

Key Messages

- This is the first study to provide data on the *Candida albicans* colonisation rates of continent compared to incontinent acute care patients and those with incontinence-associated dermatitis.
- On admission to hospital, there was a non-significant trend towards greater *Candida albicans* colonisation in incontinent compared to continent patients.
- Incontinence-associated dermatitis was common among incontinent patients.
- No significant association was found between *Candida* colonisation and clinical presentation of incontinence-associated dermatitis on admission to hospital.
- Accurate estimates of *Candida* colonisation in patients with incontinence-associated dermatitis, and continent compared to incontinent patients may contribute to understanding factors that regulate *Candida* colonisation and transformation to *Candida* infection in this group.

Introduction

Candida, a genus of yeasts, is the most common fungal commensal organism in humans, and is responsible for a wide range of mucosal and invasive diseases (Clancy & Nguyen, 2012; Fidel, 1999; Odds, 1988). Systemic infection by *Candida* (predominately *Candida albicans*) is the leading cause of nosocomial fungal bloodstream infection, with a mortality rate of 30%-40% (Clancy & Nguyen, 2012; Lionakis, 2014; Magill et al., 2014). *Candida albicans* is the most common fungal human mucosal coloniser, with oropharyngeal and vulvovaginal the most frequent *Candida* mucosal infection sites. These mucosal *Candida* infections are responsible for considerable morbidity, discomfort, and decreased quality of life for affected individuals (Revankar & Sobel, 2012). For example, 65% of denture wearers will experience *Candida*-associated denture stomatitis, while up to 75% of women will experience an episode of vulvovaginal *Candida* infection (Fidel, 1999; Revankar & Sobel, 2012).

Candida species (spp.) form part of the normal mucosal microflora and can colonise several anatomical sites, with the organism being present in the gastrointestinal and genito-urinary tracts of up to 80% of individuals (Moran et al., 2012), Under certain conditions, *Candida* can transform from an innocuous commensal organism to a harmful pathogen (Fidel, 1999). The primary source of both invasive and superficial *Candida* infection is endogenous, with colonisation being a necessary antecedent to infection (Kumamoto, 2011; Moran et al., 2012; Odds et al., 2006). The high frequency of occurrence, morbidity, and mortality associated with superficial and mucosal *Candida* infections, coupled with the ability of the organism to grow in a wide range of conditions means that *Candida* infections are important human diseases (Fidel, 1999; Moran et al., 2012).

In adults, *Candida* infections have been associated with a condition known as incontinence–associated dermatitis (IAD). (Beeckman et al., 2015; Black et al., 2011; Bliss & Powers, 2011; Gray et al., 2007). This is an irritant contact dermatitis that can occur as a consequence of skin exposure to urine and/ or faeces as a result of incontinence. IAD is characterised by inflammation and erythema, and may present with blisters, erosion, or serous exudate (Beeckman et al., 2015; Gray et al., 2007), is a painful, complex condition, and can result in increased morbidity and length of stay for hospital patients (Doughty et al., 2012; Gray et al., 2007). Commonly, IAD is complicated by a fungal infection, with *Candida albicans* being reported as the most frequent aetiological organism (Beeckman et al., 2015; Gray et al., 2007). *Candida* infections associated with incontinence or IAD can present clinically as either as a bright red maculopapular rash spreading from a central area, with characteristic satellite lesions at the margins of the rash extending into normal skin, or present with non-specific confluent papules, making clinical diagnosis difficult (Beeckman et al., 2015; Habif, 2015).

It has been reported that *Candida* infections play a central role in the pathogenesis of diaper dermatitis in infants (Bonifaz et al., 2013; Dixon, Warin, & English, 1969; Dorko et al., 2003; Ferrazzini et al., 2003; Jefferson, 1966; Leyden & Kligman, 1978; Montes, Pittillo, Hunt, Narkates, & Dillon, 1971). Several studies have shown significantly higher rates of *Candida* colonisation in oral, inguinal, and perianal sites in infants with diaper dermatitis than those without, with colonisation rates correlating with the severity of the diaper dermatitis (Ferrazzini et al., 2003;

Montes et al., 1971). Despite the reported frequency of *Candida* infections as a complication of adult IAD (Beeckman et al., 2015; Black et al., 2011; Bliss & Powers, 2011; Gray et al., 2007), the role of *Candida* colonisation or infection has not been widely considered in the pathogenesis of adult IAD. It remains unclear whether incontinence predisposes to increased *Candida* colonisation, or whether incontinence acts as a trigger for *Candida* to transform from commensal to pathogen in those already colonised. Furthermore, it is unclear whether *Candida* plays a role in the pathogenesis of IAD in incontinent individuals. Understanding the epidemiology incontinence-associated *Candida* infections requires accurate estimates of *Candida* of colonisation in continent compared to incontinent patients, as well as those with IAD. Knowledge of the epidemiology of *Candida* colonisation in these situations may guide assessment and prevention strategies for these patients.

Aims and research questions

The purpose of this study was to identify the rate of *Candida albicans* colonisation in incontinent patients compared to continent patients and those with IAD. The specific research questions were:

4. Is colonisation with *Candida albicans* more common at hospital admission in incontinent patients compared with continent patients?
5. In incontinent patients (urinary or urinary and faecal), is there an association between *Candida albicans* colonisation and clinical presentation of IAD at admission to hospital?

Methods

Study design

An observational cross-sectional study design was used.

Study setting and sample

This study was conducted in the Internal Medicine Service (IMS) wards at a 929-bed major acute care metropolitan teaching hospital in Australia. The facility provides a comprehensive range of specialities, delivering care in 2012 to almost 94,000 inpatients, 520,000 outpatients, with 72,000 emergency department presentations. The IMS has approximately 240 beds, and is comprised of over 16 specialty medical areas, including general medicine, cardiology, dermatology, endocrinology, infectious diseases, renal, rheumatology, and thoracic medicine.

This study used a purposive sample of participants in three groups; (1) continent; (2) incontinent of urine, but continent of faeces; (3) incontinent of both urine and faeces (double incontinence).

Inclusion and exclusion criteria

Hospitalised adults aged 18 years or older admitted consecutively to all wards in the IMS, with an expected hospital stay of three or more days, and where data could be collected within 48 hours of admission were eligible for inclusion in the study. Excluded patients were those who had current treatment with systemic or topical antifungal agents, a pre-existing skin condition, those receiving radiation treatment to the pelvic area, or those who were pregnant or breastfeeding.

Procedures

Patient recruitment and enrolment took place from April - October 2014. Prior to data collection, all research nurses (n = 3) were trained in the study procedures, use of the data collection instrument (see Appendix H), pelvic skin inspection, identification of IAD, clinical presentation of *Candida* infection, and pressure injuries, as well as the technique for the collection of the microbiological specimens. Research nurses screened and enrolled patients admitted consecutively to the IMS. The research nurses visited each medical ward Monday to Friday, where the Nurse Manager or shift co-ordinator identified patients admitted within the last 48 hours. If the newly admitted patient met the study inclusion criteria (this was determined by the bedside nurse together with the research nurse), the patient was asked by the bedside nurse if they were willing to receive information about the study from the research nurse. Written consent was obtained from each participant (see Appendices K & L). Data were collected from participants within 48 hours of admission, and extracted from medical records, with supplementary information sought from the patient and the bedside nurse, a pelvic skin inspection (perianus, perineum, groins, buttocks, labia/scrotum, and lower abdomen) was conducted, as well as collection of microbiological specimens.

Each patient had two microbiological specimens collected with a dry flocked swab (without transport medium), pre-moistened in an ampoule of saline (as per the laboratory protocol). The inguinal specimen was collected using one swab, and the perianal specimen was collected from the anal verge, with any faecal matter removed from the skin prior to specimen collection.

Specimens were cultured directly to Sabouraud's medium for yeasts and incubated at 37° Celsius (98.6° Fahrenheit) for 48-72 hours. Chloramphenicol and gentamycin were added to the culture medium to inhibit bacterial growth on the plate. *Candida albicans* was identified by performing a germ tube test. The ability to form germ tubes after incubation in serum for two hours at 37°C (98.6° Fahrenheit) is presumptive evidence of *Candida albicans* (Leyden & Kligman, 1978; Moran et al., 2012). The laboratory reports specified either *Candida albicans* or non-*Candida albicans* spp. Semi-quantitative results were reported as scant, 1+, 2+, and 3+. The laboratory did not culture for other pathogens. Results were entered into the facility pathology reporting system. Routine hospital reporting procedures were followed for those patients identified with IAD, *Candida* infection, or any adverse findings.

Measures

Candida colonisation: In this study, the presence of any *Candida albicans* or *Candida* spp. at either the perianal or inguinal sites was classified as colonised (Fidel, 1999; Jarvis, 1996; Sobel et al., 1998).

Incontinence: Incontinence is the primary risk factor for the development of IAD (Beeckman et al., 2015; Gray et al., 2007). It is defined as the inability to control the flow of urine and or faeces at any time in the previous 24 hours (Junkin & Selekof, 2007). In this study, patients with an indwelling urinary catheter were deemed continent for the purpose of data analysis. The presence of an indwelling catheter negates the irritant effects of urine on the skin. This categorisation is consistent with previous studies (Campbell et al. ,2014; Halfens et al., 2013; Junkin & Selekof, 2007). Patients were recruited according to continence status, that is, continent, incontinent of urine only, or incontinent of both urine and faeces (double incontinence). Continence status was determined by a combination of patient self-report, clinical documentation, and communication with the bedside nurse.

Incontinence-associated dermatitis (IAD): IAD is defined as the presence of any skin redness and/or erosion caused by skin contact with urine and/or faeces (rather than other sources of moisture) on the buttocks, coccyx, rectal area, labia, scrotum, lower abdomen, upper thighs, gluteal cleft, or groins in an incontinent patient (Beeckman et al., 2015). IAD severity was determined using the skin assessment tool (SAT) (Kennedy & Lutz, 1996) (used with permission, see Appendices A & B). The SAT derives a severity score (maximum score = 10), by

adding scores within categories of skin redness, area of skin breakdown (cm^2), and erosion. Word descriptors were designated to match IAD severity categories (Campbell et al., 2014).

Clinical presentation of a *Candida* infection: Clinical presentation of *Candida* infection was determined by a physical assessment conducted by the research nurse. *Candida* infections associated with incontinence or IAD commonly present as a central maculopapular rash with characteristic satellite lesions at the margins of the rash extending into normal skin. These rashes may also present as non-specific confluent papules in patients with IAD (Beeckman et al., 2015; Habif, 2015). In darker skin tones, the central area of fungal infection may be darker (Beeckman et al., 2015).

Incontinence-associated *Candida* infection: The term 'incontinence-associated *Candida* infection' has been used to ensure clarity with reference to incontinence, IAD, and *Candida* infections. Terms commonly used in the literature, such as secondary *Candida* infection or superimposed *Candida* infection, imply a causal relationship between IAD and *Candida* infection, however this relationship is uncertain. Incontinence-associated *Candida* infection was measured by culturing the microbiological specimens collected for the study.

Patient descriptors: Demographic data (age, gender, ward, and length of stay), admission diagnosis, co-morbidities, current medications, as well as height, weight, continence status, incontinence containment product, and presence of faecal or urinary stoma were recorded on a study specific data collection instrument (see Appendix H). Pressure ulcers were identified and staged according to current international guidelines for staging pressure ulcers (National Pressure Ulcer Advisory et al., 2014). Malnutrition was measured using the Subjective Global Assessment (SGA) (see Appendix I), a valid and reliable tool, which assesses nutritional status based on patient history and physical examination (Agarwal et al., 2012; Detsky et al., 1987; Steenson et al., 2013). Results of both of these assessments are combined to produce an overall global rating; well nourished (SGA-A), moderately malnourished or suspected of being malnourished (SGA-B), and severely malnourished (SGA-C) (Agarwal et al., 2012; Detsky et al., 1987). Mobility status was measured because immobility has been associated with incontinence (Miu, Lau, & Szeto, 2010). The immobility subscale from the Braden Scale for predicting

pressure sore risk was used (Bergstrom et al., 1987) (see Appendix J) and administered by the research nurse. Convergent construct validity has been reported for the mobility subscale of the instrument (Powers et al., 2004). Mobility categories were; immobile, very limited, slightly limited, and no limitations (Bergstrom et al., 1987).

Ethical considerations

The study was approved by the Human Research Ethics Committees for both the research site and the university. The study was conducted in accordance with ethical standards set forth in the 1975 Helsinki Declaration (see Appendices M, N & O).

Data Analysis

All data were entered into the IBM SPSS Statistics for Windows (Version 22.0, Armonk, NY, USA). A random ten per cent of data entry was crosschecked for accuracy by the first author. Descriptive statistics were used to describe sample characteristics (means and standard deviations for continuous variables, frequencies and percentages for categorical variables). Characteristics were compared between the three groups. Bivariate analyses using descriptive correlational statistics (χ^2 test for independence with Yates continuity correction and Fisher's exact test where expected cell counts were less than five for categorical variables, and one way between groups analysis of variance (ANOVA) with post-hoc analysis using the Tukey test for continuous variables). *Candida albicans* colonisation was compared between continent and incontinent participants, and between incontinent participants with and without IAD. Normality of the data distribution scores was tested using the Kolmogorov-Smirnov statistic. *P* values less than .05 were considered statistically significant.

Results

Over six months 1,777 adult inpatients were assessed for eligibility (see Figure 7.1), with 362 patients not meeting the inclusion criteria, while 1,333 patients were eligible, but not enrolled. Recruitment targets for each group took varying times to meet. The recruitment target was for 28 participants in each group. The recruitment target for the continent group was reached within two months; the target for the urinary incontinent group was reached within three months, while the

recruitment target for the doubly incontinent group took six months to reach 25 participants. This meant that while recruiting for the doubly incontinent group only, it was still necessary to screen all new admissions and record those who met eligibility criteria for the study (n = 1,083). However, whilst these patients were eligible, they were not enrolled as they belonged to groups whose recruitment targets had already been met (that is continent or incontinent of urine only) (see Figure 7.1). A total of 82 patients were recruited to the study. Data for 81 patients were available for analysis, as one patient withdrew consent prior to data collection

All variables were found to follow normal distributions. The mean age of the sample was 76 years (SD = 12.22), with 53%, (n = 43) being male. The mean number of comorbidities and regular medications for each participant was five (SD = 2.02) and eight (SD = 3.10) respectively. Of the total sample, 35% (n = 28) of participants were continent, 35% (n = 28) were incontinent of urine but continent of faeces, and 31% (n = 25) were incontinent of both urine and faeces. Table 7.1 provides an overview of the characteristics of these three groups. Overall, the urinary incontinent group was significantly associated with a higher BMI $F(2, 67) = 3.9$, $p = .025$ than the continent and doubly incontinent groups. Double incontinence was significantly associated with older age, $F(2, 78) = 5.3$, $p = .007$, immobility, or very limited mobility, $\chi^2(2, N = 81) = 25.9$, $p < 0.001$), as well as the risk of malnutrition or malnutrition, $\chi^2 (2, N = 81) = 15.2$, $p = .003$.

Candida albicans was present at the perianal site in 31% (n = 25) and the inguinal site for 15% (n = 12) of the sample, while non-*albicans* spp. were present at the perianal site in 7% (n = 6) and in the inguinal site for 6% (n = 5) of the sample. Incontinent participants (n = 53), showed a non-significant trend towards higher colonisation with *Candida albicans* or *Candida* spp. (43%, n = 23) at the perianal site compared to continent (n = 28) participants (28%, n = 8), $\chi^2 (1, N = 81) = 4.453$, $p = .638$. At the inguinal site, there was a non-significant trend towards higher colonisation with *Candida albicans* or *Candida* spp. 24% (n = 13) of incontinent participants compared to 14% (n = 4), $\chi^2 (1, N = 81) = 6.868$, $p = .258$.

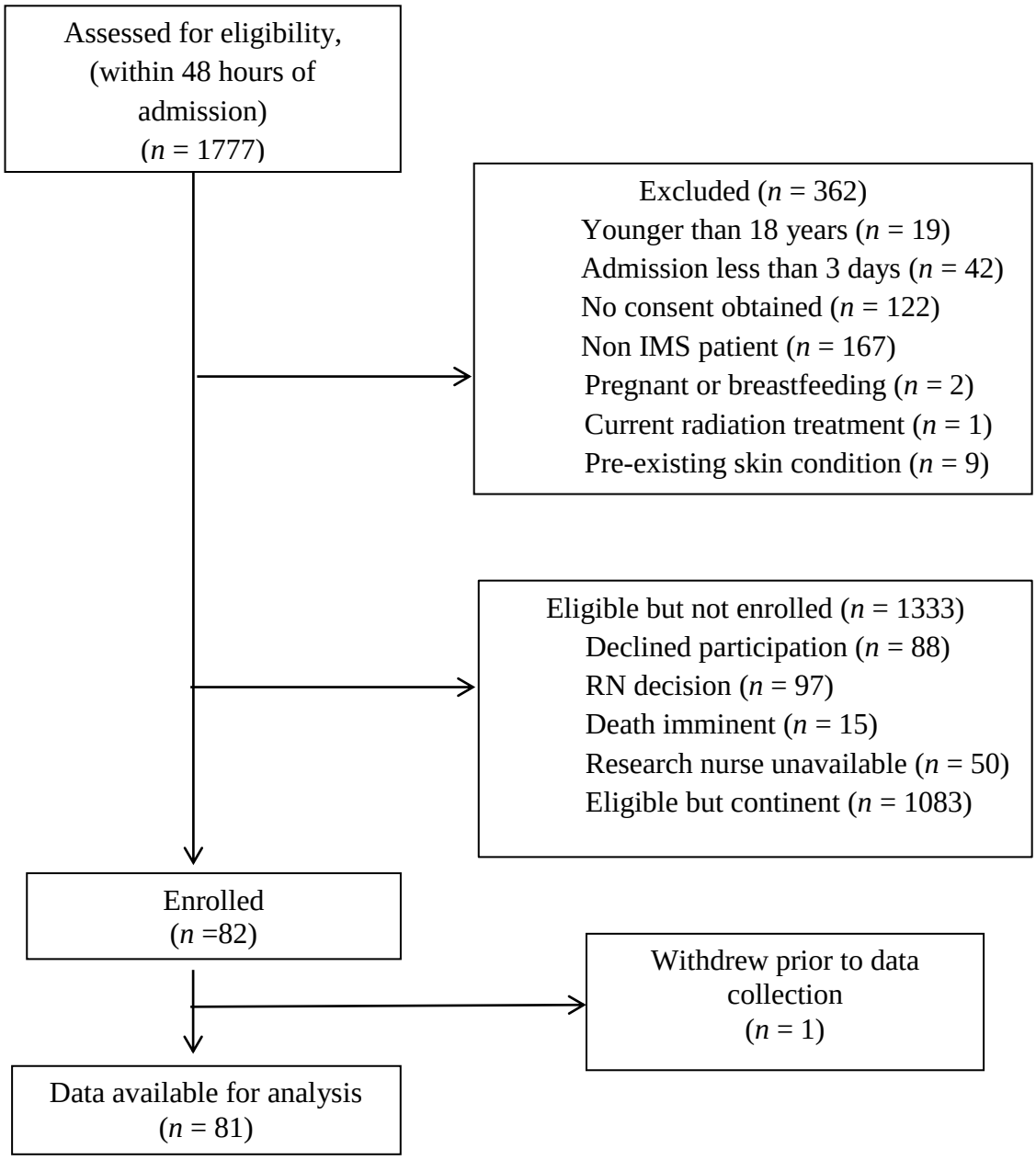


Figure 7.1 Patient enrolment, eligibility and exclusion diagram.

Figures 7.2 and 7.3 show the frequency of *Candida albicans* and *Candida* spp. according to continence status at the perianal and inguinal sites respectively. The highest semi-quantitative level of *Candida albicans* at the perianal site was 1+ (8.6%, *n* = 7) and at the inguinal site 1+ (2.5%, *n* = 2). The highest semi-quantitative level of *Candida* spp. at both perianal and inguinal sites was 3+ (1.2%, *n* = 1).

Table 7.1

Sample Characteristics (N = 81)

	Continent (*n* = 28) *n* (%)	Incontinent of urine (*n* = 28) *n* (%)	Incontinent of urine and faeces (*n* = 25) *n* (%)
SGA[a] score[b]			
A- Normal	20 (71.4)	18 (64.3)	6 (24)
B- At risk of malnutrition	4 (14.3)	8 (28.6)	12 (48)
C- Malnourished	4 (14.3)	2 (7.1)	7 (28)
Mobility[c]			
No limitation	12 (42.9)	5 (17.9)	0 (0)
Slightly limited	10 (35.7)	13 (46.4)	5 (20)
Very limited	5 17.9)	9 (32.1)	15 (60)
Completely immobile	1 (3.6)	1 (3.6)	5 (20)
Pressure ulcer[d]	1 (3.6)	1 (3.6)	4 (16)
Diabetes -Type 1 & 2[e]	11 (39)	12 (43)	10 (40)

[a]SGA = Subjective global assessment.
[b]$\chi^2(2, N = 81) = 15.2, p = .003$.
[c]$\chi^2(2, N = 81) = 25.9, p < .001$.
[d]$\chi^2(2, N = 81) = 3.17, p = .236$.
[e]$\chi^2(2, N = 81) = 1.0, p = .1.26$.

IAD was present in 41% (*n* = 22) of the incontinent patients (*n* = 53). There was no significant difference between the type of incontinence (that is urinary only or double incontinence) in those with IAD, $\chi^2(2, N = 53) = .044, p = .833$. IAD severity ranged from mild 73% (*n* = 16), to moderate (27%, *n* = 6). Perianal *Candida albicans* or *Candida* spp. colonisation rates showed no significant difference in participants with IAD (*n* = 10) compared to the incontinent participants without IAD (*n* = 31), (45%, *n* =10), compared to 42%, *n* =13), respectively, $\chi^2(1, N = 53) = .000$, $p = 1.000$. Inguinal *Candida albicans* or *Candida* spp. colonisation rates showed no significant difference in participants with IAD compared to incontinent participants without IAD (27%, *n* = 6, compared to 23%, *n* = 7), $\chi^2(1, N = 53) = .000$, $p = 1.000$. Clinical signs of a *Candida* infection were observed in 18% (*n* = 4) of participants

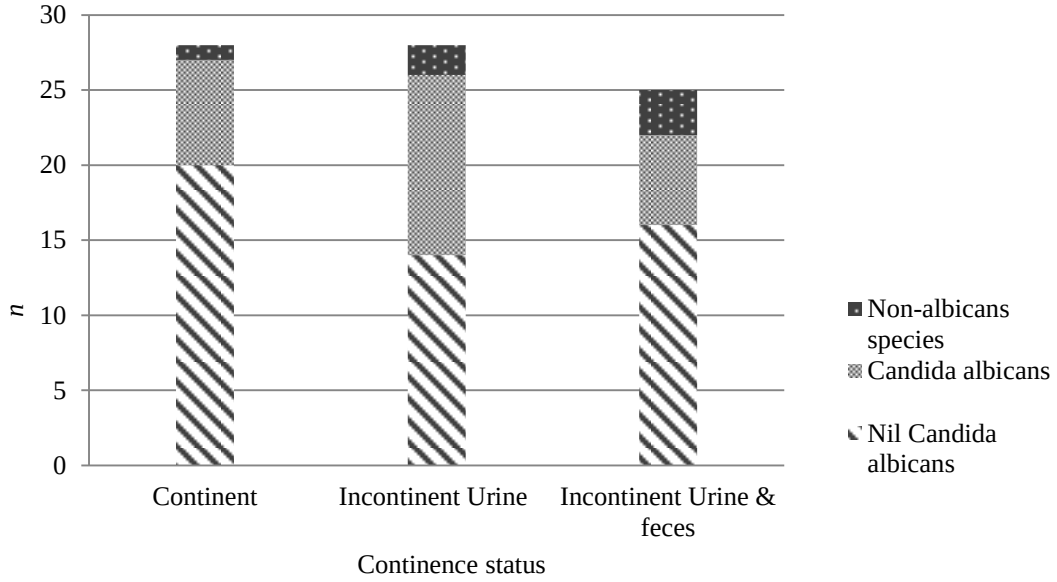


Figure 7.2 Continence status and *Candida albicans* and non-*albicans* spp. colonisation rates at the perianal site (*N* = 81).

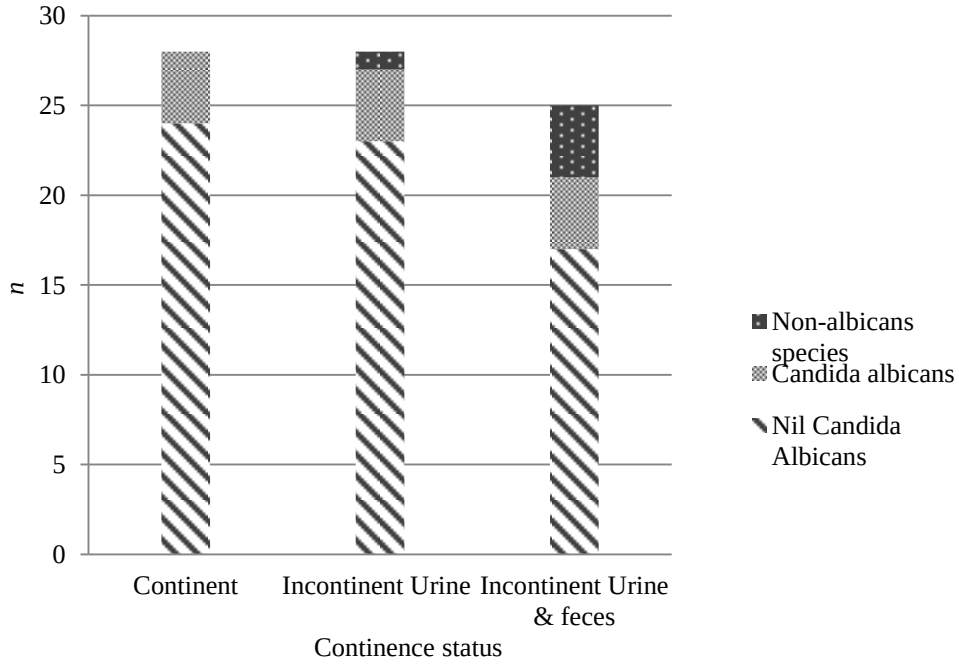


Figure 7.3 Continence status and *Candida albicans* and non-*albicans* colonisation at the inguinal site (*N* = 81).

with IAD, with the presence of *Candida* confirmed with microbiological testing in 75% (n = 3) of those participants.

Discussion

This study is the first to provide surveillance data indicating the extent of *Candida albicans* colonisation at perianal and inguinal sites in continent and incontinent acute care patients and in those patients with IAD. We found no significant difference in colonisation rates between continent and incontinent patients at either the perianal or inguinal sites, although there was a trend towards higher *Candida* colonisation rates in incontinent patients. *Candida* colonisation rates between incontinent patients with and without IAD showed no difference. The rate of incontinence-associated *Candida* infection in patients with IAD was lower than we anticipated. Despite general acceptance that *Candida* infection is a common complication of IAD (Beeckman et al., 2015; Gray et al., 2007; Gray et al., 2011; Junkin & Selekof, 2007; Nix & Haugen, 2010), data presenting microbiological confirmation of *Candida* infections in patients with a clinical presentation of IAD is scant.

Despite the ubiquitous presence of *Candida albicans* as a human commensal (Fidel, 1999; Moran et al., 2012) there is a paucity of data that identifies *Candida* colonisation rates in continent compared to incontinent acute care adults. *Candida* colonisation varies greatly depending on the anatomical site. The highest colonisation rates are in the genitourinary and gastrointestinal tracts (Moran et al., 2012; Odds, 1988), with vaginal colonisation rates reported to range between 10% - 20% in asymptomatic women of childbearing age (Revankar & Sobel, 2012; Sobel et al., 1998). Rectal colonisation is reported to range from 8% to 29% in hospitalised patients (Barlow & Chattaway, 1969; Hilton & Warnock, 1975; Rose & Kurup, 1977; Smits, Prior, & Arblaster, 1966), with no difference found between faecal and rectal colonisation rates (Odds, 1988). One study reports inguinal colonisation of hospital patients to be three percent (Somerville, 1972). Odds (1988) found oral *Candida* colonisation to range between 6% and 70%, with a mean of 41% in a compilation of studies. Overall, our study was unable to demonstrate an association between continence status and *Candida* colonisation. Moreover, we found no association between faecal frequency and/or quality and *Candida* colonisation.

It has been reported that patients with double incontinence and/or liquid faeces are more likely to develop IAD (Beeckman et al., 2015; Gray et al., 2007). It is proposed that the association between double incontinence or frequent liquid faeces and IAD is linked to the presence of digestive enzymes in faeces (higher in liquid faeces) that are capable of damaging the stratum corneum (Beeckman et al., 2015). The higher water content in liquid faeces is also damaging to the skin barrier (Gray et al., 2007). In addition to a higher risk of developing IAD, *Candida* infection is frequently cited as a common complication of IAD (Beeckman et al., 2015). Therefore, it is reasonable to expect an association between *Candida* colonisation and IAD. However, empirical data to support this is limited. Amongst our patients with IAD, 45% were colonised with *Candida albicans* or spp, similar to the colonisation rate in incontinent, non-IAD patients (42%). Limited data is available in the literature to enable comparison of *Candida* colonisation between adult patients with and without IAD. In one of the few studies to present such data, Foureur et al., (2006) reported *Candida* infection prevalence to be 63% in a group of elderly patients (mean age = 85 years) in a long-term care unit who presented with IAD. Furthermore, our study found no association between the type of incontinence and IAD. Moreover, in our study, patients with urinary incontinence had higher *Candida* colonisation rates at the perianal site than doubly incontinent patients (43% versus 24 %) respectively.

In contrast to the limited empirical data available reporting associations between *Candida* and IAD in adults, there is a multiplicity of data reporting associations with *Candida* colonisation and diaper dermatitis in infants (Dixon et al., 1969; Ferrazzini et al., 2003; Montes et al., 1971). Two paediatric studies (Brookes et al., 1971; Warin & Faulkner, 1961) found no difference in *Candida* colonisation between infants with and without diaper dermatitis. On the other hand, several paediatric studies found higher *Candida* colonisation rates in infants with diaper dermatitis (Dixon et al., 1969; Ferrazzini et al., 2003; Montes et al., 1971). Associations between *Candida* colonisation and *Candida* infection in infants with diaper dermatitis raise questions about the possible role of *Candida* in the aetiology of the condition. Paediatric data should be extrapolated to adults with caution, due to differences between the subjects, such as skin physiology, health status, and medications. However, unlike paediatric data regarding diaper dermatitis and

associated *Candida* colonisation and infection, there is very little data available investigating these associations in adults with IAD.

Data reporting microbiological confirmation of incontinence-associated *Candida* infection following a clinical diagnosis is scarce. We found 18% of participants with IAD showed clinical signs of a *Candida* infection, which was subsequently confirmed with microbiological testing in 75% of cases. The study by Fourer and colleagues (2006) found that 60% of the initial clinical infection diagnoses were confirmed on mycological swab cultures or histological examination. One reason for the scarcity of microbiological data may be that in the clinical setting, microbiological testing for the presence of *Candida* associated with IAD is not routine practice. This may be because cultures require a 48-72 hour period for a reliable result (Revankar & Sobel, 2012). Usually, a presumptive diagnosis is made based on clinical presentation, which is then followed by empirical treatment. According to Odds (1988), accuracy of the diagnosis of superficial forms of *Candida* infections is contentious, as clinical presentation of superficial infections may be characteristic of *Candida*, but not unique to it. Microbiological confirmation of *Candida* is required, combined with careful evaluation of the clinical presentation for a diagnosis of *Candida* infection to be made. Conversely, the presence of microbiologically demonstrated *Candida* at superficial sites is not indicative of infection without due consideration of the clinical presentation (Odds, 1988).

The differences in characteristics between the urinary incontinent group and the doubly incontinent groups in this study are worthy of comment (see Table 7.1). The patients in the urinary incontinent group compared to the doubly incontinent group were younger, tended to be female, were well nourished or overweight, and generally had no major mobility limitations. In comparison, the participants who were doubly incontinent were older, malnourished or at risk of malnutrition, and were either completely immobile or had very limited mobility. These characteristics may reflect differences in the underlying cause and severity of incontinence. Double incontinence appeared to be a manifestation of frailty, while urinary incontinence was likely to be related to obstetric/gynaecological risk factors (for example parity), menopause, and obesity.

Limitations

Several limitations need to be acknowledged for this study. This was a pilot study intended to provide initial estimates of colonisation rates in this population. Post hoc power calculations show that the study had 80% power to detect a difference of 35% (for example, 45% in the incontinent group vs 10% in the continent group), and the observed differences were much smaller (10% at the inguinal site and 15% at the perianal site), which may help to inform sample size calculations for further studies in this area. The study was conducted in a single centre and single admitting service; therefore, the data may not be generalisable to other acute care settings or admitting services. Larger multi-site studies including a variety of acute care admitting services would be of value in the future. While every effort was made to recruit all eligible patients, respondents who were older tended to consent to participation more frequently, with the majority of patients who declined participation under 50 years of age. This may have biased the sample. Many of those respondents made comments that reflected the belief that incontinence was an old person's problem and therefore not relevant to them. Further, the nature of the skin inspection and collection of microbial samples can be intrusive and may have influenced the decision not to participate.

Microbiological testing for *Candida albicans* only was based on the extensive literature identifying *Candida albicans* as the most common human fungal coloniser and pathogen (Fidel, 1999; Moran et al., 2012). However, we found those with non-*albicans* spp. constituted higher colonisation severity compared to *Candida albicans*. Future studies would benefit from identifying all *Candida* species that may be present.

Conclusion

This is the first study to report the colonisation rates of *Candida albicans* in continent and incontinent hospitalised adults as well as those with IAD. *Candida* colonisation was common at the perianal and inguinal sites at admission to hospital. We found no significant difference in *Candida* colonisation between continent and incontinent patients or those with IAD, although there was a non-significant trend towards *Candida* colonisation in those who were incontinent.

Candida albicans is reported as the most common aetiological agent in incontinence-associated *Candida* infection, with the primary source of pathogen

being an individual's endogenous commensal organisms (Clancy & Nguyen, 2012; Fidel, 1999). Therefore, awareness of the patterns and frequencies of *Candida* colonisation in these patients is imperative for improving understanding of factors that regulate colonisation and potential transformation to *Candida* infection, particularly in incontinent patients. Further research is warranted to understand specific factors that precipitate *Candida* infections in incontinent adults.

References

Agarwal, E., Ferguson, M., Banks, M., Bauer, J., Capra, S., & Isenring, E. (2012). Nutritional status and dietary intake of acute care patients: Results from the Nutrition Care Day Survey 2010. *Clinical Nutrition, 31*(1), 41-47.

Barlow, A., & Chattaway, F. (1969). Observations on the carriage of *Candida albicans* in man. *British Journal of Dermatology, 81*(2), 103-106.

Beeckman, D., Campbell, J., Campbell, K., Chimentao, D., Coyer, F., Domansky, R., & Gray, M. (2015). Proceedings of the Global IAD expert Panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International*. Retrieved from http://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf

Bergstrom, N., Braden, B., Laguzza, A., & Holman, V. (1987). The Braden scale for predicting pressure sore risk. *Nursing Research, 36*(4), 205-210.

Black, J., Gray, M., Bliss, D., Kennedy-Evans, K., Logan, S., Baharestani, M., . . . & Ratliff, C. (2011). MASD part 2: Incontinence-associated dermatitis and intertriginous dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 38*(4), 359-370.

Bliss, D., & Powers, J. (2011). Faecal incontinence and its associated problems in hospitalised patients: The need for nursing management. *World Council of Enterostomal Therapists Journal, 31*(2), 35-39

Bonifaz, A., Tirado-Sanchez, A., Graniel, M. J., Mena, C., Valencia, A., & Ponce-Olivera, R. M. (2013). The efficacy and safety of sertaconazole cream (2 %) in diaper dermatitis candidiasis. *Mycopathologia, 175*(3-4), 249-254.

Brookes, D., Hubbert, R., & Sarkany, I. (1971). Skin flora of infants with napkin rash. *British Journal of Dermatology, 85*(3), 250-253.

Campbell, J., Coyer, F., & Osborne, S. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting. *International Wound Journal*.doi:10.1111/iwj.12322

Clancy, C., & Nguyen, M. (2012). Systemic candidiasis: Candidemia and deep-organ infection. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis* (pp. 429-441). Washington DC: ASM press.

Detsky, A. S., Baker, J., Johnston, N., Whittaker, S., Mendelson, R., & Jeejeebhoy, K. (1987). What is subjective global assessment of nutritional status? *Journal of Parenteral and Enteral Nutrition, 11*(1), 8-13.

Dixon, P. N., Warin, R. P., & English, M. P. (1969). Role of *Candida albicans* infection in napkin rashes. *British Journal of Dermatology, 2*(5648), 23-27.

Dorko, E., Virágová, S., & Pilipčinec, E. (2003). *Candida*—Agent of the diaper dermatitis? *Folia Microbiologica, 48*(3), 385-388.

Doughty, D., Junkin, J., Kurz, P., Selekof, J., Gray, M., Fader, M., . . . & Logan, S. (2012). Incontinence-associated dermatitis: Consensus statements, evidence-based guidelines for prevention and treatment, and current challenges. *Journal of Wound Ostomy & Continence Nursing, 39*(3), 303-315

Ferrazzini, G., Kaiser, R. R., Hirsig Cheng, S., Wehrli, M., Della Casa, V., Pohlig, G., . . . & Jörg, W. (2003). Microbiological aspects of diaper dermatitis. *Dermatology 206*(2), 136-141.

Fidel, P. J. (1999). *Candida albicans:* From commensal to pathogen. In G. W. Tannock (Ed.), *Medical Importance of the Normal Microflora* (pp. 441-476). Dordrecht, The Netherlands: Kluwer Academic Publishers.

Foureur, N., Vanzo, B., Meaume, S., & Senet, P. (2006). Prospective aetiological study of diaper dermatitis in the elderly. *British Journal of Dermatology, 155*(5), 941-946.

Gray, M., Black, J., Baharestani, M., Bliss, D., Colwell, J., Goldberg, M., . . . & Ratliff, C. (2011). Moisture-associated skin damage: Overview and pathophysiology. *Journal of Wound Ostomy & Continence Nursing, 38*(3), 233-241

Gray, M., Bliss, D., Doughty, D., Ermer-Seltun, J., Kennedy-Evans, K., & Palmer, M. (2007). Incontinence-associated dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 34*(1), 45-56

Habif, T. P. (2015). *Clinical dermatology: A color guide to diagnosis and therapy*. Philadelphia: Saunders.

Halfens, R. J. G., Meesterberends, E., Nie-Visser, N. C., Lohrmann, C., Schönherr, S., Meijers, J. M. M., . . . & Schols, J. M. G. A. (2013). International prevalence measurement of care problems: Results. *Journal of Advanced Nursing, 69*(9), e5-e17.

Hilton, A., & Warnock, D. (1975). Vaginal candidiasis and the role of the digestive tract as a source of infection. *British Journal of Obstetrics & Gynaecology, 82*(11), 922-926.

Jarvis, W. R. (1996). The Epidemiology of Colonization. *Infection Control & Hospital Epidemiology, 17*(1), 47-52.

Jefferson, J. (1966). Napkin psoriasis. *British Journal of Dermatology, 78*(11), 614-614.

Junkin, J., & Selekof, J. (2007). Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of Wound Ostomy & Continence Nursing, 34*(3), 260-269

Kennedy, K., & Lutz, L. (4th October 1996). *Comparison of the efficacy and cost-effectiveness of three skin protectants in the management of incontinent dermatitis.* Paper presented at the Proceedings of the European Conference on Advances in Wound Management. Amsterdam, Netherlands

Kumamoto, C. A. (2011). Inflammation and gastrointestinal *Candida* colonization. *Current Opinion in Microbiology, 14*(4), 386-391.

Leyden, J. J., & Kligman, A. M. (1978). The role of microorganisms in diaper dermatitis. *Archives of Dermatology, 114*(1), 56-59.

Lionakis, M. S. (2014). New insights into innate immune control of systemic candidiasis. *Medical Mycology, 52*(6), 555-564.

Magill, S. S., Edwards, J. R., Bamberg, W., Beldavs, Z. G., Dumyati, G., Kainer, M. A., . . . & Fridkin, S. K. (2014). Multistate point-prevalence survey of healthcare-associated infections. *New England Journal of Medicine, 370*(13), 1198-1208.

Miu, D. K., Lau, S., & Szeto, S. S. (2010). Etiology and predictors of urinary incontinence and its effect on quality of life. *Geriatrics & Gerontology International, 10*(2), 177-182.

Montes, L., Pittillo, R., Hunt, D., Narkates, A., & Dillon, H. (1971). Microbial flora of infant's skin: Comparison of types of microorganisms between normal skin and diaper dermatitis. *Archives of Dermatology, 103*(6), 640-648.

Moran, G., Coleman, S., & Sullivan, D. (2012). An introduction to the medically important *Candida* species. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis* (pp. 11-25). Washington, DC: ASM Press.

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance. (2014). *Prevention and treatment of pressure ulcers: clinical practice guideline* (E. Haesler Ed.). Perth, Australia: Cambridge Media.

Nix, D., & Haugen, V. (2010). Prevention and management of incontinence-associated dermatitis. *Drugs & Aging, 27*(6), 491-496.

Odds, F. C. (1988). *Candida and candidosis*. London; Philadelphia: Baillière Tindall.

Odds, F. C., Davidson, A. D., Jacobsen, M. D., Tavanti, A., Whyte, J. A., Kibbler, C. C., . . . & Gow, N. A. (2006). *Candida albicans* strain maintenance, replacement, and microvariation demonstrated by multilocus sequence typing. *Journal of Clinical Microbiology, 44*(10), 3647-3658.

Powers, G. C., Zentner, T., Nelson, F., & Bergstrom, N. (2004). Validation of the mobility subscale of the Braden Scale for predicting pressure sore risk. *Nursing Research, 53*(5), 340-346.

Revankar, S., & Sobel, J. (2012). Mucosal candidiasis. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis.* (pp. 419-427). Washington, DC: ASM Press.

Rose, H., & Kurup, V. (1977). Colonization of hospitalized patients with yeast-like organisms. *Sabouraudia, 15*(3), 251-256.

Smits, B., Prior, A., & Arblaster, P. (1966). Incidence of *Candida* in hospital in-patients and the effects of antibiotic therapy. *British Medical Journal, 1*(5481), 208.

Sobel, J. D., Faro, S., Force, R. W., Foxman, B., Ledger, W. J., Nyirjesy, P. R., . . . & Summers, P. R. (1998). Vulvovaginal candidiasis: Epidemiologic, diagnostic, and therapeutic considerations. *American Journal of Obstetrics and Gynecology, 178*(2), 203-211.

Somerville, D. A. (1972). Yeasts in a hospital for patients with skin diseases. *Journal of Hygiene, 70*(4), 667-675.

Steenson, J., Vivanti, A., & Isenring, E. (2013). Inter-rater reliability of the Subjective Global Assessment: A systematic literature review. *Nutrition, 29*(1), 350-352.

Warin, R., & Faulkner, K. (1961). Napkin Psoriasis. *British Journal of Dermatology, 73*(12), 445-447.

7.3 CHAPTER SUMMARY

Study 2 is the first study to provide data that contribute to the understanding of *Candida* colonisation rates in acute care patients according to continence and IAD status. Study 2 found that overall, on admission to hospital, regardless of continence status (N = 81), *Candida* was present at the perianal site in 38% of patients, and the inguinal site for 21% of patients. On admission there was a non-significant trend towards more frequent *Candida albicans* colonisation in incontinent than in continent patients. *Candida* was present at the perianal site in 43% of incontinent participants compared to 28% of continent patients. At the inguinal site, more incontinent (24%) patients were colonised with *Candida* than continent (14%) patients were colonised with *Candida.*

While there are several studies that identify high levels of *Candida* organisms in both paediatric patients with diaper dermatitis (Ferrazzini et al., 2003) and older patients with IAD (Foureur et al., 2006), until now, there has been no analysis that compares baseline *Candida* colonisation data between incontinent and continent patients. The study presented in Publication 2 found that incontinence is associated with older age and places patients at risk for the skin injuries of IAD and pressure injury. Furthermore, developing IAD places a patient at risk of developing a *Candida* infection. These consequences of older age and incontinence are important for both the patient and the healthcare provider. Therefore, a crucial step in understanding these consequences is to understand patterns of *Candida* colonisation in these specific patient groups. This study provides unique *Candida* colonisation data for these patients.

This study also provides evidence to support the inclusion of several constructs in the Skin Safety Model (SSM). Study 2 demonstrated significant associations between several study variables and the first construct of the model, potential contributing factors to skin injury. Patient factors identified by the model include advanced age, incontinence, poor nutrition and mobility limitation. Study 2 showed that double incontinence was significantly associated with older age, immobility, or very limited mobility, as well as the risk of malnutrition or malnutrition. This also supports the inclusion of a range of variables as potentially contributing to skin injury in the SSM. The study investigated the variables,.

comorbidities and number of concurrent medications. While these variables were not significantly associated with older age, the mean age of the sample was 76 years (*SD* = 12.22). Further studies with a larger sample size may demonstrate associations between these variables. All of the patients in Study 2 were exposed to one or more acute situational stressors (the first construct of the SSM) by virtue of their hospital admission.

Of the incontinent patients (*n* = 53) in Study 2, 41% developed IAD, with 18% of those presenting with a fungal infection. This supports the incluson of the second construct in the model, that is, that skin exposure to urine and/or faeces can result in a skin injury (IAD), the third construct of the model, which can subsequently lead to an infection (*Candida*), which is the final construct of the model.

The following chapter presents Publication 5, which investigated potential risk factors for *Candida* colonisation.

Chapter 8: RISK FACTORS FOR *CANDIDA* COLONISATION AT THE PERIANAL AND INGUINAL SITES IN PATIENTS ADMITTED TO ACUTE MEDICAL WARDS

8.1 INTRODUCTION

This chapter comprises the following manuscript, which represents Study 2 two and Publication 5 of this of this thesis.

Campbell J., Coyer, F., Mudge A., & Osborne S. Risk factors for *Candida* colonisation at the perianal and inguinal sites in patients admitted to acute medical wards. (This manuscript is to be submitted to *Journal of Hospital Infection*).

This study addressed the following research question:

6. In acute medical patients, are gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or body mass index (BMI) risk factors for *Candida* colonisation?

Study 2 presented a unique contribution to understanding the differences between *Candida* colonisation in continent, and incontinent patients and those with IAD. While the results of Study 2 did not reveal a significant association between *Candida* colonisation, incontinence, or IAD, other factors may have confounded this relationship. The publication presented in this chapter (Publication 5) investigated whether there were specific risk factors for *Candida* colonisation in these patients. It is a short report that analysed data from the study reported in Chapter 7, Publication 4.

8.2 PUBLICATION 5

Risk Factors for *Candida* Colonisation at the Perianal and Inguinal Sites in Patients Admitted to Acute Medical Wards

Summary

Candida albicans is the most common human fungal commensal organism. It can transform from commensal organism to harmful pathogen in certain situations, with colonisation a necessary precursor to infection. *Candida* has been reported to have an aetiological role in paediatric diaper dermatitis. While *Candida* infections have been associated with incontinence-associated dermatitis in adults, there is limited understanding of the risk factors for perianal and inguinal colonisation in adults. Understanding the risk factors for *Candida* colonisation in this group may enhance the understanding of *Candida* infection. This exploratory study investigated potential risk factors for *Candida* colonisation in a sample of continent and incontinent adult acute care medical inpatients (N = 81). We found on admission, 42% (n = 34) of patients were colonised with *Candida.* Colonisation was not significantly associated with age, gender, obesity, diabetes, or diarrhoea, however, there was a trend to greater antibiotic use, poorer nutritional status, and mobility limitation in the colonised group.

Key words: *Candida albicans*, colonisation, incontinence-associated dermatitis, incontinence, antibiotics

Introduction

Candida albicans is the most common human fungal commensal organism, with colonisation occurring in 30%-60% of healthy individuals (Odds, 1988). There are certain conditions in which commensal organisms can transform into pathogens and result in mucocutaneous *Candida* infections (Fidel, 1999; Odds, 1988). Colonisation is almost always a precursor to infection (Fidel, 1999). *Candida* infections have been reported to be a complication of incontinence-associated dermatitis (IAD) in adults (Beeckman et al., 2015). In infants, *Candida* has been reported to have an aetiological role in diaper dermatitis (the paediatric equivalent to adult IAD) (Dixon et al., 1969; Ferrazzini et al., 2003), however; it is uncertain whether *Candida* may have an aetiological role in IAD in adults. In view of the

relationship between *Candida* colonisation and possible transformation to infection, as well as the understanding of the relationship between paediatric diaper dermatitis and *Candida* colonisation, it is logical then, that incontinence may lead to *Candida* colonisation. A recent observational study (under review for publication) did not find a significant association between incontinence and *Candida* colonisation or IAD, but other risk factors such as age, gender, administration of antibiotics, or the presence of diabetes reported as risk factors for *Candida* colonisation (Moran et al., 2012; Odds, 1988) may have confounded this relationship. There is limited evidence regarding risk factors for *Candida* colonisation at the perianal or inguinal regions of acute care medical patients. The aim of this study was to explore potential risk factors associated with perianal and inguinal *Candida* colonisation in a purposive sample of continent and incontinent adult patients in order to enhance understanding of pathogenesis of IAD.

Aims and research questions

In order to advance the understanding of *Candida* colonisation and infection in incontinent patients and those with IAD, the aim of this exploratory study was to identify risk factors for *Candida* colonisation in patients admitted to acute care medical units.

The research question was:

6. In acute care medical patients, are gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or body mass index risk factors for Candida colonisation?

Methods

This cross-sectional observational study was conducted in the Internal Medicine Service (IMS) wards at a 929-bed major acute care metropolitan teaching hospital in Australia. Purposive sampling recruited three groups, (1) continent; (2) incontinent of urine, but continent of faeces; (3) incontinent of both urine and faeces. Hospitalised adults aged 18 years and older admitted consecutively to all wards in the IMS who had an expected hospital stay of three days or more days, and where data could be collected within 48 hours of admission were eligible for inclusion in the study. Excluded patients were those receiving treatment with systemic or topical antifungal agents, had a dermatological condition as the admission diagnosis, were

receiving radiation treatment, or were pregnant or breastfeeding. Patient recruitment and enrolment took place between April and October 2014. Detailed recruitment methods are reported elsewhere (see Publication 4, Chapter 7).

Candida colonisation was defined as the presence of *Candida albicans* or other *Candida* spp. at either the perianal or inguinal site, identified systematically by two dry flocked swabs. transported immediately to the laboratory, and cultured in Sabourand's medium. The laboratory reported *Candida albicans* or non-*Candida albicans* spp. in semi-quantitative manner (scant, 1+, 2+, and 3+).

Potential explanatory variables were explored on the basis of a literature review to determine risk factors for *Candida* colonisation or infection. These were identified as age, gender, comorbid diabetes, antibiotic treatment, body mass index, nutritional status, mobility status, continence status, and stool quality (Dan, Segal, Marder, & Leibovitz, 2006; Fanello et al., 2006; Fidel, 1999; Moran et al., 2012; Odds, 1988). Nutritional status was measured using the Subjective Global Assessment (SGA), a validated assessment tool which reports nutritional status as well nourished (SGA-A), moderately malnourished (SGA-B), and severely malnourished (SGA-C). Mobility status was measured using the categories from the Braden scale for predicting pressure injury: immobile, very limited, slightly limited, and no limitations. Faecal quality was based on the Bristol Stool Form scale, collapsed into a dichotomous variable (formed, and semi-formed-liquid) for analyses.

The study was approved by the Human Research Ethics Committees for both the research site and the university.

All data were entered into the IBM SPSS Statistics for Windows (Version 22.0, Armonk, NY, USA). Descriptive statistics were used to describe sample variables (means and standard deviations for continuous variables; frequencies and percentages for categorical variables). Bivariate analyses were conducted using descriptive correlational statistics (χ^2 test for independence with Yates continuity correction when expected cell frequency is less than ten or Fisher's exact test when expected cell frequency is less than five and independent-samples-t-test for continuous variables). *P* values less than .05 were considered statistically significant.

Results

A total of 81 patients were recruited to the study. The mean age of the sample was 76 years (*SD* = 12.22), with 53%, (*n* = 43) of being male. Overall, 35% (*n* = 28) of the participants were continent, 35% (*n* = 28) were incontinent of urine, but continent of faeces, and 31% (*n* = 25) were incontinent of both urine and faeces. Of the total sample, 41.9% (*n* = 34) of participants were colonised with *Candida*, 33.4% (*n* = 27) with *Candida albicans*, and 8.6% (*n* = 7) with other *Candida* species. Colonisation at both sites occurred in 17.3% (*n* = 14) participants, and at the perianal area only in 21.0% (*n* = 17), and 7.7% (*n* = 3) at the inguinal site only. There were no significant differences in age between the group with *Candida* colonisation (*M* = 77.4 years, *SD* = 11.8) and the group with no colonisation (*M* = 75.0 years, *SD* = 12.5), *t*(79) = .875), *p* = 0.38. No significant differences in BMI were found between those with Candida colonisation, (*M* = 28.9 kg/m2, *SD* = 12.0) and those with no colonisation (*M* = 29.7 kg/m2, *SD* = 8.7), *t*(68) = .320, *p* = 0.75. The significance of the differences between risk factors are shown in Table 8.1. Although there was a trend towards greater antibiotic use, poorer nutritional status, and greater mobility limitation in the colonised group, none of these risk factors were statistically significant. The significance of the difference between diarrhoea, diabetes and *Candida* colonisation is shown in Table 8.1.

Discussion

This exploratory study investigated risk factors for *Candida albicans* colonisation at perianal and inguinal sites in typical internal medicine patients, purposively recruited to represent both continent and incontinent patients. We found over 40% of newly admitted medical patients were colonised with *Candida* at these sites, revealing a significant potential pathogenic reservoir in the inpatient population. Colonisation was not significantly associated with age, gender, obesity, diabetes, or diarrhoea, however, there was a trend to greater antibiotic use, poorer nutritional status, and mobility limitation in the colonised group.

Our overall colonisation rate (42%) was double that of a study by Schulte and colleagues (2015) who reported a perianal colonisation rate of 19%. Reasons for this difference is unclear, but may be accounted for, in part, by difference in average age between our sample (mean age 76 years) and Schulte and colleagues' (2015) sample (mean age 56 years), with older age potentially contributing to the higher

Table 8.1

Frequencies, Percentages and χ^2 Scores for the Risk Factors forNot Colonised (n = 47) and Colonised (n = 34) (N = 81)

	Not colonised (*n* = 47)	Colonised (*n* = 34)	(χ^2)	*p*
	n (%)	*n* (%)		
Gender				
Female	20 (42.5)	18 (52.9)	.855	.355
Male	27 (57.44)	16 (34.0)		
Patients receiving antibiotics (oral or intravenous) at time of data collection				
No	35 (74.4)	18 (52.9)	3.146	.076
Yes	12 (25.5)	16 (34.0)		
Diabetes (Type 1 or 2)				
No				
Yes	26 (55.3)	22 (64.7)	.384	.536
	21 (44.6)	12 (35.3)		
Mobility				
No limitation	13 (27.6)	4 (11.7)	3.404	.340
Slightly limited	15 (31.9)	13 (38.2)		
Very limited	16 (34.0)	13 (38.2)		
Completely immobile	3 (6.4)	4 (11.7)		
Stool frequency				
1 per day	29 (61.7)	23 (67.6)	.588	.799
2-3 per day	15 (31.4)	10 (29.4)		
> 3 per day	3 (6.4)	1 (2.9)		
Stool quality				
Formed	30 (63.8)	24 (47.4)	.406	.635
Semi-formed/liquid	17 (36.1)	10 (29.4)		
SGA[a] score				
A- Normal	28 (59.5)	16 (47.4)	1.468	.480
B- At risk of malnutrition	13 (27.6)	11 (32.3)		
C- Malnourished	6 (12.7)	7 (20.5)		

[a]SGA = Subjective global assessment.

colonisation in our study. Older age has been identified as a risk factor for mucosal *Candida* infection and colonisation (Moran et al., 2012; Odds, 1988). Consistent with the study conducted by Schulte and colleagues (2015), we found a trend towards

greater colonisation in those with poorer nutrition status and impaired mobility, common markers of frailty and old age in this population.

Association between the presence of liquid faeces and/or increased faecal frequency and *Candida* infection or colonisation at the perianal or inguinal site remains unclear. Faecal colonisation with *Candida* has been reported to be 26% for hospital patients (Odds, 1988). This indicates that faecal contact with the perianal region may result in skin exposure to *Candida* organisms. It is feasible to expect increased skin exposure to faeces and therefore increased exposure to *Candida* organisms in patients with diarrhoea may result in higher *Candida* colonisation rates at the perianal or inguinal area. In addition, administration of broad-spectrum antibiotics have also been found to increase *Candida* colonisation in the gastro-intestinal tract by disrupting the bacterial microbiome and allowing *Candida albicans* to proliferate (Fanello et al., 2006; Pittet, Monod, Suter, Frenk, & Auckenthaler, 1994; Schulte et al., 2015). Our study found no association between *Candida* colonisation and diarrhoea, however, there was a trend toward higher antibiotic use and *Candida* colonisation. Other factors reported to influence colonisation or infection are specific to certain patient groups and anatomical sites, for example, women have a vaginal *Candida* colonisation rate of 10% - 20% during the childbearing years, with pregnancy and the use of estrogen medications associated with even higher asymptomatic colonisation rates, although postmenopausal women have much lower vaginal *Candida* colonisation rates than women of childbearing age, (Dan et al., 2006; Revankar & Sobel, 2012). It is uncertain if vaginal *Candida* colonisation rates are similar to perianal and inguinal *Candida* colonisation rates in the same women. Our study showed no association with *Candida* colonisation and gender. Some evidence shows that *Candida* colonisation is higher in individuals with diabetes (Moran et al., 2012). However; consistent with other studies (Fanello et al., 2006; Fanello, Bouchara, Jousset, Delbos, & LeFlohic, 2001; Schulte et al., 2015) we found no association between *Candida* colonisation and diabetes.

Several limitations need to be acknowledged. Our findings are limited by the small sample size and inclusion criteria, which limit generalisability to other acute care settings or admitting services. The mean age was old (76 years), which may bias

results, as older age is reported to be a risk factor for *Candida* colonisation and infection.

Conclusion

In summary, this small, yet unique study is the first to investigate risk factors for *Candida* colonisation at the perianal and inguinal sites of acute medical patients. This study found that *Candida* colonisation was common in the inguinal and perianal region of adult medical patients at admission to hospital, however, there was no clear association with risk factors. Further studies are needed to advance the understanding of risk factors for *Candida* colonisation in acute care medical patients. Importantly, this may inform future prevention and management strategies in groups identified as being at risk for increased *Candida* colonisation and subsequent infection.

References

Beeckman, D., Campbell, J., Campbell, K., Chimentao, D., Coyer, F., Domansky, R., & Gray, M. (2015). Proceedings of the Global IAD expert Panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International*. http://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf

Dan, M., Segal, R., Marder, V., & Leibovitz, A. (2006). *Candida* colonization of the vagina in elderly residents of a long-term-care hospital. *European Journal of Clinical Microbiology and Infectious Diseases, 25*(6), 394-396.

Dixon, P. N., Warin, R. P., & English, M. P. (1969). Role of *Candida albicans* infection in napkin rashes. *British Medical Journal, 2*(5648), 23-27.

Fanello, S., Bouchara, J., Sauteron, M., Delbos, V., Parot, E., Marot-Leblond, A., . . . & Brangerd, B. (2006). Predictive value of oral colonization by *Candida* yeasts for the onset of a nosocomial infection in elderly hospitalized patients. *Journal of Medical Microbiology, 55*(2), 223-228.

Fanello, S., Bouchara, J. P., Jousset, N., Delbos, V., & LeFlohic, A. M. (2001). Nosocomial *Candida albicans* acquisition in a geriatric unit: Epidemiology and evidence for person-to-person transmission. *Journal of Hospital Infection, 47*(1), 46-52.

Ferrazzini, G., Kaiser, R. R., Hirsig Cheng, S., Wehrli, M., Della Casa, V., Pohlig, G., . . . & Jörg, W. (2003). Microbiological aspects of diaper dermatitis. *Dermatology 206*(2), 136-141

Fidel, P. J. (1999). *Candida albicans*: From commensal to pathogen. In G. W. Tannock (Ed.), *Medical Importance of the Normal Microflora* (pp. 441-476). Dordrecht, The Netherlands: Kluwer Academic Publishers.

Moran, G., Coleman, S., & Sullivan, D. (2012). An introduction to the medically important *Candida* species. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis.* (pp. 11-25). Washington, DC: ASM Press.

Odds, F. C. (1988). *Candida and candidosis*. London; Philadelphia: Baillière Tindall.

Pittet, D., Monod, M., Suter, P. M., Frenk, E., & Auckenthaler, R. (1994). *Candida* colonization and subsequent infections in critically ill surgical patients. *Annals of Surgery, 220*(6), 751.

Revankar, S., & Sobel, J. (2012). Mucosal candidiasis. In R. Calderone & C. Clancy (Eds.), *Candida and Candidiasis.* (pp. 419-427). Washington, DC: ASM Press.

Schulte, D., Sethi, A., Gangnon, R., Duster, M., Maki, D. G., & Safdar, N. (2015). Risk factors for *Candida* colonization and co-colonization with multi-drug resistant organisms at admission. *Antimicrobial Resistance and Infection Control, 4*, 46.

8.3 CHAPTER SUMMARY

This chapter presented the results of a study investigating potential risk factors for *Candida* colonisation. It was found that colonisation was common at the perianal and inguinal sites of adult medical patients at baseline. Colonisation was not significantly associated with specific risk factors; however, there was a trend to greater antibiotic use, poorer nutritional status, and mobility limitation in the colonised group. This investigation provides data that will inform further research into risk factors for *Candida* colonisation in acute care patients.

This study also provides evidence to support the inclusion of several constructs in the Skin Safety Model (SSM). The variables gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or BMI were investigated to determine if they are risk factors for *Candida* colonisation. There was a trend towards greater antibiotic use, poorer nutritional status, and greater mobility limitation in the colonised group, none of these risk factors were statistically significant. The inclusion of the factors advanced comorbidities, mobility limitation and poor nutrition in the first construct of the model is supported by empirical evidence, however, studies with larger sample sizes are required to investigate this trend and to support the inclusion of the variable in the model.

The following chapter presents a discussion of the results and limitations of the studies conducted for this research program.

Chapter 9: DISCUSSION AND LIMITATIONS

9.1 INTRODUCTION

This chapter discusses the conceptual framework developed to underpin this thesis, the Skin Safety Model (SSM), as well as its strengths and limitations. This is followed by a discussion of the results, implications and limitations of Study 1, Publications 2 and 3, and Study 2 and Publications 4 and 5 and a discussion of the significance of the combined research.

The aims of this thesis by publication were to explore the phenomenon of incontinence-associated dermatitis (IAD) in the acute care setting by investigating the prevalence of IAD in an Australian acute care setting, and also investigating the epidemiology of *Candida* colonisation and infection associated with continence status and IAD in these patients. Furthermore, this research aimed to present a new conceptual model in which to reconceptualise the phenomenon of IAD within the broader domain of maintaining skin integrity in this setting. An additional aim of the research was to test key constructs (selected based on gaps in the research) of the proposed model.

9.1.1 Conceptual framework: Skin Safety Model

The literature review revealed a multitude of skin integrity frameworks, practice guidelines, and consensus documents that address the aetiology, prevention, and management of specific skin injuries, including IAD (Beeckman et. al., 2015; Black et al., 2011; Callan et. al., 2011; Carville et al., 2007; DeFloor, 1999; Gray et al., 2007; LeBlanc & Baranoski, 2011; McNichol et al., 2013). These injury-specific frameworks and guidelines are crucially important in the skin integrity domain, draw together global expert consensus from a variety of skin integrity sub-specialties, and supported by the most contemporary skin integrity research. However, while there are several frameworks that deal with IAD aetiology (Beeckman, Schoonhoven, Verhaeghe, Heyneman, & Defloor, 2009b; Brown & Sears, 1993; Jeter & Lutz, 1996; Newman, 2001) and several proposed IAD severity classification tools (Beeckman et al., 2015; Borchert et al., 2010; Junkin & Selekof, 2008; Kennedy & Lutz, 1996; Nix, 2002), there was no comprehensive and holistic framework that

conceptualised IAD as an integral component of the much broader imperative of maintaining intact skin, specifically in the acute care patient.

As a result, the current approach to skin integrity, which is underpinned by multiple, injury-specific frameworks, can result in duplicated, fragmented, or missed care (Blackman et al., 2014; Campbell et al., 2015; Kalisch et al., 2009; Shortell & Singer, 2008). This approach is driven, in part, by the imperative for healthcare providers to improve key patient safety indicators, avoid penalties in the form of sanctions or financial disincentives, or meet accreditation requirements (Eagar et al., 2013). According to Shortell and Singer (2008), the greatest barrier to patient safety is the inherent fragmentation of the system of care. Consistent with this assertion, it can be argued that fragmentation of the system of skin integrity care poses a threat to skin safety within the acute care setting.

Furthermore, parallels can be seen between current siloed and somewhat fragmented approaches to maintaining skin integrity, and biomedical models of disease. Biomedical models of disease focus on aetiology arising from cellular and pathological processes, explaining a disease or condition, and exclude psychosocial or environmental conditions (Wade & Halligan, 2004). Service delivery in the acute care setting is structured around the biomedical model of disease, which, while successful in many respects, can also foster specialised care delivery in specialised departments, rather than a fully integrated continuum of care (Wade & Halligan, 2004), with the complexity and individuality of the patient lost in the specialty silo (Shortell & Singer, 2008). The influence of the biomedical model of disease and the resultant focus on specialised care specific to maintaining skin integrity is reflected in the presence of multiple, injury-specific skin integrity conceptual frameworks. These injury-specific paradigms, with attendant narrow solutions, are neither sustainable, nor desirable in the modern healthcare environment (Shortell & Singer, 2008).

The rationale for developing a new conceptual framework was based on the imperative for a new paradigm to guide and unify skin integrity care in the hospital setting. The rapidly changing environment of contemporary healthcare, that is, ageing populations, the dramatic increase in chronic disease, and the overwhelming growth in healthcare cost, mean that the number of older, frailer, immobile, and incontinent individuals occupying acute care beds will continue to increase in

ensuing decades. Overall, these changes provide the impetus for developing a new and innovative framework that breaks down silos, and facilitates cost-effective, efficient, patient-centred care. Innovative, unified, and effective care in the skin integrity domain needs to be underpinned by a conceptual framework that is comprehensive, holistic, and patient-centred, and that integrates a range of antecedents and possible skin injuries into a single model. However, no such model existed. The SSM was developed and tested to address this gap.

The SSM was developed from a review of the relevant literature, drawing on a range of frameworks, consensus documents, and position papers in the skin integrity, patient safety, and quality improvement literature. The critical point of difference between the SSM and other skin integrity frameworks lies in the conceptualisation of the overarching construct of skin integrity. The SSM proposes a reconceptualisation of multiple dimensions of skin integrity into a holistic, integrated framework, underpinned by the goal of maintaining skin integrity. This unified perspective recognises the complexity of maintaining skin integrity, and integrates the influence of multiple contributing factors that arise within the patient, the patient's interaction with the hospital environment, as well as further interaction with acute situational stressors. The SSM accommodates multiple skin injuries into a single document, providing a unique and practical framework to guide clinicians in the understanding of the factors influencing skin integrity in the acute care patient. Overall, the SSM provides a new perspective that contrasts with the traditional siloed approach of managing skin integrity.

Positioning the patient's experience of a skin injury as a central outcome of the SSM is novel. While a patient may sustain a skin injury, the experience of that injury is embedded in the domain of wellbeing, or more accurately, the disturbance of wellbeing. According to Augustin and colleagues (2012), in order to assess wellbeing, it is essential to approach patients with a wound as a complex individual, with specific and individual needs across the domains of physical, mental, social and spiritual/cultural wellbeing and to focus on their experiences, as well as have a thorough understanding of their medical condition, quality of life, and how the wound impacts on their everyday living. The experience of a skin injury can encompass multiple dimensions that may interact. These experiences can include pain, infection, extended length of hospital stay, disfigurement, disability, or even

death. In contrast to traditional skin integrity frameworks where the patient experience of a wound is overlooked, the patient experience of the skin injury is a central construct of the SSM. Hence, the SSM provides a framework that guides the clinician to appreciate skin integrity and/or injury outcomes from the patient perspective.

Health care providers and patients can have very different perspectives and goals regarding the outcome of an episode of care. For example, the healthcare provider may be focused on the goals of healing the skin injury, preventing deterioration or preventing additional skin injuries. In contrast, the patient may be focused on the goals of dealing with pain associated with the skin injury, regaining functional ability following a skin injury, or needing to leave hospital in a timely manner (Porter, 2010). Healthcare outcomes are often measured against individual medical services that have been provided in individual departments, rather than measured against an entire episode of care (Porter, 2010; Pronovost et al., 2014). According to Porter (2010), outcomes are inherently multidimensional and should be a reflection of the success in meeting patient needs, rather than a narrow measure pertaining to fragmented aspects of a larger episode of care. A crucial first step in reducing the disparity between patient and consumer expectations is to locate the patient experience as a central healthcare outcome, which is a novel focus of the SSM.

Empirical support for the Skin Safety Model

The findings of this research support the inclusion of a number of constructs in the SSM. This research investigated one skin injury, (IAD), from a range of potential skin injuries identified by the SSM. Therefore, not all constructs of the SSM were tested by this research. However, the SSM was developed from empirical research, and expert consensus, which supports the construct validity of the model.

Answers to the Study 1 research questions revealed important prevalence data on incontinence, IAD and the products used for continence and perineal skin care. The high prevalence of incontinence and IAD in this study has implications for patient safety. Clinical governance is concerned with ensuring that health care delivery is safe and appropriate for the needs of the patient (Youngberg, 2013). As highlighted in Chapter 2 (Section 2.2.1), effective clinical governance is a critical determinant of patient safety and quality outcomes. This study provides prevalence

data that can guide skin safety protocols and procedures at the level of clinical governance. Given the responsibility that clinical governance has in responding to and managing prevalence data, the serious prevalence results revealed by Study 1 indirectly support the validity of including the construct of clinical governance in the SSM.

Study 1 also found that incontinence was associated with advancing age, while Study 2 found an association between urinary and faecal incontinence, advancing age, impaired mobility and under-nutrition. These elements are identified in the first construct of the model - multiple contributing factors to skin injury. Both studies highlighted that skin assessment, a systems factor in the first construct of the model, is vital for the accurate classification and differentiation of IAD, PI and clinical evidence of fungal infection. Both studies confirmed that the presence of exacerbating elements (that is urine and/or faeces and moisture), the second construct in the model, was necessary for the development of the potential skin injury (the third model construct), IAD. Study 1 also found that IAD was more common in those with semi-formed or liquid stool. Study 2 tested the final construct of the model, potential outcomes of skin injury by examining infection, in this case with *Candida albicans.* The research found that infection was a common outcome of IAD and incontinence. Overall, the research findings supported the inclusion of the constructs proposed in the SSM, specifically those applicable to IAD in the acute care patient.

Although the data presented in Publication 3 (Chapter 5) did not directly test the constructs of the SSM, the results underline the importance of the construct of clinical governance in the model. Clinical governance sets the patient safety and skin safety agenda within organisations (Youngberg, 2013), and is underpinned by information that guides decision making, evaluation of improvement or performance initiatives and informs resource allocation. In a similar way patient safety and quality are underpinned by the requirement for information (Australian Commission on Safety and Quality in Healthcare, 2010; Youngberg, 2013). Therefore, skin integrity prevalence data forms an integral component of the ability of the organisation to deliver safe care, and, as such, is required for effective clinical governance. Publication 3 presented a review of PI and IAD data that was collected over a five-year period. During that time, the important initiative of combining the PI and IAD prevalence data was introduced. This meant that the organisation had access to

previously unrecorded IAD data, and subsequently gained an insight into the considerable prevalence of the skin injury within the facility. Therefore, the findings presented in Publication 3 indirectly support the inclusion of clinical governance as a systems factor in the first construct of the SSM, as it is this body that has the responsibility to maintain and respond to prevalence data.

All of the included constructs and their relationships were based on evidence, so while not all constructs were tested in this research, their inclusion was considered valid. Furthermore, the significant results found in Studies 1 and 2 indicate that the model shows great promise in providing a new theory with which to address the challenges of maintaining skin integrity for older adults in contemporary hospitals.

9.2 DISCUSSION OF RESEARCH QUESTIONS

9.2.1 Prevalence of incontinence

In answer to research question 1 regarding the prevalence of incontinence in the acute care setting, Study 1 found that this prevalence in the Australian setting was 24%. Among the incontinence sub-sample, double incontinence (combined urinary and faecal) was the most common (50.5%), followed by faecal incontinence (35%), while the least prevalent type was urinary incontinence (14%).

The study contributed important data on the prevalence of incontinence and revealed that nearly one in four hospitalised patients were incontinent. The prevalence of incontinence in Study 1 is consistent with the findings of Junkin and Selekof (2007) who reported a prevalence of 19.7%. On the other hand, Ostaskiewicz and colleagues (2008) reported a prevalence of urinary incontinence ranging between 10%-43% and faecal incontinence ranging between 7%-33%. However, these results may be called into question because of the unreliable measurement of using self-reports. These data differ from the results of Study 1, although the difference may be due, in part, to the difference in study methods. Data on incontinence in the Australian acute care setting are limited (Ostaskiewicz et al., 2008), so Study 1 provides valuable insight to fill this gap.

Incontinence carries a high risk of developing IAD; therefore, it is vitally important to collect incontinence data in order to understand the extent of risk that exists for the development of IAD in a facility (Eresser et. al., 2005). Moreover, in order to develop IAD, a patient must first be incontinent (Beeckman et. al., 2015).

Study 1 found that almost one quarter of patients were incontinent, and, therefore, at risk of developing IAD. This data highlights the alarming number of patients at risk of developing a skin injury, namely IAD, within the acute care setting. As a component of the safety and quality obligations, healthcare providers are required to be cognisant of injury risks that exist for their patients (Youngberg et. al., 2013). However, the substantial risk that exists for the development of IAD in the acute care setting has been mostly unrecognised by healthcare providers. Gathering incontinence and IAD data in the same study highlights the imperative of understanding both conditions, and contributes valuable data that inform the level of risk that exists for IAD.

Furthermore, population ageing (United Nations, 2011; World Health Organisation, 2011), and the burgeoning prevalence of chronic disease and geriatric syndromes (Inouye et. al., 2007; Lakhan et.al., 2011; Scommegna, 2012; World Health Organisation, 2011), means that the prevalence of incontinence is set to rise. Therefore, the results from Study 1 demonstrate that the importance of improving the understanding of the prevalence of the condition in vital in informing management protocols and developing risk mitigation strategies for this important problem.

9.2.2 Prevalence of IAD

In answer to research question 2 regarding the prevalence of IAD in the acute care setting, Study 1 found that of the patients who were incontinent, the prevalence of IAD was an alarming 42%, whereas Junkin and Selekof (2007) found a much lower prevalence of IAD of 20%. The reasons for this difference are unclear, but may be due to the differences in IAD prevention and management protocols and product use between the research facilities.

Study 1 also found that almost a third of incontinent patients with IAD had an infection indicative of a fungal infection. Data for comparison is limited; however, the results of Study 1 differ from the results of the Junkin and Selekof study (2007) who reported the presence of a fungal rash in only 10% of incontinent patients. The reasons for the higher prevalence of a rash indicative of a fungal infection may be associated with the higher prevalence of IAD in Study 1 compared to the Junkin and Selekof (2007) study. The high prevalence of patients in Study 1 with IAD and a fungal rash indicates that infection associated with incontinence and IAD is a serious problem that merits further investigation.

The answers to research questions 1 and 2 reinforce the importance of having empirical knowledge of the prevalence of health conditions as a key component of quality healthcare delivery. In Australia, the National Health performance framework serves to support performance assessment planning and benchmarking in the health sector nationally, as well as supporting comparisons of Australia's health internationally (Australian Institute of Health and Welfare, 2014). The first construct in the National Health Performance Framework relates specifically to the necessity of understanding the prevalence of disease, disorder or injury or other health-related states (Australian Institute of Health and Welfare, 2014). Furthermore, the core constructs of the Australian Safety and Quality Framework are driven by information, consumer-centred and organised for safety (Australian Commission on Safety and Quality in Healthcare, 2010), highlighting the imperative for empirical information in the delivery of safe and high quality healthcare. It is clear that prevalence data is a key form of information guiding healthcare decision-making. In the skin integrity domain, understanding the prevalence of PIs has underpinned clinical governance decision-making in regard to patient and skin integrity programs and informed decisions regarding quality initiatives, strategic planning, resource allocation, clinical governance, benchmarking, as well tracking outcomes of clinical initiatives (Pieper & National Pressure Ulcer Advisory, 2012)

Beyond PI prevalence, it is increasingly important to understand the prevalence of other skin injuries in the acute care population. As discussed in Chapter 2, acute care patients may be exposed to multiple skin vulnerabilities, and there can be the temptation to utilise prevalence data in silos that is similar to the delivery of care in silos. While the specific prevalence data is valuable when used in this manner, it may be more be valuable when used to understand broader perspectives of skin integrity risk and injury within an organisation. Comparing and contrasting prevalence data from different injuries may reveal previously missed trends or relationships, or shed light on the influence a particular skin injury may have on another. For example, an organisation may focus enormous resources on lowering an unacceptable pressure PI rate, but be unaware of the prevalence of IAD or incontinence among its patients. The SSM can provide further insight into the overarching, holistic nature of skin vulnerability and help break down the tendency to utilise prevalence data in silos, that is, used to monitor one skin injury in isolation.

The use of the SSM can help illuminate relationships between various conditions or skin injuries. For example, an appreciation of the prevalence of incontinence is essential to understanding the magnitude of risk for IAD in a facility, while understanding the prevalence of incontinence and IAD can shed light on the scope of risk for *Candida* infection faced by these patients. Further, it is now understood that both incontinence and IAD are risk factors for pressure injury (Beeckman et al., 2014; Gefen, 2014; National Pressure Ulcer Advisory et al., 2014). Therefore, an appreciation of the prevalence of all of these conditions is imperative for the delivery of safe and quality healthcare.

To date, Study 1 is the only Australian acute care IAD prevalence study. The study was conducted in conjunction with the facility's annual pressure injury prevalence survey, and as such, demonstrated the utility of combining data collection for incontinence, IAD, and PI prevalence into a single activity. The conduct of Study 1 highlighted the need for consensus to be reached regarding IAD prevalence methodology, the use of an IAD categorisation instrument, formulae for calculating IAD prevalence, and also agreement on the format for reporting IAD prevalence data. Publication 3 of this thesis highlighted these issues, as well as reviewed pressure injury prevalence before and after the introduction of the combined protocol. This publication also discussed the practicability of combining the two protocols.

A significant contribution of Study 1 was that it highlighted the success of the combined pressure injury and IAD prevalence survey methodology. The research facility has subsequently, with minor adaptations, adopted the combined protocol as standard procedure for its annual pressure injury prevalence surveys. In addition, from 2012, as a result of the combined IAD and pressure injury prevalence survey protocol adopted in the research facility, the state-wide Queensland Bedside Audit (QBA) conducted by the Patient Safety and Quality Improvement Service Clinical Excellence Division developed and distributed new surveyor educational resources to facilitate improved inter-rater reliability for the state-wide pressure injury prevalence surveys, as well as including a category noting the presence of IAD on the data extraction form, (J. Whitemore, personal communication, November 18, 2015). These procedural changes adopted by the research facility and then by the

Queensland Patient Safety and Quality Improvement Service represent the immediate and significant impacts of this research program.

Prevalence studies are difficult and costly to perform and require a significant number of adequately trained personnel. In view of the high cost of conducting these studies, and the imperative that resultant data are valid and reliable, it is logical to combine the PI and IAD audits into a single protocol. While the cost-effectiveness of combining these activities was not evaluated in this research, the combined survey was conducted over the same two-day time period as was routinely allocated for the annual facility PI audit, using the same number of research assistants. This indicates that no additional time or personnel costs were incurred by the facility. However, the facility gained valuable and previously unknown data regarding the magnitude of incontinence, IAD, and fungal infection, thus adding enormous value to an already costly annual PI audit. Organisational awareness of the magnitude of these issues is a key first step in developing a strategic, multi-level response to skin integrity risks and challenges. Further, baseline data is vital for ongoing evaluation of interventions and benchmarking within the facility and between organisations.

A further contribution of Study 1 was the training of the 32 research assistants to accurately classify IAD and fungal infections, and differentiate them from PIs. Difficulty in distinguishing between these lesions is well-documented in the literature (Beeckman et al., 2008; Defloor et al., 2006; Doughty, 2012; D.Voegeli, 2011) and has implications for the accuracy of prevalence data, and more widely, clinical practice and organisational performance indicators. These research assistants gained valuable, new clinical assessment skills to take back to their respective clinical areas. However, most importantly, misclassification of these lesions has important implications for patient outcomes, in that the different skin injuries have different aetiologies and require different prevention and management. The inter-rater reliability training represented an important improvement in the skills of the research assistants to accurately classify pelvic skin lesions and thereby improve the accuracy of the prevalence data.

9.2.3 Products for continence and skin care

In answer to research question 3 regarding the products worn to manage incontinence and the products provided at the bedside for perineal skin care, Study 1 found that the most common aids worn by incontinent patients were disposable

incontinent briefs (77%); soap/water and disposable washcloths were the most common incontinence clean-up products at the bedside for incontinent patients (60%), moisturising products were present at the bedside of 34% of patients, with skin protection products present at the bedside of 57% patients. These results are consistent with the findings of Junkin and Selekof (2007) who found that 73% of patients wore disposable products to manage double incontinence, 54% of patients had washcloths at the bedside and that dimethicone containing skin protectant was the most common (47%) at the bedside. The current best practice recommendations for the prevention and treatment of IAD include appropriate management of incontinence, and a systematic and structured approach to skin care, following three steps: (i) gentle cleansing, (ii) skin protection and (iii) restoration of skin barrier function using a moisturising product where appropriate (Beeckman et. al., 2015). However the study found that the lack of available products at the bedside of many suggests there may be a gap between care recommendations and skin care practice.

9.2.4 Candida colonisation

In answer to research question 4 on whether colonisation with *Candida albicans* is more common at hospital admission in incontinent patients than in continent patients, Study 2 found that on admission there was a non-significant trend towards more frequent *Candida albicans* colonisation in incontinent than in continent patients. *Candida* was present at the perianal site in 43% of incontinent participants compared to 28% of continent patients. At the inguinal site, more incontinent (24%) patients were colonised with *Candida* compared to continent (14%) patients were colonised with *Candida.* Overall, on admission, colonisation was common, with *Candida* more frequently present (38%) at the perianal site, and lower (21%) at the inguinal site. There is limited data available from previous studies for comparison. However, Schulte et al. (2015) reported a lower perianal colonisation rate (19%) than the present study, with the average age of the sample being 56 years (*SD* = 15.2). The reasons for the differences in colonisation may be explained by the difference in the average age of the samples, which was 76 years (*SD* = 12.22) with the participants in Study 2. Data from Study 2 fills a gap in the comparative understanding of the epidemiology of *Candida* colonisation between continent and incontinent hospital patients, and reveals an important, potentially pathogenic reservoir of *Candida* in this group. It also provides important data to

inform future studies investigating *Candida* colonisation and infection in these patients.

9.2.5 Candida colonisation and IAD

In answer to research question 5 regarding the association between *Candida albicans* colonisation and clinical presentation of IAD at admission to hospital, Study 2 found that the prevalence of IAD was high (41%) among incontinent patients; however, clinical signs of a *Candida* infection were observed in less than half (18%) of patients with IAD. No significant association was found between *Candida* colonisation and the clinical presentation of IAD on admission to hospital.

Infection with *Candida albicans* has been found to be a common complication of IAD (Beeckman et al., 2015; Foureur et al., 2006; Gray et al., 2007); thus, it is feasible to expect a higher level of colonisation in patients with IAD. However, no significant association was found between *Candida* colonisation and clinical presentation of IAD on admission to hospital in the present study. No data from previous studies were available to compare *Candida albicans* colonisation levels in continent and incontinent patients, but the study by Foureur and collegues (2006) found that *Candida* prevalence in patients with IAD was high (63%). Although there was no continent group data reported in the Foureur and colleagues (2006) study, their finding is much higher than the prevalence of *Candida* colonisation in patients with IAD in Study 2. The reasons for the difference are unclear but may be due to the difference between patient admission time, with the patients in Fourer and colleagues (2006) study being long-term rehabilitation patients, compared to the patients in Study 2 whose data was collected within 48 hours of admission. It may be that length of stay in a healthcare facility influences *Candida* colonisation levels.

Study 2 advances the understanding of the epidemiology of *Candida albicans* colonisation in patients with IAD and the understanding of *Candida* colonisation in incontinent when compared to continent patients. Further, this research presents a new and novel frame of reference for investigating the association between *Candida albicans* and IAD. *Candida albicans* is the most prevalent human fungal commensal that can cause a wide range of mucosal and invasive diseases, with the primary source of both invasive and cutaneous *Candida* infection being endogenous. Importantly, colonisation with *Candida* is a necessary antecedent of infection

(Kumamoto, 2011; Moran et al., 2012; Odds et al., 2006). The gap in the understanding of the epidemiology of *Candida* colonisation in these patients was surprising, in light of the understanding of *Candida* colonisation being a precursor to *Candida* infection.

This is the first study to investigate the differences in *Candida albicans* colonisation between continent and incontinent patients and those with IAD in the acute care setting. It remains unclear whether incontinence predisposes to increased *Candida* colonisation, or whether it acts as a trigger for *Candida* infection in those already colonised. While the role of *Candida albicans* in the aetiology of diaper dermatitis has been investigated in the paediatric domain (Bonifaz et al., 2013; Dixon, Warin, & English, 1969; Dorko et al., 2003; Ferrazzini et al., 2003; Jefferson, 1966; Leyden & Kligman, 1978; Montes, Pittillo, Hunt, Narkates, & Dillon, 1971), this question has had limited consideration in adults with IAD (Foureur et al., 2006). Study 2 has provided valuable data that can contribute to the understanding of the natural history of *Candida albicans* colonisation in relation to continence status and in patients with IAD, which may in turn lead to improved understanding of the pathogenesis of *Candida* infection and IAD in incontinent patients. In addition, this data may inform sample size calculations for future studies. Study 2 also provides important baseline data and understanding of the feasibility of conducting a larger study to investigate these research questions.

9.2.6 Risk factors for Candida colonisation

In answer to research question 6 regarding risk factors for *Candida* colonisation, Study 2 found there was no significant association with *Candida* colonisation and gender, mobility, nutritional status, faecal frequency and quality, treatment with antibiotics, diabetes (Type 1 or 2), age, or body mass index (BMI). However, there was a non-significant trend towards an association between colonisation and greater antibiotic use, poorer nutritional status, and greater mobility limitation in the colonised group. These factors have been reported in the literature as predisposing to candidiasis or increased *Candida* colonisation levels (Al-Attas & Amro, 2010; Anaissie et al., 2003; Dorko et al., 2003; Ferrazzini et al., 2003; Fidel, 1999; Lionakis, 2014; Odds, 1988; Sobel et al., 1998). The results may have been non-significant due to the small sample size in this study. Study 2 has provided valuable data that addressed the gap in the understanding of possible risk factors for

Candida colonisation. This understanding of the risk factors for *Candida* colonisation in acute care patients may assist in developing targeted strategies that may prevent *Candida* infection.

9.3 LIMITATIONS

The following section presents a discussion of the research limitations and their potential impact on the outcome of the results.

The SSM presented in this thesis is not a risk assessment tool, rather, it is a framework designed to guide clinicians and healthcare providers in the recognition and consideration of the complexity of skin injury aetiology and outcomes. Although the model is comprehensive and based on expert consensus and evidence, it is a new model that requires refinement from future research.

A limitation of this research was the small sample size and the generalisability of the results. Study 1 was conducted at a single centre, while data for Study 2 were collected in a single admitting service, and a single centre. Therefore, the results may be limited in their generalisability to other acute care specialties or settings. Study 2 was a pilot study conducted to test the feasibility of the study design, recruitment, study instruments microbiological sampling, to provide initial estimates of colonisation rates in this population, and, to investigate associations between variables of interest, that is, *Candida* colonisation, continence status and IAD. Post hoc power calculations showed that this study had 80% power to detect a difference of 35% (for example 45% in the incontinent group compared to 10% in the continent group). The observed differences were much smaller (15% at the perianal site and 10% at the inguinal site), and may help inform sample size calculations in future studies. Larger, multi-site studies with recruitment from a range of acute care specialties would be of value in the future to improve the precision and generalisability of the results.

Several limitations need to be acknowledged with regard to patient recruitment. The intrusive nature of direct clinical examination and microbiological sampling of the pelvic girdle can be uncomfortable and may have constrained enrolment (69% for Study 1). Every effort was made to enrol all eligible participants. Of the patients who declined to participate in Study 2, 48% informed the researcher they were not comfortable with the skin inspection and the specimen collection

aspects of the study, while 33% respondents made comments that reflected the belief that incontinence was an ‘old person’s problem’ and therefore not relevant to them. Data was not collected on the age of eligible patients that declined to participate. Overall, the majority of patients who declined to participate in Study 2 were younger than age 50, which may mean that sampling may have been biased with regard to the age of participants.

A further limitation of the study regarding recruitment and enrolment was that substitute decision-makers declined participation for four patients who were doubly incontinent. This meant that the recruitment target of 28 participants in the doubly incontinent group was not met, which may have biased the study results. In each case, the reason cited for non-participation by the substitute decision-maker was that the patient was not incontinent. This discrepancy between the bedside nurse report and the family member's perception regarding the continence status of their relative may be a reflection of the broader stigma, fear, and shame associated with incontinence, and subsequently presents a barrier for researchers in this area.

In addition, a limitation that may have decreased recruitment, particularly for the doubly incontinent group, was research participation fatigue. This was stated by 14% of patients as the reason for declining participation. These patients made comments to the researchers, such as ‘I really want to help, but I have had three different groups of medical students examine me today and I’m exhausted’, ‘they asked me to be a patient for the doctor’s exams and I have been downstairs for three hours being interviewed by student doctors’, ‘I’m already in another study’. This meant that potentially eligible patients were unable to be enrolled.

A further limitation of this study was the number of patients that did not reach the study endpoint, which was deemed to be the collection of two or more sets of data. This, in turn, limited collection of longitudinal data. The primary reason many patients did not reach the study endpoint was a short length of hospital stay (that is, less than three days). Of the 81 patients enrolled, more than half (58%) had only one set of data collected and were discharged prior to any further data collection, with 42% of patients having two sets of data collected, followed by 7% of patients having three sets of data collected, and only one patient having four sets of data collected (see Figure 9.1).

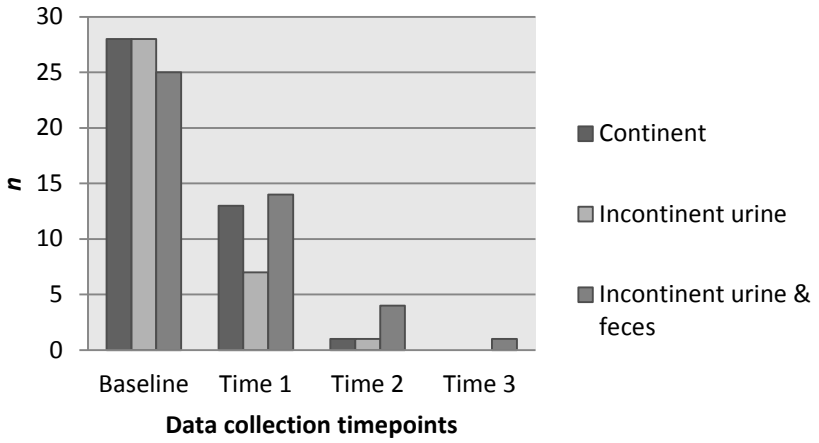


Figure 9.1 Participant numbers at data collection time-points.

The low number of participants with longitudinal data sets meant that time-to-event data analyses, although preferable, were not possible; therefore, inferences could not be made regarding the role of *Candida* colonisation in the pathogenesis of IAD. In response to the low number of patients reaching the study endpoint, the research team and statistician conferred, and it was decided to amend the research design from an observational time-to-event cohort study to an observational study, and recruit all eligible incontinent patients at baseline, regardless of IAD status.

A further limitation was that patients experienced multiple and competing demands on their time, energy and physical presence, which limited opportunities to collect repeat data, which reduced longitudinal data available for analyses. Reduced length of hospital stays, intensive patient interventions, and reduced hospital bed numbers result in increased care intensity (Aitken et al.; 2014). Increased care intensity is consistent with the recruitment experience in this study and the comments made to researchers during this process. Many participants reported that several medical teams had visited them in one morning, and some had also been visited by several allied health professionals. Coupled with the number of health professionals delivering care was the burden for the patients of blood tests, x-rays, or procedures. This meant that research nurses often made multiple attempts to collect data but the patient was either off ward, with a care provider, or too exhausted, resulting in repeat data not being collected.

Other limitations of the study resulted from the instrument used. The IAD Severity Assessment Tool (SAT) was used to measure IAD severity (Kennedy &

Lutz, 1996), which requires researchers to estimate the area and depth of skin breakdown, which is difficult and subjective. This subjectivity may have influenced data accuracy and, therefore, reduced the reliability of the results.

A further limitation was that *Candida albicans* was the only species reported in a semi-quantitative manner by the laboratory. This may have limited the specificity of the results. While the study showed that *Candida albicans* was the most frequent species present, the level of non-*albicans* colonisation had the highest severity. The decision not to specify other non-*albicans* species present on microbiological culture, or to report the semi-quantitative results on non-*albicans* culture was based on extensive literature identifying *Candida albicans* as the most common human fungal coloniser and pathogen (Fidel, 1999; Moran et al., 2012; Odds, 1988). Future studies would benefit from identifying all *Candida* species that may be present.

Both studies collected a large proportion of categorical and dichotomous data. As a result, data analyses and subsequent results may have lacked precision, compared to the use of continuous data where possible. Further studies would benefit from larger sample sizes and the use of rating scales, where appropriate, to allow for the collection of continuous variables, and, therefore, the utilisation of more sophisticated statistical analyses.

9.4 CHAPTER SUMMARY

The combined significance of the research program lies in its contribution of new and unique insights into the phenomenon of IAD in the acute care setting in broad and specific ways. The development of the SSM provides comprehensive and holistic framework to guide skin integrity care in the acute care patient, as well as a framework to guide the research for this thesis. This broad view of the requirement to maintain skin integrity in the acute care setting was followed by research that investigated the prevalence of IAD and incontinence in the acute care setting, and *Candida albicans* colonisation rates in continent and incontinent patients and those with IAD. Both of these studies investigated specific aspects of maintaining skin integrity. Significant gaps were addressed in the understanding of the prevalence of IAD in acute care, and the understanding the natural history of *Candida* colonisation in this group.

In addition, several constructs of the SSM were tested by the research. There is significant evidence to support the inclusion of these constructs in the model, resulting in a new theoretical model that is based on empirical evidence. Underpinned by the SSM, the results showed an understanding of IAD and associated infection at this specific level is essential to inform the broader understanding of the phenomenon of IAD in the acute care setting. The SSM can help guide the understanding of the contextualisation of IAD in terms of its relationships, interactions, and implications for a range of other skin integrity challenges and outcomes in the acute care setting.

The following chapter presents a summary of the research findings, recommendations arising from this research, and conclusions of the thesis.

Chapter 10: CONCLUSION AND RECOMMENDATIONS

10.1 INTRODUCTION

The final chapter of this thesis highlights the main findings and contribution of the research. This is followed by recommendations for clinical practice, education, policy, and future research. The final section presents the conclusions for this thesis.

The aim of this thesis was to explore the phenomenon of incontinence-associated dermatitis (IAD) in the acute care setting. This involved an investigation of the prevalence of IAD, and an exploration of the epidemiology of *Candida* colonisation and infection associated with continence status and IAD in acute care patients. Furthermore, this research aimed to present a new conceptual model in which to reconceptualise the phenomenon of IAD within the broader domain of maintaining skin integrity in this setting. An additional aim of the research was to test key constructs of the proposed model

10.2 RESEARCH CONTRIBUTION

The research program for this thesis provided several significant contributions in theory and research findings.

A significant contribution of Study 1 was to highlight the considerable and previously un-identified prevalence of IAD in the Australian acute care setting. IAD is one disruption to skin integrity in a range of possible nosocomial skin injuries in older acute care patients. However, the magnitude of this significant skin injury was unknown in the Australian acute care setting, with limited data available on its prevalence in the acute care setting internationally. In addition, *Candida* infection is reported to be a common complication of IAD. Even though it is understood that *Candida* is the most common human fungal commensal organism, there was little data available to quantify *Candida* colonisation rates in continent compared to incontinent patients in order to understand the association between continence status and *Candida* colonisation levels. Furthermore, it was unknown if differences in

Candida colonisation levels existed in incontinent patients with or without IAD, or if there were risk factors for *Candida* colonisation in this group.

This thesis has made a considerable contribution to the understanding of the phenomenon of IAD in the acute care setting. Study 1, the first of its kind in Australia, shed light on the magnitude of the problem, revealing that a significant number of acute care patients were incontinent and, therefore, at risk of developing IAD, while a significant number of these had actually developed IAD. Study 2, also the first of its kind, investigated the unique question of *Candida* colonisation levels and possible associations with continence and/or IAD status, as well as potential risk factors for *Candida* colonisation. While no significant association was demonstrated between continence status and IAD, Study 2 demonstrated a non-significant trend towards higher *Candida* colonisation levels at the perianal and inguinal sites in incontinent compared to continent patients. However, no significant association was demonstrated between *Candida* colonisation and incontinent patients with or without IAD. Furthermore, no factors emerged as risk factors for *Candida* colonisation in this group. These findings offer new empirical evidence that highlights an association between incontinence and *Candida* colonisation, which has not previously been considered in adults. This novel frame of reference regarding *Candida* colonisation, continence status and IAD offers a new direction for future research. Furthermore, understanding patterns of *Candida* colonisation in these patients may help to predict patients who may be at risk of colonisation or infection, which in turn may assist in developing prevention and treatment strategies in the future.

The most important contribution of the SSM is to offer a novel comprehensive and holistic conceptualisation of skin injury for acute care patients. The Skin Safety Model proposes relationships between a multitude of risk factors that may influence the development of a range of skin injuries. In addition, it proposes risk factors that may not traditionally be conceptualised for skin integrity, but which can have a direct impact on skin integrity outcomes. A salient example of this is the direct association between the prevalence of incontinence and the subsequent magnitude of risk the development of IAD in a facility.

10.3 RECOMMENDATIONS

From the results of the studies in this thesis, eight recommendations are made in the domains of clinical practice, education, healthcare policy and future research.

10.3.1 Clinical practice

Recommendation 1: Adopt the constructs in the Skin Safety Model to facilitate comprehensive, holistic skin integrity care.

An appreciation of the concepts proposed in the Skin Safety Model in clinical practice can encourage clinicians and healthcare providers to reframe the manner in which skin integrity is conceptualised and managed for older acute care patients. The findings from the research program suggest that a fundamental change is required, that is, a paradigm shift away from preventing a specific skin injury (a traditional siloed, specialist approach) and toward a broader, holistic goal of skin injury prevention. This may include preventing pressure injuries, as well as IAD and skin tear prevention, thus providing holistic skin integrity care. Depending on an individual patient's circumstances, it may require implementing a suite of interventions that are not traditionally associated with maintaining skin integrity. For example, a mobility and toileting program could have positive impacts on functional status and continence, while simultaneously reducing the risk of IAD, *Candida* infection, and pressure injury.

Recommendation 2: Combine pressure injury, IAD, and incontinence prevalence surveys into a single protocol.

The Skin Safety Model proposes inter-relationships between a range of diverse, yet shared risk factors for skin injury. Consequently, improving understanding of the prevalence of these diverse skin injury risks and skin injuries in a facility is imperative for the delivery of holistic skin integrity care. Prevalence surveys that produce accurate and valid data are an essential for underpinning clinical and governance decisions that ultimately influence skin integrity outcomes.

Support for this recommendation was demonstrated in Publication 3 of this thesis. The single IAD, incontinence and PI survey protocol, conducted for Study 1 of this research, provided the healthcare facility with a multitude of valuable skin integrity data that was not previously collected by the facility. As a result of this research, the facility has adopted this combined protocol, and is likely to have improved understanding of the skin integrity risks that exist for its patients.

However, in the future, it would also be prudent to include skin tears in in a skin inspection prevalence survey, allowing benchmarking of a range of common hospital-acquired skin wounds.

Recommendation 3: Include IAD and incontinence prevalence data with pressure injury data for benchmarking activities.

The prevalence of these other nosocomial skin injuries warrants inclusion in skin integrity benchmarking activities. Benchmarking is a process of comparative evaluation in healthcare, whereby an organisation can measure and compare its performance and processes with others and identify high levels of performance, as well as areas for improvement (Ettorchi-Tardy, Levif, & Michel, 2012). Benchmarking is a component of continuous quality improvement and can take place within an organisation, as well as externally (Ettorchi-Tardy et al., 2012). According to Eagar and colleagues (2013) the strongest evidence regarding improving quality and safety exists for the use of benchmarking systems. Pressure injury prevalence data is widely used for benchmarking (Stotts et al., 2013); however, including IAD and incontinence prevalence data is consistent with the ultimate goal of improving quality and safety specifically in the domain of maintaining skin integrity.

Recommendation 4: Employ microbiological testing to confirm the presence of incontinence- associated Candida infection.

The results of Study 2 suggested the need to confirm incontinence-associated *Candida* infection with microbiological testing in order to improve diagnostic accuracy. The current clinical practice is for presumptive diagnosis and empirical treatment of a *Candida*-like rash. This may lead to over- or under-diagnosis of the infection. Therefore, microbiological testing to confirm the presence of *Candida,* coupled with careful consideration of the clinical presentation is likely to improve the accuracy of diagnosing incontinence-associated *Candida* infection.

10.3.2 Education

Recommendation 5: Develop and deliver skin integrity education programs to health professionals, particularly at undergraduate and postgraduate levels that focus on comprehensive and integrated skin integrity models of care.

Several recommendations for education at different levels arise from this research. Firstly, the need to deliver more comprehensive skin integrity education programs to health professionals, with the focus on understanding and addressing complexity and diversity of skin integrity risk and skin vulnerability in the acute care

patient. These relationships are highlighted in the Skin Safety Model. Furthermore, emphasis on the patient experience of skin injury and input from affected consumers in the development and delivery of skin integrity education programs is likely to assist in strengthening the delivery of patient-centred skin care. These education programs may be best provided at undergraduate and postgraduate levels for nurses, medical practitioners, and other healthcare providers, as well as professional development programs for experienced professionals. Secondly, as study one highlighted, clinicians face challenges when differentiating pressure injuries and IAD. Therefore, it is imperative that any education programs regarding pressure injury severity classification contain a mandatory training on how to differentiate between pressure injury, IAD, and fungal infections.

Finally, both undergraduate and postgraduate education programs should include education specifically designed to improve the accuracy of the diagnosis of incontinence-associated *Candida* infection, including specific training on the clinical presentation of the infection, as well as the requirement for microbiological confirmation.

10.3.3 Healthcare policy

Recommendation 6: Include strategies in future health and policy standards that acknowledge and address the broader dimensions of maintaining skin integrity.

In Australia, the National Safety and Quality Health Service (NSQHS) standards provide a nationally consistent statement about the level of care consumers can expect. These standards are linked to the national safety and quality accreditation scheme for healthcare service organisations, and they include an entire standard concerned with preventing and managing pressure injuries. (Australian Commission on Safety and Quality in Healthcare, 2015). Feedback was provided by the PhD candidate to the NSQHS (based on Publications 1 and 2 of this thesis) recommending that that future standards include strategies that encompass the broader dimensions of maintaining skin integrity, rather than the current focus on PI prevention only. There is scope to implement innovative, evidence-based policies and protocols that facilitate new and comprehensive approaches to maintaining skin integrity.

The facility involved in this research has adopted these recommendations in response to the results of this research program. The review and expansion of the terms of reference of the Pressure Injury Prevention Committee means that the

committee now has governance and leadership responsibilities for a range of iatrogenic skin injuries, including pressure injuries IAD and skin tears. Accompanying the new terms of reference for the committee was an official name change from the Royal Brisbane and Women's Hospital (RBWH) Pressure Injury Prevention Committee to the RBWH Skin Safety Committee (personal communication from Kelly McDonagh, 30th November, 2011). In addition, combined pressure injury and IAD prevalence surveys are now the standard protocol at this facility. This example of the implementation of this recommendation offers a guide for its adoption by other facilities and organisations.

Furthermore, in Queensland annual state-wide pressure injury prevalence surveys are conducted by the Patient Safety and Quality Improvement Service Clinical Excellence Division and are known as the Queensland Bedside Audit (QBA). As a result of the success of the combined IAD and pressure injury prevalence survey protocol adopted in the research facility, in 2012, QBA developed and distributed new surveyor educational resources to facilitate improved inter-rater reliability for the state-wide PI surveys, as well as an updated data survey instrument that included a category noting the presence of IAD (J. Whitmore, personal communication,18th November, 2015). The implications of the adoption of this recommendation are twofold. Firstly, organisations could gain a comprehensive understanding of the risk and burden of nosocomial skin injury, beyond PI, that exists in their organisations, and secondly, this broad understanding of skin integrity status affords opportunities to formulate and implement comprehensive and holistic skin safety policies, procedures and quality improvement activities, that can be innovative, efficient and effective. Future research

Recommendation 7: Further testing of the Skin Safety Model.

The findings of this thesis provide a basis for further research in several areas. Further testing is required to validate the constructs of the SSM in a variety of clinical settings with larger sample sizes. In addition, further research is required to enable the operationalisation of the model.

Recommendation 8: Replicate Studies 1 and 2 in larger, multi-centre studies.

Replicating Study 1 involving large patient cohorts both in Australia and internationally would provide more comprehensive epidemiological data regarding the prevalence of IAD, incontinence, and fungal infection. In addition, this could

serve as baseline data for benchmarking these conditions. However, further research is required to reach international agreement regarding standardised methods for IAD data collection.

Study 2 could be replicated in multi-centre research sites, with larger sample sizes that could provide a more powerful test of hypotheses. Furthermore, Study 2 tested for *Candida albicans* only, and while this is the most frequent colonising organism, future studies would benefit from testing for all *Candida* species to gain a more comprehensive understanding of the patterns of colonisation of all *Candida* species in these patients.

Due to the recruitment challenges faced in Study 2 associated with the difficulty in collecting longitudinal data, the research aim of determining the aetiological role *of Candida* colonisation in the development of IAD was not addressed. An important consideration in future studies would be to ensure their design and recruitment strategies facilitate optimum enrolment and retention, as well as to plan for an adequate recruitment timeframe in order to collect collection of longitudinal data.

10.4 CONCLUSION

This thesis has advanced the understanding of the phenomenon of IAD in the acute care setting and delivered a new skin integrity framework in which to contextualise this skin injury. The objectives of this research have been fulfilled on several levels. Overall, it can be seen that this thesis has addressed several significant gaps in the skin integrity field of study. Firstly, the development of the SSM offered a previously unavailable comprehensive and integrated framework to guide skin integrity care in the acute care setting. Secondly, the understanding of the burden of IAD in the Australian acute care setting was unknown. Study 1 addressed this lack of quantitative data, which was the first IAD prevalence study in an Australian acute care hospital. Finally, understanding of the epidemiology of *Candida albicans* colonisation in relation to continence status and IAD was inadequate. Study 2 addressed this gap. In turn, data from Studies 1 and 2 provided validation of the SSM that could facilitate comprehensive, holistic, evidence-based decision-making and practice in the skin integrity field of practice.

The Skin Safety Model offers a novel framework in which to contextualise a range of nosocomial skin injuries, including IAD, into a single approach for application in the acute care setting. The model offers a new, holistic perspective that unifies divergent and siloed approaches to maintaining skin integrity. Drawing together the critical determinants of nosocomial skin injury, as well as multiple potential skin injuries into a single model, the SSM positions the patient experience of the injury rather than the actual injury as the central outcome. This overarching approach to maintaining skin integrity in the acute care patient sets this framework apart from others as a new approach to the conceptualisation of skin integrity care in this setting. Furthermore, the SSM can guide understanding of the complexity and multidimensional nature of skin vulnerability, as well as the imperative of maintaining skin integrity in this setting. The model has implications for shifting the paradigm of skin care from a siloed, fragmented approach concerned with preventing a PI to a comprehensive and integrated approach to maintaining skin integrity. This shift in skin integrity care may improve patient outcomes, patient safety and quality initiatives, nosocomial skin injury risk assessment and management, as well as influence skin integrity research.

Specifically, Study 1 revealed the alarming prevalence of IAD in the Australian setting. IAD is a painful, costly condition that exposes patients to the risk of the serious complications of perineal infection or PI. However, the burden of this serious skin injury was unknown in Australia. The study presented compelling evidence that IAD is a skin injury revealing that almost one quarter of hospitalised patients were incontinent and, therefore, at risk of developing IAD, with more than 40% of these incontinent patients having developed IAD. This data has implications for patient safety and the obligation to prevent nosocomial injury, and warrants urgent attention.

Study 2 presented an innovative perspective, advancing understanding of and investigating previously unexplored dimensions of the epidemiology of *Candida* colonisation, continence status and IAD. The results of Study 2 provide previously unavailable empirical data on *Candida* colonisation, with specific comparisons of continent and incontinent patients. The study also presents unique quantitative data on the *Candida* colonisation levels of patients with IAD who had not developed clinical evidence of a *Candida* infection.

Internationally, contemporary healthcare faces the challenge of reform. The drivers for healthcare reform can be found in the increasing demand for healthcare services as a result of ageing populations, growing rates of chronic disease, increased consumer expectations, and the requirement to deliver healthcare that is safe and of high quality (American Nurses Association; 2008; Australian Government, 2014; Shortell & Singer, 2008). There are urgent imperatives for modern healthcare to transition to a system whereby the complex, multidimensional, and long-term healthcare needs of patients can be accommodated in effective, efficient, and equitable ways, with quality and safety at the heart of all reform (American Nurses Association; 2008; Australian Government, 2014; Shortell & Singer, 2008). As such, quality and safety imperatives form an integral element in healthcare reform. In fact, these values of safety, information and consumer-centered care underpin the Australian Safety and Quality Framework (Australian Commission on Safety and Quality in Healthcare, 2010). At the heart of healthcare reform is a requirement for new paradigms that recognise and accommodate the complexity of the contemporary patient. The Skin Safety Model provides such a paradigm, is consistent with the goals of healthcare reform, and offers a clinical reframe of the complex skin integrity needs of acute care patients. An imperative of this recalibration of the approach to skin integrity management in contemporary healthcare is that it is evidence-based and consumer-centred. These dimensions of skin integrity care are addressed by this thesis.

In the coming years, the number of older, incontinent patients is set to rise in acute care settings. Consequences of incontinence include the risk of developing IAD, the risk of developing an incontinence-associated *Candida* infection, or even developing a pressure injury. These are serious sequale of incontinence and represent challenges for patients and healthcare providers alike. By providing a new framework in the form of the Skin Safety Model to guide clinicians in understanding the complexities of skin safety in vulnerable older adults, as well as presenting data regarding the prevalence of IAD, and data enhancing the understanding of *Candida* colonisation, this thesis has made a substantial contribution towards a deeper and more comprehensive understanding of the phenomenon of IAD in the acute care setting.

REFERENCES

Abrams, P., Andersson, K. E., Birder, L., Brubaker, L., Cardozo, L., Chapple, C., . . . & Wyndaele, J. (2010). Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and faecal incontinence. *Neurourology and Urodynamics, 29*(1), 213-240.

Abrams, P., Blaivas, J. G., Stanton, S. L., & Andersen, J. T. (1988). Standardisation of terminology of lower urinary tract function. *Neurourology and Urodynamics, 7*(5), 403-427.

Admi, H., Shadmi, E., Baruch, H., & Zisberg, A. (2015). From research to reality: Minimizing the effects of hospitalization on older adults. *Rambam Maimonides Medical Journal, 6*(2)e0017.

Agarwal, E., Ferguson, M., Banks, M., Bauer, J., Capra, S., & Isenring, E. (2012). Nutritional status and dietary intake of acute care patients: Results from the Nutrition Care Day Survey 2010. *Clinical Nutrition, 31*(1), 41-47.

Agency for Healthcare, Research and Quality, Patient Safety Network, (n.d.). Retrieved from https://psnet.ahrq.gov/glossary/p

Ahmed, N. N., & Pearce, S. E. (2010). Acute care for the elderly: A literature review. *Population Health Management, 13*(4), 219-225.

Aiken, L., Sloane, D., Bruyneel, L., Van den Heede, K., Griffiths, P., Busse, R., . . . & Sermeus, W. (2014). Nurse staffing and education and hospital mortality in nine European countries: A retrospective observational study. *The Lancet, 383*(9931), 1824-1830.

Al-Attas, S., & Amro, S. (2010*). Candida* colonization, strain diversity, and antifungal susceptibility among adult diabetic patients. *Annals of Saudi Medicine, 30*(2), 101-108.

Ali, S., & Yosipovitch, G. (2013). Skin pH: From basic science to basic skin care. *Acta Dermato-Venereologica*.

Aly, R., Shirley, C., Cunico, B., & Maibach, H. (1978). Effect of prolonged occlusion on the microbial flora, pH, carbon dioxide and transepidermal water loss on human skin. *Journal of Investigative Dermatology, 71*(6), 378-381.

American Nurses Association. (2008). ANA's Health System Reform Agenda. American Nurses Association. Retrieved from http://www.nursingworld.org/Content/HealthcareandPolicyIssues/Agenda/ANAsHealthSystemReformAgenda.pdf

Amlung, S., Miller, W., & Bosley, L. (2001). The 1999 National Pressure Ulcer Prevalence Survey: A benchmarking approach. *Advances in Skin & Wound Care, 14*(6), 297-301.

Anaissie, E., Pfaller, M., & McGinnis, M. (2003). *Clinical mycology*. New York Churchill Livingstone.

Anderson, K. (2010). A review of healthcare reform in the United States and in Alaska. *International Journal of Circumpolar Health, 69*(5), 424-436. Retrieved from http://gateway.library.qut.edu.au/login?url=http://search.proquest.com/docview/851367082?accountid=13380

Antonio, T., & Conrad, K. (2013). Clinical and economic improvements in pressure injury care at Ballarat Health Services. *Wound Practice and Research* 2013;21(1):4-

Arain, M., Campbell, M., Cooper, C., & Lancaster, G. (2010). What is a pilot study? A review of current practice and editorial policy. *BioMed Central Medical Research Methodology,10*(1), 67-74.

Arnold-Long, M., Reed, L., Dunning, K., & Ying, J. (2009). Incontinence-associated dermatitis in a long-term acute care facility: A prospective study. 41st Annual Wound, Ostomy and Continence Nurses Annual Conference, St. Louis, Missouri, June 6-10, 2009. *Journal of Wound Ostomy & Continence Nursing, 36*(3S), S59-S59

Arnold-Long, M., Reed, L., Dunning, K., & Ying, J. (2011). Incontinence-associated dermatitis in a long-term acute care facility: Findings from a 12 week prospective study. *Journal of Wound Ostomy & Continence Nursing, 38*(3S), S7-S7

Ashmore, S., Ruthven, T., & Hazelwood, L. (2011). Stage 1: Preparation, planning and organisation of clinical audit. In R. Burgess (Ed.), *New principles of best practice in clinical audit* (2nd ed., pp. 23-58). Oxford: Radcliffe Pub. association.,

Augustin, M., Carville, K., Clark, M., Curran, J., Flour, M., Lindholm, C., … &Young, T. (2012). International consensus: Optimising wellbeing in people living with a wound. An expert working group review. London: *Wounds International*. Retrieved from http://www.woundsinternational.com/media/issues/554/files/content_10309.pdf

Australian Commission on Safety and Quality in Healthcare (2010). Australian safety and quality framework for healthcare. Retrieved from http://www.safetyandquality.gov.au/wp-content/uploads/2012/04/Australian-SandQ-Framework1.pdf

Australian Commission on Safety and Quality in Healthcare (2012). Safety and Quality Improvement Guide Standard 1:Governance for Safety and Quality in Health Service Organisations. Sydney Retrieved from http://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard1_Oct_2012_WEB1.pdf

Australian Commission on Safety and Quality in Healthcare. (2015). *National Safety and Quality Health Service Standards Version 2: Consultation draft*. Retrieved from Sydney: http://www.safetyandquality.gov.au/our-work/accreditation-and-

the-nsqhs-standards/current-consultations/piloting-of-the-draft-version-2-of-the-nsqhs-standards/Australian Government.

Australian Government. (2016). Ageing. Retrieved from http://www.aihw.gov.au/ageing/

Australian Institute of Health and Welfare. (2014). *Australia's Health 2014.* Retrieved from Canberra ACT, Australia: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129547577

Australian Institute of Health and Welfare. (2016). *25 years of health expenditure in Australia 1989–90 to 2013–14.* Retrieved from; http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129554396

Australian Institute of Health and Welfare. (2012). Health expenditure Australia 2010-11. *Health and welfare expenditure series no. 47.* Retrieved from http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737423003

Australian Wound Management Association. (2001). *Clinical Practice Guidelines for the prediction and prevention of pressure ulcers.* (1st ed.). West Leederville: Cambridge Publishing.

Australian Wound Management Association. (2012). *Pan Pacific clinical practice guideline for the prevention and management of pressure injury*. Cambridge Publishing, Osborne Park, Western Australia:

Aydin, C., Donaldson, N., Stotts, N. A., Fridman, M., & Brown, D. S. (2015). Modeling hospital-acquired pressure ulcer prevalence on medical-surgical units: Nurse workload, expertise, and clinical processes of care. *Health Services Research, 50*(2), 351-373.

Baharestani, M., Black, J., Carville, K., Clark, M., Cuddigan, J., Dealey, C., . . . & Takahashi, M.(2010). International Review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A Consensus document. Retrieved from; http://www.woundsinternational.com/consensus-documents/view/international-review-pressure-ulcer-prevention-pressure-shear-friction-and-microclimate-in-context-1

Baharestani, M., Black, J., Carville, K., Clark, M., Cuddigan, J., Dealey, C., . . . & Sanada, H. (2009a). Dilemmas in measuring and using pressure ulcer prevalence and incidence: An international consensus. *International Wound Journal, 6*(2), 97-104.

Baharestani, M., Black, J. M., Carville, K., Clark, M., Cuddigan, J., Dealey, C., . . . & Sanada, H. (2009b). International Guidelines. Pressure ulcer prevention: prevalence and incidence in context. A consensus document. *Wounds International*. Retrieved from http://www.woundsinternational.com/other-resources/view/international-guidelines-pressure-ulcer-prevention-prevalence-and-incidence-in-context-a-consensus-document

Barlow, A., & Chattaway, F. (1969). Observations on the carriage of *Candida albicans* in man. *British Journal of Dermatology, 81*(2), 103-106.

Baroni, A., Buommino, E., De Gregorio, V., Ruocco, E., Ruocco, V., & Wolf, R. (2012). Structure and function of the epidermis related to barrier properties. *Clinics in Dermatology, 30*(3), 257-262.

Baumgarten, M. (1998). Methodology. Designing prevalence and incidence studies. *Advances in Wound Care, 11*(6), 287-293.

Beeckman, D. (2016) A decade of research on Incontinence-Associated Dermatitis (IAD): Evidence, knowledge gaps and next steps. *Journal of Tissue Viability*. Retrieved from http://dx.doi.10.1016/j.jtv.2016.02.004

Beeckman, D., Campbell, J., Campbell, K., Chimentao, D., Coyer, F., Domansky, R., …Wang, L. (2015). Proceedings of the Global IAD expert Panel. Incontinence-associated dermatitis: Moving prevention forward. *Wounds International*. Retrieved from http://www.woundsinternational.com/media/other-resources/_/1154/files/iad_web.pdf

Beeckman, D., Defloor, T., Demarré, L., Van Hecke, A., & Vanderwee, K. (2010). Pressure ulcers: Development and psychometric evaluation of the Attitude towards Pressure ulcer Prevention instrument (APuP). *International Journal of Nursing Studies, 47*(11), 1432-1441.

Beeckman, D., Schoonhoven, L., Boucque, H., Van Maele, G., & Defloor, T. (2008). Pressure ulcers: e-learning to improve classification by nurses and nursing students. *Journal of Clinical Nursing, 17*(13), 1697-1707.

Beeckman, D., Schoonhoven, L., Fletcher, J., Furtado, K., Gunningberg, L., Heyman, H., . . . & Defloor, T. (2007). EPUAP classification system for pressure ulcers: European reliability study. *Journal of Advanced Nursing, 60*(6), 682-691.

Beeckman, D., Schoonhoven, L., Verhaeghe, S., Heyneman, A., & Defloor, T. (2009). Prevention and treatment of incontinence-associated dermatitis: Literature review. *Journal of Advanced Nursing, 65*(6), 1141-1154.

Beeckman, D., Van Lancker, A., Van Hecke, A., & Verhaeghe, S. (2014). A systematic review and meta-analysis of incontinence-associated dermatitis, incontinence, and moisture as risk factors for pressure ulcer development. *Research in Nursing & Health, 37*(3), 204-218.

Beeckman, D., Vanderwee, K., Demarre, L., Paquay, L., Van Hecke, A., & Defloor, T. (2010). Pressure ulcer prevention: Development and psychometric validation of a knowledge assessment instrument. *International Journal of Nursing Studies, 47*(4), 399-410.

Beeckman, D., Verhaeghe, S., Defloor, T., Schoonhoven, L., & Vanderwee, K. (2011). A 3-in-1 perineal care washcloth impregnated with dimethicone 3% versus water and pH neutral soap to prevent and treat incontinence-associated dermatitis: A randomized, controlled clinical trial. *Journal of Wound Ostomy & Continence Nursing, 38*(6), 627-634.

Beeckman, D., Woodward, S., Rajpaul, K., & Vanderwee, K. (2011). Clinical challenges of preventing incontinence-associated dermatitis. *British Journal of Nursing,20*(13), 784-790.

Beitz, J. (2006). Fecal incontinence in acutely and critically ill patients: Options in management. *Ostomy Wound Management, 52*(12), 56-58, 60, 62-56.

Benoit, R., & Mion, L. (2012). Risk factors for pressure ulcer development in critically Ill patients: A conceptual model to guide research. *Research in Nursing & Health, 35*(4), 340-362.

Benson, R. A., Slobody, L. B., Lillick, L., Maffia, A., & Sullivan, N. (1947). A new treatment for diaper rash preliminary report. *The Journal of Pediatrics, 31*(4), 369-374.

Berg, R., Milligan, M., & Sarbaugh, F. (1994). Association of skin wetness and pH with diaper dermatitis. *Pediatric Dermatology, 11*(1), 18-20.

Bergstrom, N., Braden, B., Laguzza, A., & Holman, V. (1987). The Braden scale for predicting pressure sore risk. *Nursing research, 36*(4), 205-210.

Bergstrom, N., Allman, R. M., Carlson, C. E., Eaglstein, W., Frantz, R. A., & Garber, S. L. (1992). *Clinical Practice Guideline, Number 3.* Rockville, MD: Agency for Health Care Policy and Research. Public Health Service, US Department of Health and Human Services. Retrieved from; http://journals.lww.com/psnjournalonline/Citation/1992/01230/Pressure_Ulcers_in_Adults__Prediction_and.6.aspx

Bethell, E. (2002). Incidence and prevalence data: Can we ensure greater accuracy? *Journal of Wound Care, 11*(8), 285-288.

Black, J., Baharestani, M., Cuddigan, J., Dorner, B., Edsberg, L., Langemo, D., . . . & Taler, G. (2007). National Pressure Ulcer Advisory Panel's updated pressure ulcer staging system. *Advances in Skin & Wound Care, 20*(5), 269-274.

Black, J., Gray, M., Bliss, D., Kennedy-Evans, K., Logan, S., Baharestani, M., . . . & Ratliff, C. (2011). MASD part 2: Incontinence-associated dermatitis and intertriginous dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 38*(4), 359-370.

Blackman, I., Henderson, J., Willis, E., Hamilton, P., Toffoli, L., Verrall, C., . . . & Harvey, C. (2014). Factors influencing why nursing care is missed. *Journal of Clinical Nursing*

Blank, I. H. (1953). Further observations on factors which influence the water content of the stratum corneum. *Journal of Investigative Dermatology, 21*(4), 259-271.

Bliss, D., Johnson, S., Savik, K., Clabots, C., & Gerding, D. (2000). Fecal incontinence in hospitalized patients who are acutely ill. *Nursing Research, 49*(2), 101-108.

Bliss, D., & Powers, J. (2011). Faecal incontinence and its associated problems in hospitalised patients: The need for nursing management. *World Council of Enterostomal Therapists Journal, 31*(2), 35-39.

Bliss, D., Savik, K., Harms, S., Fan, Q., & Wyman, J. (2006). Prevalence and correlates of perineal dermatitis in nursing home residents. *Nursing Research, 55*(4), 243-251.

Bliss, D., Savik, K., Thorson, M., Ehman, S., Lebak, K., & Beilman, G. (2011). Incontinence-associated dermatitis in critically ill adults: Time to development, severity, and risk factors. *Journal of Wound Ostomy & Continence Nursing, 38*(4), 433-445.

Bonifaz, A., Tirado-Sanchez, A., Graniel, M. J., Mena, C., Valencia, A., & Ponce-Olivera, R. M. (2013). The efficacy and safety of sertaconazole cream (2 %) in diaper dermatitis candidiasis. *Mycopathologia, 175*(3-4), 249-254.

Borchert, K., Bliss, D. Z., Savik, K., & Radosevich, D. M. (2010). The incontinence-associated dermatitis and its severity instrument: Development and validation. *Journal of Wound Ostomy & Continence Nursing, 37*(5), 527-535.

Braden, B., & Bergstrom, N. (1987). A conceptual schema for the study of the etiology of pressure sores. *Rehabilitation Nursing, 12*(1), 105-109.

Brookes, D., Hubbert, R., & Sarkany, I. (1971). Skin flora of infants with napkin rash. *British Journal of Dermatology, 85*(3), 250-253.

Brown, & Sears, M. (1993). Perineal dermatitis: a conceptual framework. *Ostomy Wound Management, 39*(7), 20-22, 24-25.

Brown, J., Wimpenny, P., & Maughan, H. (2004). Skin problems in people with obesity. *Nursing standard, 18*(35), 38-42.

Brown, L., Abello, A., Thurecht, L. (2011). Length of hospital stay by older Australians: Bed-blocking or not? *National centre for social and economic modelling.* Working paper 11/08, University of Canberra. Retrieved from http://www.natsem.canberra.edu.au/storage/WP8%20Final.pdf

Bry, K. E., Buescher, D., & Sandrik, M. (2012). Never say never: A descriptive study of hospital-acquired pressure ulcers in a hospital setting. *Journal of Wound Ostomy & Continence Nursing, (3)*, 274-281.

Callan, L., Beals, D., Harwood, J., Kingan, M., Parker, D., Porras, K., Webb, M-L., & Wilson, M. (2011). *Incontinence-associated dermatitis (IAD):Best practice for clinicians.* Wound Ostomy & Continence Nurses Society, Mount Laurel, NJ

Campbell, J., Coyer, F., & Osborne, S. (2014). Incontinence-associated dermatitis: A cross-sectional prevalence study in the Australian acute care hospital setting. *International Wound Journal*. doi: 10.111/iwj.12322

Campbell, J., Coyer, F., & Osborne, S. (2015). The Skin Safety Model: Reconceptualizing skin vulnerability in older patients. *Journal of Nursing Scholarship*, *48*(1), 14-22.

Campbell, K. E. (2009). A new model to identify shared risk factors for pressure ulcers and frailty in older adults. *Rehabilitation Nursing, 34*(6), 242-247.

Carville, K. (2012). *Wound care manual* (6th ed.). Perth: Silver Chain Foundation.

Carville, K., Leslie, G., Osseiran-Moisson, R., Newall, N., & Lewin, G. (2014). The effectiveness of a twice-daily skin-moisturising regimen for reducing the incidence of skin tears. *International Wound Journal, 11*(4), 446-453. doi:10.1111/iwj.12326

Carville, K., Lewin, G., Newall, N., Haslehurst, P., Michael, R., Santamaria, N., & Roberts, P. (2007). STAR: A consensus for skin tear classification. *Primary Intention: The Australian Journal of Wound Management, 15*(1), 18-28.

Charles, P., Dalle, F., H., A., Doise, J., Quenot, J., Aho, L., . . . & Blettery, B. (2005). *Candida* spp. colonization significance in critically ill medical patients: A prospective study. *Intensive Care Medicine, 31*(3), 393-400.

Chiarelli, P., Bower, W., Wilson, A., Attia, J., & Sibbritt, D. (2005). Estimating the prevalence of urinary and faecal incontinence in Australia: Systematic review. *Australasian Journal on Ageing, 24*(1), 19-27.

Clancy, C., & Nguyen, M. (2012). Systemic candidiasis: Candidemia and deep-organ infection. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis* (pp. 429-441). Washington DC: ASM press.

Clark, M., Romanelli, M., Reger, S. I., Ranganathan, V. K., Black, J., & Dealey, C. (2010). International review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document. *London, UK: Wounds International*.

Coggon, D., Barker, D. J. P., & Rose, G. (2003). *Epidemiology for the uninitiated* (Vol. 5th). London: BMJ.

Coleman, S., Gorecki, C., Nelson, E. A., Closs, S. J., Defloor, T., Halfens, R., . . . & Nixon, J. (2013). Patient risk factors for pressure ulcer development: Systematic review. *International Journal of Nursing Studies, 50*(7), 974-1003.

Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., . . . & Nelson, E. A. (2014). A new pressure ulcer conceptual framework. *Journal of Advanced Nursing, 70*(10), 2222-2234.

Colwell, J., Ratliff, C., Goldberg, M., Baharestani, M., Bliss, D. Z., Gray, M., . . . & Black, J. (2011). MASD Part 3: Peristomal moisture-associated dermatitis and periwound moisture-associated dermatitis: A Consensus. *Journal of Wound, Ostomy & Continence Nursing, 38*(5), 541-553.

Coyer, F., Gardner, A., Dobrovsky, A., Cole, R., Ryan, F. M., Allen, C., & McNamara, G. (2015). Reducing pressure injuries in critically ill patients by using a patient skin integrity care bundle (InSPiRE). *American Journal of Critical Care, 24*(3), 199-209.

Dan, M., Segal, R., Marder, V., & Leibovitz, A. (2006). *Candida* colonization of the vagina in elderly residents of a long-term-care hospital. *European Journal of Clinical Microbiology and Infectious Diseases, 25*(6), 394-396.

DeFloor, T. (1999). The risk of pressure sores: A conceptual scheme. *Journal of Clinical Nursing, 8*(2), 206-216.

Defloor, T., Clark, M., Witherow, A., Colin, D., Lindholm, C., Schoonhoven, L., & Moore, Z. (2005). EPUAP statement on prevalence and incidence monitoring of pressure ulcer occurrence in 2005. *European Pressure Ulcer Advisory Panel, 6*(3), 74-80.

Defloor, T., & Schoonhoven, L. (2004). Inter-rater reliability of the EPUAP pressure ulcer classification system using photographs. *Journal of Clinical Nursing, 13*(8), 952-959.

Defloor, T., Schoonhoven, L., Vanderwee, K., Weststrate, J., & Myny, D. (2006). Reliability of the European Pressure Ulcer Advisory Panel classification system. *Journal of Advanced Nursing, 54*(2), 189-198.

Denham, C. R. (2009). The no outcome-no income tsunami is here: Are you a surfer, swimmer, or sinker? *JONA's Healthcare Law, Ethics, and Regulation, 11*(2), 57-69.

Department of Health, Q. G. (2013). *Health funding principles and guidelines 2013-14*. Retrieved from Brisbane: https://publications.qld.gov.au/.../health-fund-pples-n-guidelines-13-14.pdf

Detsky, A. S., Baker, J., Johnston, N., Whittaker, S., Mendelson, R., & Jeejeebhoy, K. (1987). What is subjective global assessment of nutritional status? *Journal of Parenteral and Enteral Nutrition, 11*(1), 8-13.

Di Meglio, P., Perera, Gayathri K., & Nestle, Frank O. (2011). The multitasking organ: Recent insights into skin immune function. *Immunity, 35*(6), 857-869.

Dixon, P. N., Warin, R. P., & English, M. P. (1969). Role of *Candida albicans* infection in napkin rashes. *British Medical Journal, 2*(5648), 23-27.

Dooley, Y., Kenton, K., Cao, G., Luke, A., Durazo-Arvizu, R., Kramer, H., & Brubaker, L. (2008). Urinary incontinence prevalence: Results from the National Health and Nutrition Examination Survey. *The Journal of Urology, 179*(2), 656-661.

Dorko, E., Virágová, S., & Pilipčinec, E. (2003). *Candida*—Agent of the diaper dermatitis? *Folia Microbiologica, 48*(3), 385-388.

Doughty, D. (2012). Differential assessment of trunk wounds: Pressure ulceration versus incontinence-associated dermatitis versus intertriginous dermatitis. *Ostomy Wound Management, 58*(4), 20.

Doughty, D., Junkin, J., Kurz, P., Selekof, J., Gray, M., Fader, M., . . . & Logan, S. (2012). Incontinence-associated dermatitis: Consensus statements, evidence-based guidelines for prevention and treatment, and current challenges. *Journal of Wound Ostomy & Continence Nursing, 39*(3), 303-315.

Driver, D. S. (2007). Perineal dermatitis in critical care patients. *Critical Care Nurse, 27*(4), 42-46.

Duckett, S. (2016). Don't just blame older Australians for increased hospital demand. *Grattan Institute*. Retrieved from https://grattan.edu.au/news/dont-just-blame-older-australians-for-increased-hospital-demand/

Duckett, S. (2016). Ageing population will not cause collapse of health system. Grattan institute. Retrieved from: https://www.theguardian.com/australia-news/2016/jul/21/grattan-institute-ageing-population-will-not-cause-collapse-of-health-system

Eagar, K., Sansoni, J., Loggie, C., Elsworthy, A., McNamee, J., Cook, R., & Grootemaat, P. (2013). A literature review on integrating quality and safety into hospital pricing systems. *Australian Health Services Research Institute.* Retrieved from; http://www.safetyandquality.gov.au/wp-content/uploads/2012/12/Literature-Review-on-Integrating-Quality-and-Safety-into-Hospital-Pricing-Systems1.pdf

Ersser, S., Getliffe, K., D.Voegeli, D., & Regan, S. (2005). A critical review of the inter-relationship between skin vulnerability and urinary incontinence and related nursing intervention. *International Journal of Nursing Studies, 42*(7), 823-835.

Ettorchi-Tardy, A., Levif, M., & Michel, P. (2012). Benchmarking: a method for continuous quality improvement in health. *Healthcare Policy, 7*(4), e101-119.

Ezeh, A. C., Bongaarts, J., & Mberu, B. (2012). Global population trends and policy options. *Lancet, 380*(9837), 142-148.

Fanello, S., Bouchara, J., Sauteron, M., Delbos, V., Parot, E., Marot-Leblond, A., . . . & Brangerd, B. (2006). Predictive value of oral colonization by *Candida* yeasts for the onset of a nosocomial infection in elderly hospitalized patients. *Journal of Medical Microbiology, 55*(2), 223-228.

Fanello, S., Bouchara, J. P., Jousset, N., Delbos, V., & LeFlohic, A. M. (2001). Nosocomial *Candida albicans* acquisition in a geriatric unit: Epidemiology and evidence for person-to-person transmission. *Journal of Hospital Infection, 47*(1), 46-52. doi:10.1053/jhin.2000.0849

Fang, E. F., Scheibye-Knudsen, M., Jahn, H. J., Li, J., Ling, L., Guo, H., . . . & Ng, T. B. (2015). A research agenda for aging in China in the 21st century. *Ageing Research Reviews, 24*(Pt B), 197-205. doi:10.1016/j.arr.2015.08.003

Farage, M. A., Miller, K. W., Berardesca, E., & Maibach, H. I. (2007). Incontinence in the aged: Contact dermatitis and other cutaneous consequences. *Contact Dermatitis, 57*(4), 211-217.

Farage, M. A., Miller, K. W., Elsner, P., & Maibach, H. I. (2007). Structural characteristics of the aging skin: A review. *Cutaneous and Oocular Toxicology, 26*(4), 343-357.

Farage, M. A., Miller, K. W., Elsner, P., & Maibach, H. I. (2008). Functional and physiological characteristics of the aging skin. *Aging Clinical & Experimental Research, 20*(3), 195-200.

Farage, M.A., Miller, K. W., Elsner P., Maibach H.I. (2013). Characteristics of the ageing skin. *Advances in Wound Care, 2*(1),5-10.

Fawcett, J & DeSanto-Madeya, S., (2013). *Contemporary nursing knowledge. analysis and evaluation of nursing models and theories*. (3rd ed.). F.A. Davis, Philadelphia

Ferrazzini, G., Kaiser, R. R., Hirsig Cheng, S., Wehrli, M., Della Casa, V., Pohlig, G., . . . & Jörg, W. (2003). Microbiological aspects of diaper dermatitis. *Dermatology,206*(2), 136-141.

Fidel, P. J. (1999). *Candida albicans*: From commensal to pathogen. In G. W. Tannock (Ed.), *Medical Importance of the Normal Microflora* (pp. 441-476). Dordrecht, The Netherlands: Kluwer Academic Publishers.

Fonda, D., Nickless, R., & Roth, R. (1988). A prospective study of the incidence of urinary incontinence in an acute care teaching hospital and its implications on future service development. *Australian clinical review/Australian Medical Association [and] the Australian Council on Hospital Standards, 8*(30), 102-107.

Fore, J. (2006). A review of skin and the effects of aging on skin structure and function. *Ostomy Wound Management, 52*(9), 24-37.

Foureur, N., Vanzo, B., Meaume, S., & Senet, P. (2006). Prospective aetiological study of diaper dermatitis in the elderly. *British Journal of Dermatology, 155*(5), 941-946.

Fowler, H. W., Fowler, F. G., & Crystal, D. (2011). *The concise Oxford dictionary of current English*. Oxford: Oxford University Press.

Francis R., (2013). Report of the Mid Staffordshire NHS Foundation Trust public enquiry. Volume 1:Analysis of evidence and lessons learned (Part1). The Stationary Office: London Retrieved from http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/report

Fried, L. P., Tangen, C. M., Walston, J., Newman, A. B., Hirsch, C., Gottdiener, J., . . . & McBurnie, M. A. (2001). Frailty in older adults: Evidence for a phenotype. *The Journals of Gerontology Series 56*(3), M146-M152.

Furlanetto, K., & Emond, K. (2014). 'Will I come home incontinent?' A retrospective file review: Incidence of development of incontinence and correlation with length of stay in acute settings for people with dementia or cognitive impairment aged 65 years and over. *Collegian, 23*(1), 79-86.

García-Fernández, F. P., Agreda, J. J. S., Verdú, J., & Pancorbo-Hidalgo, P. L. (2014). A new theoretical model for the development of pressure ulcers and other dependence-related lesions. *Journal of Nursing Scholarship, 46*(1), 28-38.

Gefen, A. (2014). From incontinence associated dermatitis to pressure ulcers. *Journal of Wound Care, 23*(7), 345.

Gokalp, A. S., Aldirmaz, C., Oguz, A., Gultekin, A., & Bakici, M. Z. (1990). Relation between the intestinal flora and diaper dermatitis in infancy. *Tropical and Geographical Medicine, 42*(3), 238-240.

Goldberg M. (2012). General acute care. In Pieper. B. (Ed.), *Pressure Ulcers: Prevalence, Incidence, and Implications for the Future.* (pp. 27-45). Washington DC.: National Pressure Ulcer Advisory Panel.

Goldstein, L. S. (1949). Napkin dermatitis caused by ammoniacal urine; Treatment with methionine. *Archives of Pediatrics, 66*(12), 553-560.

Gordis, L. (2009). *Epidemiology*. Philadelphia: Elsevier/Saunders.

Gray, M. (2004). Preventing and managing perineal dermatitis: A shared goal for wound and continence care. *Journal of Wound Ostomy & Continence Nursing, 31*(1), S2-12.

Gray, M. (2007). Incontinence-related skin damage: Essential knowledge. *Ostomy Wound Management, 53*(12), 28-32.

Gray, M., Bliss, D., Doughty, D., Ermer-Seltun, J., Kennedy-Evans, K., & Palmer, M. (2007). Incontinence-associated dermatitis: A consensus. *Journal of Wound Ostomy & Continence Nursing, 34*(1), 45-56.

Gray, M. (2011). Optimal management of incontinence-associated dermatitis in the elderly. *Journal of Wound Ostomy & Continence Nursing*(4S), S29-S29.

Gray, M., Beeckman, D., Bliss, D. Z., Fader, M., Logan, S., Junkin, J., . . . & Kurz, P. (2012). Incontinence-associated dermatitis: A comprehensive review and update. *Journal of Wound Ostomy & Continence Nursing, 39*(1), 61-74.

Gray, M., Black, J., Baharestani, M., Bliss, D., Colwell, J., Goldberg, M., . . . Ratliff, C. (2011). Moisture-associated skin damage: Overview and pathophysiology. *Journal of Wound Ostomy & Continence Nursing, 38*(3), 233-241.

Green, J. P., Smoker, I., Ho, M. T., & Moore, K. H. (2003). Urinary incontinence in subacute care-a retrospective analysis of clinical outcomes and costs. *Medical Journal of Australia, 178*(11), 550-553.

Greene, R. A., Dasso, E., Ho, S., & Genaidy, A. M. (2014). A person-focused model of care for the twenty-first century: A system-of-systems perspective. *Population Health Management, 17*(3), 166-171.

Gunningberg, L., Donaldson, N., Aydin, C., & Idvall, E. (2012). Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action. *Journal of Evaluation in Clinical Practice, 18*(4), 904-910.

Habif, T. P. (2015). *Clinical dermatology: A color guide to diagnosis and therapy*. Philadelphia: Saunders.

Halfens, R. J. G., Meesterberends, E., Nie-Visser, N. C., Lohrmann, C., Schönherr, S., Meijers, J. M. M., . . . & Schols, J. M. G. A. (2013). International prevalence measurement of care problems: results. *Journal of Advanced Nursing, 69*(9), e5-e17.

Halland, M., & Talley, N. J. (2012). Fecal incontinence: Mechanisms and management. *Current opinion in gastroenterology, 28*(1), 57-62.

Hayakawa, R., & Matsunaga, K. (1987). Common conditions and factors associated with diaper dermatitis. *Pediatrician, 14 Suppl 1*, 18-20.

Herdman, T. (2012). *Nanda international nursing diagnoses: Definitions & Classification, 2012-2014*. Oxford: Wiley-Blackwell.

Hilton, A., & Warnock, D. (1975). Vaginal candidiasis and the role of the digestive tract as a source of infection. *BJOG: An International Journal of Obstetrics & Gynaecology, 82*(11), 922-926.

Homma, Y. (2008). Lower urinary tract symptomatology: Its definition and confusion. *International Journal of Urology, 15*(1), 35-43.

Honoré, P. A., Wright, D., Berwick, D. M., Clancy, C. M., Lee, P., Nowinski, J., & Koh, H. K. (2011). Creating a framework for getting quality into the public health system. *Health Affairs, 30*(4), 737-745.

Honig, P. J. (1983). Diaper dermatitis. Factors to consider in diagnosis and treatment. *Postgraduate Medicine, 74*(6), 79-84, 88.

Hou, J. W., & Li, K. (2011). The aging of the Chinese population and the cost of healthcare. *The Social Science Journal, 48*(3), 514-526.

Inouye, S. K., Studenski, S., Tinetti, M. E., & Kuchel, G. A. (2007). Geriatric syndromes: clinical, research, and policy implications of a core geriatric concept. *Journal of the American Geriatrics Society, 55*(5), 780-791.

Irwin, D. E., Milsom, I., Hunskaar, S., Reilly, K., Kopp, Z., Herschorn, S., . . . Abrams, P. (2006). Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: Results of the EPIC study. *European Urology, 50*(6), 1306-1315.

Jarvis, W. R. (1996). The epidemiology of colonization. *Infection Control & Hospital Epidemiology, 17*(1), 47-52.

Jefferson, J. (1966). Napkin psoriasis. *British Journal of Dermatology, 78*(11), 614-614.

Jeter, K. F., & Lutz, J. B. (1996). Skin care in the frail, elderly, dependent, incontinent patient. *Advanced Wound Care, 9*(1), 29-34.

Junkin, J. (2008). Incontinence-Associated Dermatitis Intervention Tool (IADIT).

Retrieved from;
http://ltctoolkit.rnao.ca/sites/ltc/files/resources/continence/Continence_EducationResources/IADIT.pdf

Junkin, J., & Selekof, J. (2007). Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of Wound Ostomy & Continence Nursing, 34*(3), 260-269.

Junkin, J., & Selekof, J. (2008). Beyond 'diaper rash': Incontinence-associated dermatitis: Does it have you seeing red? *Nursing, 38*(11 Suppl), 56hn51.

Kalisch, B. J., Landstrom, G. L., & Hinshaw, A. S. (2009). Missed nursing care: A concept analysis. *Journal of Advanced Nursing, 65*(7), 1509-1517.

Kayaoglu, S., Kivanc-Altunay, I., & Sarikaya, s. (2015). Diaper dermatitis in infants admitted to social pediatrics health center: Role of socio-demographic factors and infant care. *The Indian Journal of Pediatrics 82*(10), 904-908.

Keiter, W. E. (1970). 'Diaper dermatitis' from allergens excreted in urine. *Pediatrics, 46*(4), 649-650.

Kennedy, K., & Lutz J. (4th October 1996). *Comparison of the efficacy and cost effectiveness of three skin protectants in the management of incontinent*

dermatitis. Paper presented at the European Conference on Advances in Wound Management, Amsterdam, Netherlands.

Kinsella, K., He, W. (2009). *An aging world:2008, international population reports.* Retrieved from https://www.census.gov/prod/2009pubs/p95-09-1.pdf

Koblenzer, P. J. (1973). Diaper dermatitis: An overview with emphasis on rational therapy based on etiology and pathodynamics. *Clinical Paediatrics 12*(7), 386-392.

Kottner, J., Blume-Peytavi, U., Lohrmann, C., & Halfens, R. (2014). Associations between individual characteristics and incontinence-associated dermatitis:Aa secondary data analysis of a multi-centre prevalence study. *International Journal of Nursing Studies, 51*(10), 1373-1380.

Kowdley, G., & Ashbaker, D. (2011). Healthcare costs in America:Technology as a major driver. *Journal of SurgicalEducation, 68*(3), 231-238.

Kring, D. L. (2007). Reliability and validity of the Braden Scale for predicting pressure ulcer risk. *Journal of Wound Ostomy & Continence Nursing, 34*(4), 399-406.

Kumamoto, C. A. (2011). Inflammation and gastrointestinal *Candida* colonization. *Current Opinion in Microbiology, 14*(4), 386-391.

Lakhan, P., Jones, M., Wilson, A., Courtney, M., Hirdes, J., & Gray, L. (2011). A prospective cohort study of geriatric syndromes among older medical patients admitted to acute are hospitals. *Journal of the American Geriatrics Society, 59*(11), 2001-2008.

Lambers, H., Piessens, S., Bloem, A., Pronk, H., & Finkel, P. (2006). Natural skin surface pH is on average below 5, which is beneficial for its resident flora. *International Journal of Cosmetic Science, 28*(5), 359-370.

Langemo, D., Hanson, D., Hunter, S., Thompson, P., & Oh, I. E. (2011). Incontinence and incontinence-associated dermatitis. *Advances in Skin & Wound Care, 24*(3), 126-142.

Lawton, S. (2007). Addressing the skin-care needs of the older person. *British Journal of Community Nursing, 12*(5), 203-210.

LeBlanc, K., & Baranoski, S. (2011). Skin Tears: State of the Science: Consensus Statements for the Prevention, Prediction, Assessment, and Treatment of Skin Tears. *Advances in Skin & Wound Care, 24*(9), 2-15.

LeBlanc, K., & Baranoski, S. (2014). International Skin Tear Advisory Panel: Putting it all together, a tool kit to aid in the prevention, assessment using a simplified classification system and treatment of skin tears. *World Council of Enterostomal Therapists Journal, 34*(1), 12-27.

LeBlanc, K., & Baranoski, S. (2014). Skin tears: The forgotten wound. *Nursing Management, 45*(12), 36-46.

LeBlanc, K. A., & Christensen, D. (2011). Demystifying skin tears, part 2. *Nursing, 41*(7), 16-17.

Leon, A., Davis, L., Kraemer, H. (2010). The role and interpretation of pilot studies. *Journal of Psychiatric Studies, 45*(2011), 626-629.

Leonard, C. (1967). Dermatoses of the diaper area: An effective treatment. *Applied Therapeutics, 9*(8), 685-686.

Levant, S., Chari, K., & DeFrances, C. J. (2015). Hospitalizations for patients aged 85 and over in the United States, 2000-2010. *NCHS data brief*, (1941-4927), *182*, 1-8. Retrieved from; http://www.cdc.gov/nchs/data/databriefs/db182.pdf

Lewis, S. J., & Heaton, K. W. (1997). Stool form scale as a useful guide to intestinal transit time. *Scandinavian Journal of Gastroenterology, 32*(9), 920-924.

Leyden, J. J., & Kligman, A. M. (1978). The role of microorganisms in diaper dermatitis. *Archives of Dermatology , 114*(1), 56-59.

Lionakis, M. S. (2014). New insights into innate immune control of systemic candidiasis. *Medical Mycology, 52*(6), 555-564.

Litchfield, H. R. (1959). The treatment of intertriginous eruptions (diaper rash) and infantile eczema. *Archives of Dermatology, 76*(2), 73-77.

Lowthian, J. A., Curtis, A. J., Jolley, D. J., Stoelwinder, J. U., McNeil, J. J., & Cameron, P. A. (2012). Demand at the emergency department front door: 10-year trends in presentations. *Medical Journal of Australia, 196*, 128-132.

Maertens, J., & Marr, K. A. (Eds.). (2007). *Diagnosis of fungal infections*. CRC Press.Magill, S. S., Edwards, J. R., Bamberg, W., Beldavs, Z. G., Dumyati, G., Kainer, M. A., . . . & Fridkin, S. K. (2014). Multistate point-prevalence survey of healthcare-associated infections. *New England Journal of Medicine, 370*(13), 1198-1208.

Mahoney, M., Rozenboom, B., Doughty, D., & Smith, H. (2011). Issues related to accurate classification of buttocks wounds. *Journal of Wound Ostomy & Continence Nursing, 38*(6), 635-642.

Maklebust, J., & Magnan, M. A. (1994). Risk factors associated with having a pressure ulcer: A secondary data analysis. *Advanced Wound Care, 7*(6), 25, 27-28, 31-24.

Martin, E. A. (2015). *Concise medical dictionary* (9th ed.). Oxford: Oxford University Press.

Mayrovitz, H. N., & Sims, N. (2001). Biophysical effects of water and synthetic urine on skin. *Advances in Skin & Wound Care, 14*(6), 302-308.

McClellan, M., Kent, J., Beales, S. J., Cohen, S. I., Macdonnell, M., Thoumi, A., . . . & Darzi, A. (2014). Accountable care around the world: A framework to guide reform strategies. *Health Affairs, 33*(9), 1507-1515.

McGahan, M., Kucharski, G., & Coyer, F. (2012). Nurse staffing levels and the incidence of mortality and morbidity in the adult intensive care unit: A literature review. *Australian Critical Care, 25*(2), 64-77.

McNichol, L., Lund, C., Rosen, T., & Gray, M. (2013). Medical adhesives and patient safety: State of the science: Consensus statements for the assessment, prevention, and treatment of adhesive-related skin injuries. *Journal of Wound Ostomy & Continence Nursing, 40*(4), 365-380.

Menon, G. K., Cleary, G. W., & Lane, M. E. (2012). The structure and function of the stratum corneum. *International Journal of Pharmaceutics, 435*(1), 3-9.

Menon, G. K., & Kligman, A. M. (2009). Barrier functions of human skin: A holistic view. *Skin Pharmacology and Physiology, 22*(4), 178-189.

Meyer, R. M., & O'Brien-Pallas, L. L. (2010). Nursing services delivery theory: An open system approach. *Journal of Advanced Nursing, 66*(12), 2828-2838.

Michaels, A., Chandrasekaran, S., & Shaw, J. (1975). Drug permeation through human skin: Theory and invitro experimental measurement. *AICHE Journal, 21*(5), 985-996.

Miles, S., Fulbrook, P., Nowicki, T., & Franks, C. (2013) Decreasing pressure injury prevalence in an Australian general hospital: A10-year review. *Wound Practice and Research, 21*(4), 148-156.

Mitchell, P. H., Ferketich, S., & Jennings, B. (1998). Quality health outcomes model. American Academy of Nursing Expert Panel on Quality Healthcare. *Journal of Nursing Scholarship, 30*(1), 43-46.

Miu, D. K., Lau, S., & Szeto, S. S. (2010). Etiology and predictors of urinary incontinence and its effect on quality of life. *Geriatrics & Gerontology International, 10*(2), 177-182.

Montalvo, I. (2007). The National Database of Nursing Quality Indicators (NDNQI). *Online Journal of Issues in Nursing, 12*(3), 13p.

Montes, L., Pittillo, R., Hunt, D., Narkates, A., & Dillon, H. (1971). Microbial flora of infant's skin: Comparison of types of microorganisms between normal skin and diaper dermatitis. *Archives of Dermatology, 103*(6), 640-648.

Moran, G., Coleman, S., & Sullivan, D. (2012). An introduction to the medically important *Candida* species. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis.* (pp. 11-25). Washington, DC: ASM Press.

Mulligan, S., Prentice, J., & Scott, L. (2011). WoundsWest Wound prevalence survey 2011 State-wide overview report. *Ambulatory Care Services, Perth, Western Australia: Department of Health.*

National Health Medical Research Council. (2000). How to review the evidence: systematic identification and review of the scientific literature. Retrieved from http://www.nhmrc.gov.au/publications/synopses/_files/cp65.pdf

National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. (2009). *Prevention and treatment of pressure ulcers: Clinical practice guideline.* Washington DC: National Pressure Ulcer Advisory Panel.

National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance. (2014). *Prevention and treatment of*

pressure ulcers: Clinical practice guideline (E. Haesler Ed.). Perth, Australia: Cambridge Media.

Newman, D. K., Wallace, D. W., & Wallace, J. (2001). Moisture control and incontinence management. *Chronic wound care: A clinical source book for healthcare professionals*, 653-659.Nix, D., & Haugen, V. (2010). Prevention and management of incontinence-associated dermatitis. *Drugs & Aging, 27*(6), 491-496.

Nix, D. H. (2002). Validity and reliability of the Perineal Assessment Tool. *Ostomy Wound Management, 48*(2), 43-47.

Odds, F. C. (1988). *Candida and candidosis*. London; Philadelphia: Baillière Tindall.

Odds, F. C., Davidson, A. D., Jacobsen, M. D., Tavanti, A., Whyte, J. A., Kibbler, C. C., . . . & Gow, N. A. (2006). *Candida albicans* strain maintenance, replacement, and microvariation demonstrated by multilocus sequence typing. *Journal of Clinical Microbiology, 44*(10), 3647-3658.

Oleckno, W. A. (2008). *Epidemiology: Concepts and methods*. Illinois: Waveland.

Oomens, C. W., Bader, D. L., Loerakker, S., & Baaijens, F. (2015). Pressure induced deep tissue injury explained. *Annals of Biomedical Engineering, 43*(2), 297-305.

Organisation for Economic Cooperation and Development. (2015). Focus on health spending *OECD health statistics.* Retrieved from http://www.oecd.org/health/health-systems/Focus-Health-Spending-2015.pdf

Ostaszkiewicz, J., O'Connell, B., & Millar, L. (2008). Incontinence: Managed or mismanaged in hospital settings? *International Journal of Nursing Practice, 14*(6), 495-502.

Pieper, B. (Ed.), with the National Pressure Ulcer Advisory Panel (NPUAP). (2012). *Pressure ulcers: Prevalence, incidence, and implications for the future.* Washington, DC: NPUAP

Pittet, D., Monod, M., Suter, P. M., Frenk, E., & Auckenthaler, R. (1994). *Candida* colonization and subsequent infections in critically ill surgical patients. *Annals of Surgery, 220*(6), 751.

Porter, M. E. (2010). What is value in healthcare? *New England Journal of Medicine, 363*(26), 2477-2481.

Powers, G. C., Zentner, T., Nelson, F., & Bergstrom, N. (2004). Validation of the mobility subscale of the Braden Scale for predicting pressure sore risk. *Nursing Research, 53*(5), 340-346.

Prentice, J., Stacey, M., & Lewin, G. (2003). An Australian model for conducting pressure ulcer prevalence surveys. *Primary Intention, 11* (2):87-88,90-91, 93-96,98-100,102-109

Pronovost, P. J., Armstrong, C. M., Demski, R., Callender, T., Winner, L., Miller, M. R., . . . & Rothman, P. B. (2014). Creating a high-reliability healthcare system: Improving performance on core processes of care at Johns Hopkins Medicine. *Academic Medicine*.

Queensland Government. (2013). *Health Funding Principles and Guidelines 2013-14*. Retrieved from Brisbane, Queensland: https://publications.qld.gov.au/storage/f/2014-06-06T04:24:00.515Z/health-fund-pples-n-guidelines-13-14.pdf

Rak, S., & Coffin, J. (2013). Affordable care act. *The Journal of Medical Practice Management: 28*(5), 317-319.

Rawlings, A. V., Scott, I. R., Harding, C. R., & Bowser, P. A. (1994). Stratum corneum moisturization at the molecular level. *Journal of Investigative Dermatology, 103*(5), 731-740.

Reger, S. R. H. O. H., Ohura T, Gefan A. (2010). Shear and friction in context. *International review. Pressure ulcer prevention: Pressure, shear,friction and microclimate in context. A consensus document.* London: Wounds International. Retrieved from; http://www.woundsinternational.com/media/issues/300/files/content_8925.pdf

Revankar, S., & Sobel, J. (2012). Mucosal candidiasis. In R. Calderone & C. Clancy (Eds.), *Candida and candidiasis.* (pp. 419-427). Washington, DC: ASM Press.

Richardson, M. D & Warnock, D.,W. (2012). *Fungal infection diagnosis and management.* John Wiley& Sons:West Sussex.

Rolstad, B. S., Ermer-Seltun, J., & Bryant, R. A. (2011). Relating knowledge of anatomy and physiology to peristomal skin care. *Gastrointestinal Nursing, 9*(Sup3), 3-9.

Rose, H., & Kurup, V. (1977). Colonization of hospitalized patients with yeast-like organisms. *Sabouraudia, 15*(3), 251-256.

Royal Brisbane and Women's Hospital Marketing and Communications. (2013). *2011-2012 RBWH Year in Review*. Retrieved from http://www.health.qld.gov.au/rbwh/docs/year-review/year-review.pdf

Scanlon, M., Karsh, B-T., & Saran, K., (2008). Risk-based patient safety metrics. Advances in Patient Safety: New Directions and Alternative Approaches (Vol.1:Assessment). Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK43628/pdf/Bookshelf_NBK43628.pdf

Schofield, D. J., & Earnest, A. (2006). Demographic change and the future demand for public hospital care in Australia, 2005 to 2050. *Australian Health Review, 30*(4), 507-515.

Schulte, D., Sethi, A., Gangnon, R., Duster, M., Maki, D. G., & Safdar, N. (2015). Risk factors for Candida colonization and Co-colonization with multi-drug resistant organisms at admission. *Antimicrobial Resistance and Infection Control, 4*, (46) 2-9.

Scommegna, P. (2012). *India's ageing population*. Retrieved from Washington DC: http://www.prb.org/pdf12/TodaysResearchAging25.pdf

Shaked, E., & Gefen, A. (2013). Modeling the Effects of Moisture-Related Skin-Support Friction on the Risk for Superficial Pressure Ulcers during Patient Repositioning in Bed. *Frontiers in Bioengineering and Biotechnology, 1*, 9, 1-9

Shortell, S. M., & Singer, S. J. (2008). Improving patient safety by taking systems seriously. *The Journal of the American Medical Association, 299*(4), 445-447.

Silva, M., C., (1986). Research testing nursing theory: State of the art. Advances in Nursing Science, *14*(4), 12-21

Singleton, P., & Sainsbury, D. (2012). Dictionary of microbiology and molecular biology. Retrieved from http://www.credoreference.com/book/wileymicrob

Smits, B., Prior, A., & Arblaster, P. (1966). Incidence of *Candida* in hospital in-patients and the effects of antibiotic therapy. *British Medical Journal, 1*(5481), 208.

Sobel, J. D., Faro, S., Force, R. W., Foxman, B., Ledger, W. J., Nyirjesy, P. R., . . . & Summers, P. R. (1998). Vulvovaginal candidiasis: Epidemiologic, diagnostic, and therapeutic considerations. *American Journal of Obstetrics and Gynecology, 178*(2), 203-211.

Solomon, S. (2014). Health reform and activity-based funding. *The Medical Journal of Australia*, *200*(10), 564.

Somerville, D. A. (1972). Yeasts in a hospital for patients with skin diseases. *Journal of Hygiene (Lond), 70*(4), 667-675.

Sourdet, S., Lafont, C., Rolland, Y., Nourhashemi, F., Andrieu, S., & Vellas, B. (2015). Preventable iatrogenic disability in elderly patients during hospitalization. *Journal of the American Medical Directors Association, 16*(8), 674-681.

Stabile, M., Thomson, S., Allin, S., Boyle, S., Busse, R., Chevreul, K., . . . & Mossialos, E. (2013). Healthcare cost containment strategies used in four other high-income countries hold lessons for the United States. *Health Affairs*, *32*(4), 643-652.

Steenson, J., Vivanti, A., & Isenring, E. (2013). Inter-rater reliability of the Subjective Global Assessment: A systematic literature review. *Nutrition, 29*(1), 350-352.

Stotts, N. A., Brown, D. S., Donaldson, N. E., Aydin, C., & Fridman, M. (2013). Eliminating hospital-acquired pressure ulcers: Within our reach. *Advances in Skin & Wound Care, 26*(1), 13-18.

Stutsky, B., Laschinger, H., (2014). Development and testing of a conceptual framework for interprofessional collaborative practice. *Health and Interpersonal Practice 2*(2),1-14

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A.,Rios, L., . . . & Goldsmith, C., (2010). A tutorial on pilot studies: The what, why and how. *BMC Medical Research Methodology, 10*(1), 1-10.

The Health Roundtable. (2012). *2012 Annual Report*. The Health Roundtable Limited. Retrieved from https://www.healthroundtable.org/GetNews/tabid/1457/itemid/173/amid/5205/default.aspx

Thomason, H. A., & Hardman, M. J. (2009). Delayed wound healing in elderly people. *Reviews in Clinical Gerontology, 19*(3), 171-184.

Tobin, A. M., Ahern, T., Rogers, S., Collins, P., O'Shea, D., & Kirby, B. (2013). The dermatological consequences of obesity. *International Journal of Dermatology, 52*(8), 927-932.

Travaglia, J., Debono, D., Spigelman, A., Braithwaite, J., (2011). Clinical Governance: A review of key concepts in the literature. *Clinical Governance 16*(1), 62-77

Tsai, T. F., & Maibach, H. I. (1999). How irritant is water? An overview. *Contact Dermatitis, 41*(6), 311-314.

United Nations. (2011). *World Population Prospects: The 2010 Revision, Highlights and Advance Tables.* Retrieved from http://esa.un.org/wpp/Documentation/pdf/WPP2010_Highlights.pdf

Vanderwee, K., Clark, M., Dealey, C., Gunningberg, L., & Defloor, T. (2007). Pressure ulcer prevalence in Europe: A pilot study. *Journal of Evaluation in Clinical Practice, 13*(2), 227-235.

Vanderwee, K., Defloor, T., Beeckman, D., Demarre, L., Verhaeghe, S., Van Durme, T., & Gobert, M. (2011). Assessing the adequacy of pressure ulcer prevention in hospitals: A nationwide prevalence survey. *British Medical Journal Quality & Safety, 20*(3), 260-267.

Vangilder, C., Amlung, S., Harrison, P., & Meyer, S. (2009). Results of the 2008-2009 International Pressure Ulcer Prevalence Survey and a 3-year, acute care, unit-specific analysis. *Ostomy Wound Management, 55*(11), 39-45.

Vazquez, J. A., & Sobel, J. D. (2002). Mucosal candidiasis. *Infectious disease clinics of North America, 16*(4), 793-820, v.

Victorian Quality Council. (2008). Pressure ulcer point prevalence surveys (PUPPS): state-wide PUPPS 3 report 2006. Retrieved from https://www2.health.vic.gov.au/about/publications/researchandreports/pressure-ulcer-prevalence-survey

Voegeli, D. (2011). Pressure ulcer or moisture lesion - what's the difference? *Nursing & Residential Care, 13*(5), 222-227.

Voegeli, D. (2012). Moisture-associated skin damage: Aetiology, prevention and treatment. *British Journal of Nursing, 21*(9), 517-521.

Voegeli, D. (2013). Moisture-associated skin damage: An overview for community nurses. *British Journal of Community Nursing, 18*(1), 6, 8, 10-12.

Voegeli, D. (2016). Incontinence-associated dermatitis: New insights into an old problem. *British Journal of Nursing, 25*(5), 256-262.

Voegeli, D., & Voegeli, L. (2008). Skin care and incontinence in the elderly. *Nursing & Residential Care, 10*(10), 487-492.

Vogt, W. P. (2005). *Dictionary of Statistics & Methodology: A Nontechnical Guide for the Social Sciences*. Thousand Oaks, Calif: SAGE Publications, Inc.

Wade, D. T., & Halligan, P. W. (2004). Do biomedical models of illness make for good healthcare systems? *British Medical Journal, 329*(7479), 1398-1401.

Wallner, P. E., & Konski, A. (2008). The impact of technology on healthcare cost and policy development. *Seminars in Radiation Oncology,18,*194-200.

Warin, R., & Faulkner, K. (1961). Napkin psoriasis. *British Journal of Dermatology, 73*(12), 445-447.

White, W. (2001). Skin tears: A descriptive study of the opinions, clinical practice and knowledge base of RNs caring for the aged in high care residential facilities. *Primary Intention 9*(4),138-149.

World Health Organisation (n. d.). Patient safety. Retrieved from http://www.euro.who.int/en/health-topics/Health-systems/patient-safety

World Health Organisation. (2004). *International statistical classification of diseases and health related problems (The) ICD-10.* World Health Organization. Retrieved from http://apps.who.int/classifications/icd10/browse/2016/en

World Health Organisation. (2011). *Global health and ageing*. Retrieved from http://www.who.int/ageing/publications/global_health.pdf

Wysocki, A. (2007). Anatomy and physiology of skin and soft tissue. In R. Bryant, Nix, D. (Ed.), *Acute and chronic wounds. Current management concepts.* (3rd ed.). St Louis: Mosby Elsevier.

Youngberg, J. (2013). *Patient safety handbook,* (2nd ed.). Burlington: Jones and Bartlett Learning. Sudbury, Mass

Zhai, H., & Maibach, H. I. (2002). Occlusion vs. skin barrier function. *Skin Research and technology, 8*(1), 1-6.

Zimmerer, R. E., Lawson, K. D., & Calvert, C. J. (1986). The effects of wearing diapers on skin. *Pediatric Dermatology, 3*(2), 95-101.

Zisberg, A., Shadmi, E., Gur-Yaish, N., Tonkikh, O., & Sinoff, G. (2015). Hospital-associated functional decline: The role of hospitalisation processes beyond individual risk factors. *Journal of the American Geriatrics Society, 63*(1), 55-62.

Zulkowski, K. (2012). Diagnosing and treating moisture-associated skin damage. *Advances in Skin & Wound Care, 25*(5), 231-236; quiz 237-238.

APPENDICES

Appendix A: Skin Assessment Tool (Kennedy & Lutz, 1996)

Score	Characteristic
	Area of Skin Breakdown
0	None
1	Small area (<20 cm^2)
2	Moderate area (20-50 cm^2)
3	Large area (>50 cm^2)
	Skin Redness
0	No redness
1	Mild redness (blotchy and non-uniform)
2	Moderate redness (severe in spots but not uniform in appearance)
3	Severe redness (uniformly severe in appearance)
	Erosion
0	None
1	Mild erosion involving epidermis only
2	Moderate erosion involving epidermis and dermis with no or little exudate
3	Severe erosion of epidermis with moderate involvement of dermis with low volume or no exudate
4	Extreme erosion of epidermis and dermis with moderate volume and persistent exudate

Appendix B: Permission to use the Skin Assessment Tool (SAT)

-----Original Message-----
From: Jill Campbell <jillcampbell18@gmail.com>

To: ktulcer <ktulcer@aol.com>
Sent: Thu, Aug 29, 2013 3:08 am
Subject: Kenned-Lutz SAT tool

Dear Karen,
I am a PhD candidate at Queensland University of Technology in Brisbane Australia. My thesis topic is exploring the incontinence-associated dermatitis in the acute care setting. The thesis will be presented by publication.
I am conducting an observational prospective IAD prevalence study and a prospective observational time to event study exploring candida infection and IAD.

I would like to request your permission to use the SAT for these studies. I look forward to hearing from you soon.

Kind Regards
Jill

Jill Campbell RN, BHealthSc(Nursing) Grad Dip (Wound Care)
Clinical Nurse Skin Integrity
Royal Brisbane & Women's Hospital Butterfield Street
Herston Qld 4006 Australia
Email; jillcampbell18@gmail.com
Work; Jill_Campbell@health.qld.gov.au

From: Karen Kennedy-Evans [mailto: ktulcer@aol.com]
Sent: Thursday, August 29, 2013 1:59 PM
To: jillcampbell18@gmail.com
Cc: jlutzmail@aol.com
Subject: Re: Kenned-Lutz SAT tool

Absolutely.
We give permission.

Please keep us updated as to your progress and let us know if we can help.

I have a new e-mail. Ktulcer@me.com.
Thank you. Karen Lou Kennedy-Evans
ktulcer@aol.com

Good luck with your thesis. Let us know if we can help.

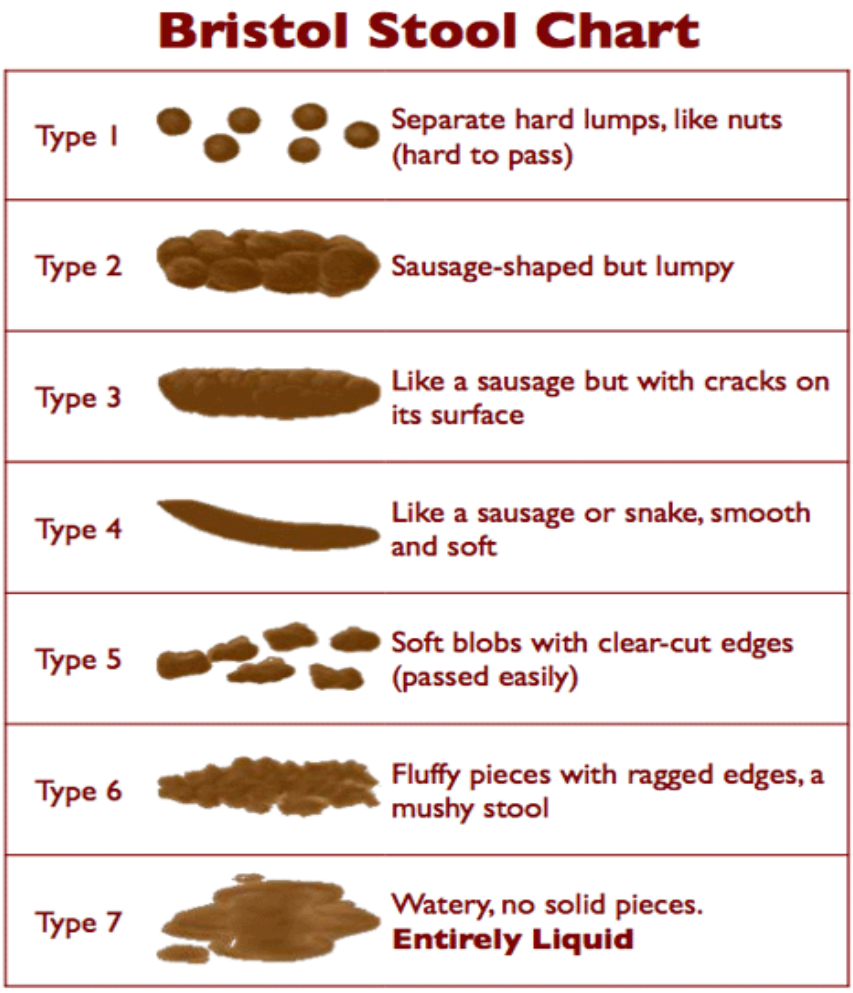
Jim Lutz, MS, CCRA
Lutz Consulting LLC
Medical Writing Services
411 Dogwood DR
Buellton, CA 93427-6810
805-245-0374 (CELL/Work)
805-688-3461 (FAX)
E-Mail: jlutzmail@aol.com

Appendix C: Data collection instrument for Study 1

Complete this form for all patients			
Patient UR:	**Ward:**	**Sex: Male ☐ Female ☐**	**DOB (year):**
Verbal Consent	**Yes ☐**	**No ☐**	
PRESSURE INJURY PRESENT (tick all that apply)			
sacrum/coccyx ☐ Stage ☐		Ischial tuberosities ☐ Stage ☐	
buttock ☐ Stage ☐		Trochanter/hip ☐ Stage ☐	
CONTINENCE STATUS		**STOOL QUALITY & FREQUENCY**	
Continent Y ☐ NB If patient continent, no further questions to be answered.		Stool Quality Formed ☐ Semi formed ☐ Liquid ☐	
Incontinent urine only Y ☐		Stool Frequency **less** than 3 per day ☐ **more** than 3 per day ☐	
Incontinent; Urine and Faeces Y ☐		Stoma Urinary Y ☐ Stoma Faecal Y ☐	
Urinary catheter insitu ☐		Faecal containment device Y ☐	
CONTINENCE AIDS (mark all that apply)			
Tab pad ☐ Pull up pad ☐ Insert pad ☐ Underpad ☐ Urodome ☐			
CONTRIBUTING FACTORS (mark all that apply)			
Antibiotics Oral ☐ IV ☐		Enteral tube feeding Y ☐ Type:	
INCONTINENCE CLEANUP & SKIN PROTECTION PRODUCTS AT BEDSIDE (specify all products present)			
Cleanse (eg soap, water & cloth; no rinse cleanser, wipes):			
Moisturiser (eg creams, lotions):			
Barrier Protection (eg zinc cream, barrier sprays):			
Topical Medication: Antifungal ☐ Other; Please state			
SKIN REDNESS			
None		Y ☐ N ☐	
Mild redness (blotchy & non-uniform)		Y ☐ N ☐	
Moderate redness (severe in places but non-uniform appearance)		Y ☐ N ☐	
Severe redness (uniformly red in appearance)		Y ☐ N ☐	
AREA of SKIN BREAKDOWN			
None		Y ☐ N ☐	
Small area (< 20cm²)		Y ☐ N ☐	
Moderate area (20-50cm²)		Y ☐ N ☐	
Large area (50cm²)		Y ☐ N ☐	

EROSION SEVERITY (tick one only)		**REGION AFFECTED** (tick all that apply)	
None	Y ☐ N ☐	Buttocks	Y ☐ N ☐
Mild erosion involving epidermis only	Y ☐ N ☐	Coccyx	Y ☐ N ☐
Moderate erosion involving epidermis & dermis with little or no exudate	Y ☐ N ☐	Rectal Area	Y ☐ N ☐
Severe erosion of epidermis with moderate involvement of dermis with low or no exudate	Y ☐ N ☐	Scrotum/labia	Y ☐ N ☐
		Lower abdomen	Y ☐ N ☐
		Upper thighs	Y ☐ N ☐
		Gluteal Cleft	Y ☐ N ☐
Extreme erosion of epidermis & dermis with moderate & persistent exudate	Y ☐ N ☐	Groins	Y ☐ N ☐
Evidence of fungal infection/rash	Y ☐ N ☐		

Appendix D: Bristol Stool Chart (Lewis & Heaton, 1997)



Appendix E: Ethics approval notification from Royal Brisbane and Women's Hospital Human Research Ethics Committee for Study 1

Enquiries to: Odette Petersen Coordinator
Phone: 07 3636 5490
Fax: 07 3636 5849
Our Ref: HREC/11/QRBW/399
E-mail RBWH-Ethics@health.qld.gov.au

Ms Jill Campbell
Skin Integrity Services
Level 1, Dr James Mayne Building
Royal Brisbane & Women's Hospital
Herston Q 4029

Dear Ms Campbell,

Re: Ref N^{o}: HREC/11/QRBW/399: Incontinence-associated dermatitis: A prevalence study in the acute care setting.

Thank you for submitting the above project for ethical and scientific review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (EC00172) at their meeting on 17 October, 2011.

I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project on 01 November, 2011. HREC approval is valid for three (3) years from
01.11.2011 to 01.11.2014.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition including specialties and affiliation with the Hospital *(Attachment I).*

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

The Royal Brisbane & Women's Hospital Human Research Ethics Committee is constituted and operates according to the NHMRC's National Statement on Ethical Conduct in Human Research (2007).
Royal Brisbane & Women's Hospital HREC 219 01.11.2011
Ref No: HREC/11/QRBW/399

A copy of this approval will also be sent to the District Research Governance Office (RGO). Please ensure you submit a completed Site Specific Assessment (SSA) Form to the RGO for authorisation from the CEO or Delegate to conduct this research at the Royal Brisbane & Women's Hospital Metro North District.

The documents reviewed and approved include:

Document	*Version*	*Date*
Covering Letter		24 September 2011
Application: NEAF	2.0 (2008)	27 September 2011
NEAF signature pages of A/Prof Fiona Coyer & MS Kerri McLeod		29 September 2011
IAD Prevalence Study Protocol	1.0	26 September 2011
Curriculum Vitae of Jill Campbell	1.0	26 September 2011
Memorandum of approval from Safety & Quality Unit		26 September 2011
Response to Request for Further Information		25 October 2011
Case Report Form	2	25 October 2011
Response to Request for Further Information		27 October 2011
Response to Request for Further Information		31 October 2011
Email of support from MS Kelly McDonough, Program Coordinator, Safety & Quality Unit RBWH, Pressure Injury Prevention, 3Cs and Patient Identification		31 October 2011
Participant Information Sheet: Incontinence associated dermatitis; A prevalence study in the acute care setting (IAD prevalence study)	4	31 October 2011
Pressure Injury Prevalence Audit Patient Information Sheet		31 October 2011

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - Unforeseen events that might affect continued ethical acceptability of the project.
      Serious Adverse Events must be notified to the Committee as soon as possible. In addition, the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

2. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC Coordinator. These should include a covering letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

3. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office.

4. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office (by-passing the HREC).

5. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a covering letter from the Principal Investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC Coordinator as per standard HREC SOP. Further advice on submitting amendments is available from
http://www.health.qld.gov.au/ohmr/documents/ethics/researcher_userguide.pdf

6. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

7. The HREC will be notified, giving reasons, on any sponsor reports or other information which might affect the ongoing ethical acceptability in line with the requirements of the ICH GCP guidelines as annotated by the TGA:
http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf

8. In accordance with Section 3.3.22 (b) of the National Statement the Principal Investigator will provide at least annual reports to the HREC, the first report being due on
01.11.2012 and a final report is to be submitted on completion of the study.

The District Administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on Hospital premises or claiming any association with the Hospital, or which the

Committee has approved if conducted outside Royal Brisbane & Women's Hospital Metro North Health Service District.

Should you have any queries about the HREC's consideration of your project please contact the HREC Coordinator on 07 3636 5490. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Once authorisation to conduct the research has been granted, please complete the Commencement Form *(Attachment II)* and return to the office of the Human Research Ethics Committee.
The HREC wishes you every success in your research.

Yours sincerely,

Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North DISTRICT
01.11.2011

Appendix F: Ethics approval notification from Queensland University of Technology Human Research Ethics Committee for Study 1

QUT

University Human Research Ethics Committee

HUMAN ETHICS APPROVAL CERTIFICATE

NHMRC Registered Committee Number EC00171

Date of Issue: 6/2/12 (supersedes all previously issued certificates)

Dear Ms Jill Campbell

A UHREC should clearly communicate its decisions about a research proposal to the researcher and the final decision to approve or reject a proposal should be communicated to the researcher in writing. This Approval Certificate serves as your written notice that the proposal has met the requirements of the *National Statement on Research involving Human Participation* and has been approved on that basis. You are therefore authorised to commence activities as outlined in your proposal application, subject to any specific and standard conditions detailed in this document.

Within this Approval Certificate are:

* Project Details
* Participant Details
* Conditions of Approval (Specific and Standard)

Researchers should report to the UHREC, via the Research Ethics Coordinator, events that might affect continued ethical acceptability of the project, including, but not limited to:

(a) serious or unexpected adverse effects on participants; and
(b) proposed significant changes in the conduct, the participant profile or the risks of the proposed research.

Further information regarding your ongoing obligations regarding human based research can be found via the Research Ethics website http://www.research.qut.edu.au/ethics/ or by contacting the Research Ethics Coordinator on 07 3138 2091 or ethicscontact@qut.edu.au

If any details within this Approval Certificate are incorrect please advise the Research Ethics Unit within 10 days of receipt of this certificate.

Project Details

Category of Approval:	Administrative Review		
Approved From:	7/12/2011	**Approved Until:**	1/11/2015 (subject to annual reports)
Approval Number:	1100001524		
Project Title:	Incontinence associated dermatitis: a prevalence study in the acute care setting		
Experiment Summary:	Determine the extent of incontinence associated dermatitis (IAD) as well as the presence of associated skin injury at an Australian metropolitan tertiary referral teaching hospital.		

Investigator Details

Chief Investigator: Ms Jill Campbell

Other Staff/Students:

Investigator Name	Type	Role
A/Prof Fiona Coyer	Internal	Supervisor
Dr Sonya Osborne	Internal	Supervisor

Participant Details

Participants:
Approximately 500-530

Location/s of the Work:
Royal Brisbane and Women's Hospital

Appendix G: Permission to reproduce a Table from the publication; Best practice Principles, IAD: Moving prevention forward. Global Consensus document.

Hi Jill
I am so sorry for the delay in responding to you – I received this while away on business and it dropped down in my inbox. I am delighted that you have found the document so useful and would be pleased to grant permission to use the table on distinguishing IAD from pressure ulcers. If possible, please could you include a citation to the document and encourage people to download a copy online.
Thank you for your encouragement and support
Best wishes
Kathy
Kathy Day
Publisher, Wounds UK and Wounds International
Direct: +44 (0)20 7960 9655
Mobile: +44 (0)7766 181 715
Email: kathy.day@woundsgroup.com
Wounds UK & Wounds International
1.03 Enterprise House, 1-2 Hatfields
London SE1 9PG, UK
Tel: +44 (0)20 7627 1510
A Schofield Healthcare Media Company
Registered in England & Wales No. 5638775

From: Jill Campbell <jill.campbell@hdr.qut.edu.au>
Date: Wednesday, 22 April 2015 03:39
To: Kathy Day <kathy.day@woundsgroup.com>
Subject: Request permission to reproduce table

Good afternoon Kathy,
Greetings from Australia. I was fortunate to be one of the reviewers of the excellent IAD expert paper.
As part of my PhD, I am currently writing a paper about the importance of differentiating between IAD and pressure ulcers as well as the importance of then *reporting* that differentiation data. I am writing to request permission to reproduce (from the Best practice Principles, IAD: moving prevention forward), Table 2, page 9, 'Distinguishing IAD from pressure ulcers'. It would be of great benefit in supporting the argument for accurate classification of these painful lesions.

I am really excited about how well the IAD paper has been received by clinicians here in Queensland, Australia! They have said they really like the easy to read format & one RN said it was great to have a 'one stop shop' for IAD information.
So thank you and all involved for a fabulous and really useful publication.
Warm regards
Jill

Jill Campbell
PhD Candidate
Queensland University of Technology Level 5, Centre Clinical Nursing, RBWH, Herston.
Phone 07 31381746Mobile 0419735144E
Email; Jill.Campbell@student.qut.edu.au

Appendix H: Study 2 data collection instrument

Subject Code: Intact Study _ _ _ _

Date of admission; Date of recruitment; Date of discharge/death;

LOHS (in days);
Gender: Male □ Female □ Weight Height
Smoker Yes □ No □

		Comments
Primary diagnosis		
Comorbidities: Please list		
Medications; Please list		
Antibiotics; type		
IV	Yes No Date Commenced Date Ceased	
Oral	Yes No Date Commenced Date Ceased	

Subject Code: _ _ _ _		

	Day 0	Day	Day	Day	Day	Day
Date						
Continence Status						
Incontinent urine only	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Incontinent faeces only	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Incontinent urine and faeces	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
IDC insitu & incontinent faeces	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
IDC insitu & continent	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Stoma						
Urinary	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Faecal	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Stool Frequency						
< 1 per day	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
2- 3 per day	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
> 3 per day	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Stool quality						
Formed	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

Semi-formed/liquid	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Continence aid use						
Full brief	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Insert pad	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Antibiotics						
Type						
IV	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Oral	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Enteral nutrition	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
SGA Score: A B C	A B C	A B C	A B C	A B C	A B C	A B C
Mobility						
Completely immobile	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Very limited	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Slightly limited	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
No limitation	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

Subject Code: _ _ _ _						
Physical Examination: (SAT) (Kennedy & Lutz, 1996)	Day 0	Day	Day	Day	Day	Day
Date						
Skin Redness						
None	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Mild redness	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Moderate redness	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Severe redness	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Area of skin Breakdown						
None	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Small (<20cm²)	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Moderate (20-50cm²)	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Large area(>50cm²)	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Erosion						
Mild (epidermis only)	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Moderate (epidermis &	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

dermis) little/no exudate						
Severe erosion	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Extreme erosion	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Region affected;						
Buttocks	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Coccyx	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Perianus	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Gluteal cleft	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Scrotum/labia	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Groins	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Lower abdomen	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Presence of *Candida* rash (clinical appearance)						
	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

S**ubject Code:** _ _ _ _						
	Day 0	Day	Day	Day	Day	Day
Date						
Swabs collected						
Perianus	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Groins	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Swab results; **enter result**						
Perianus						
Groins						

Appendix I: Subjective Global Assessment Tool

Name: Date:

Medical History			A	B	C
WEIGHT	Usual weight……	Current weight……			
Wt change past 6 months	Amount weight loss…….	% weight loss…….			
0-<5% loss			*		
5-10% loss				*	
>10% loss					*
Weight change past 2 weeks		Amount……			
No change; normal weight			*		
Increase to within 5%			*		
Increase (1 level above)			*	*	
No change, but below usual wt				*	
Increase to within 5-10%				*	
Decrease					*
DIETARY INTAKE					
No change; adequate			*		
No change; inadequate				*	
Change	**Duration of change**……...				
Suboptimal diet				*	
Full liquid				*	
Hypocaloric liquid					*
Starvation					*
Intake borderline; increasing			*		
Intake borderline; decreasing				*	
Intake poor; no change				*	*
Intake poor; increasing				*	
Intake poor; decreasing					*
GASTROINTESTINAL SYMPTOMS					
	Frequency (never, daily, no. of times/week)	Duration (<2wk, >2wk)			
Nausea	……	……..			
Vomiting	……	……			
Diarrhoea	……	……...			
Anorexia	……	……...			
None; intermittent			*		
Some (daily >2 week)				*	
All (daily >2 week)					*
FUNCTIONAL CAPACITY					
No dysfunction	Duration of change ……..		*		
Difficulty with ambulation/normal activities				*	
Bed/chair-ridden					*
Change past 2 week					
Improved			*		
No change				*	
Regressed					*

Physical examination		A	B	C

SUBCUTANEOUS FAT			
Under the eyes	Slightly bulging area		Hollowed look, depression, dark circles
Triceps	Large space between fingers		Very little space between fingers, or fingers touch
Biceps	Large space between fingers		Very little space between fingers, or fingers touch
MUSCLE WASTING			
Temple	Well-defined muscle/flat	Slight depression	Hollowing, depression
Clavicle	Not visible in Males; may be visible but not prominent in females	Some protrusion; may not be all the way along	Protruding/prominent bone
Shoulder	Rounded	No square look; acromion process may protrude slightly	Square look; bones prominent
Scapula/ribs	Bones not prominent; no significant depressions	Mild depressions or bone may show slightly; not all areas	Bones prominent; significant depressions
Quadriceps	Well rounded; no depressions	Mild depression	Depression; thin
Calf	Well developed		Thin; no muscle definition
Knee	Bones not prominent		Bones prominent
Interosseous muscle between thumb and forefinger	Muscle protrudes; could be flat in females		Flat or depressed area
OEDEMA (related to malnutrition)	No sign	Mild to moderate	Severe
ASCITES (related to malnutrition)	No sign	Mild to moderate	Severe
OVERALL SGA RATING	**A**	**B**	**C**

Adapted from: Detsky et al., 1994[8]; Baxter Healthcare Corporation, 1993; McCann, 1996 (Ferguson, Bauer, Banks, Capra, 1996) ©

This is a consensus document from Dietitian/ Nutritionists from the Nutrition Education Materials

Appendix J: Braden Scale – For predicting pressure sore risk

BRADEN SCALE – For Predicting Pressure Sore Risk

SEVERE RISK: Total score ≤ 9 **HIGH RISK**: Total score 10-12
MODERATE RISK: Total score 13-14 **MILD RISK**: Total score 15-18

DATE OF ASSESS ➡

RISK FACTOR	SCORE/DESCRIPTION				1	2	3	4
SENSORY PERCEPTION Ability to respond meaningfully to pressure-related discomfort	**1. COMPLETELY LIMITED –** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation, **OR** limited ability to feel pain over most of body surface.	**2. VERY LIMITED –** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness, **OR** has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. SLIGHTLY LIMITED –** Responds to verbal commands but cannot always communicate discomfort or need to be turned, **OR** has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	4. **NO IMPAIRMENT –** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.				
MOISTURE Degree to which skin is exposed to moisture	1. **CONSTANTLY MOIST–** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	2. **OFTEN MOIST –** Skin is often but not always moist. Linen must be changed at least once a shift.	3. **OCCASIONALLY MOIST –** Skin is occasionally moist, requiring an extra linen change approximately once a day.	4. **RARELY MOIST –** Skin is usually dry; linen only requires changing at routine intervals.				
ACTIVITY Degree of physical activity	1. **BEDFAST –** Confined to bed.	2. **CHAIRFAST –** Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	3. **WALKS OCCASIONALLY –** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	4. **WALKS FREQUENTLY–** Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.				
MOBILITY Ability to change and control body position	1. **COMPLETELY IMMOBILE –** Does not make even slight changes in body or extremity position without assistance.	2. **VERY LIMITED –** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	3. **SLIGHTLY LIMITED –** Makes frequent though slight changes in body or extremity position independently.	4. **NO LIMITATIONS –** Makes major and frequent changes in position without assistance.				
NUTRITION Usual food intake pattern [1]NPO: Nothing by mouth. [2]IV: Intravenously. [3]TPN: Total parenteral nutrition.	**1. VERY POOR –** Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement, **OR** is NPO[1] and/or maintained on clear liquids or IV[2] for more than 5 days.	**2. PROBABLY INADEQUATE –** Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement **OR** receives less than optimum amount of liquid diet or tube feeding.	**3. ADEQUATE –** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally refuses a meal, but will usually take a supplement if offered, **OR** is on a tube feeding or TPN[3] regimen, which probably meets most of nutritional needs.	4. **EXCELLENT –** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
FRICTION AND SHEAR	1. **PROBLEM-** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures, or agitation leads to almost constant friction.	2. **POTENTIAL PROBLEM–** Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair, restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	3. **NO APPARENT PROBLEM –** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times.					
TOTAL SCORE	**Total score of 12 or less represents HIGH RISK**							

ASSESS	DATE	EVALUATOR SIGNATURE/TITLE	ASSESS.	DATE	EVALUATOR SIGNATURE/TITLE
1	/ /		3	/ /	
2	/ /		4	/ /	

NAME-Last	First	Middle	Attending Physician	Record No.	Room/Bed

Form 3166P BRIGGS, Des Moines, IA 50306 (800) 247-2343 www.BriggsCorp.com
R304 PRINTED IN U.S.A

BRADEN SCALE

Appendix K: Participant information and consent form, Study 2

Royal Brisbane and Women's Hospital
Metro North Health Service District

Queensland University of Technology
Brisbane Australia

Participant Information Sheet/Consent Form

Royal Brisbane and Women's Hospital (RBWH)

Title	Incontinence-associated dermatitis and *Candida* detection; A pilot prospective observational study in the acute care setting.
Protocol Number	HREC/13/QRBW/394
Project Sponsor	RBWH Foundation and RBWH Research Advisory Committee
Coordinating Principal Investigator/ Principal Investigator	Jill Campbell, Clinical Nurse Skin Integrity RBWH, PhD Candidate.
Associate Investigator(s)	Associate Professor Fiona Coyer Director Academic Programs, Queensland University of Technology. Dr Sonya Osborne, Senior Lecturer, Queensland University of Technology. Dr Alison Mudge, Clinical Director, Research and Education, Department of Internal Medicine and Aged Care, RBWH; Dr Ivan Robertson, Director of Dermatology RBWH
Location	Internal Medicine Service Line, RBWH

Part 1 What does my participation involve?

You are invited to take part in a research project. This participant information document contains detailed information about this research project. Its purpose is to explain to you openly and clearly all the procedures involved in this project before you decide if you want to take part.

The project is called, Incontinence-associated dermatitis and *Candida* detection; A pilot prospective observational study in the acute care setting.

1 Purpose and Background

Being incontinent may cause a condition known as incontinence-associated dermatitis, a painful skin irritation that is caused by urine and faeces coming into contact with skin. This is similar to the condition known as nappy rash that develops in infants. Thrush may be present on moist skin such as the genital region. It may live on the skin without causing any symptoms or problems. In some cases having thrush on the skin can cause some symptoms. A thrush infection can be a common complication of incontinence associated dermatitis.
The purpose of this project is to determine if thrush infections are associated with the development of incontinence-associated dermatitis.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

The results of this research will be used by the main investigator, Jill Campbell a Registered Nurse to obtain a Doctor of Philosophy (PhD) degree, being undertaken and supervised at the Queensland University of Technology (QUT). This research has been initiated by Jill Campbell.

This research has been funded by the Royal Brisbane and Women's Hospital Foundation.

2 What does participation in this research involve?

Patients from medical wards at Royal Brisbane and Women's Hospital are being invited to participate.

Agreeing to take part in the study means you are willing to do the following things:

1. Have a swab of your bottom area and groin collected by the study nurse within 48 hours of your admission and then every Monday and Friday until you leave the hospital or until day 30 of your admission, whichever comes first. The swabs will be examined for the presence of thrush.
2. Provide answers to questions (taking approximately 10 minutes) about anything that may be associated with thrush or the development of the condition known as incontinence-associated dermatitis. You will be asked questions about your medications, particularly antibiotics, current illnesses and if you are continent or not.
3. Consent to the research staff accessing your hospital records to obtain information on your health status and medications which are relevant to thrush and/or incontinence-associated dermatitis.

You will be asked to sign a consent form prior to any study assessments being performed.

There are no costs associated with participating in this research project, nor will you be paid.

3 What do I have to do?

There is nothing specific you have to do to fully participate in the study beyond that outlined in section 2.

4 Other relevant information about the research project

This study is only being done at the Royal Brisbane and Women's Hospital. We are expecting to recruit approximately 80 patients.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. You may also want to discuss the project with your doctor or relative. Sign the consent form only after you have had a chance to ask your questions and received satisfactory answers.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Royal Brisbane and Women's Hospital.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you decide not to participate in the study, you can access information about thrush and incontinence-associated dermatitis from your ward nurse, the Skin Integrity specialist nurses at the Royal Brisbane and Women's Hospital or your medical team.

7 What are the possible benefits of taking part?

All patients will be given the same high level of care that is routinely given to patients at the RBWH. Participation in this study will in no way interfere with current of future treatments and care provided to you by your doctors. While there are no direct benefits to you, the research will result in a better understanding of thrush on the genital skin and if there is an association between this and the development of incontinence-associated dermatitis. It will help us to design more effective preventative and treatment measures. This may mean fewer people develop incontinence-associated dermatitis.

8 What are the possible risks and disadvantages of taking part?

There is a very low risk of minor discomfort involved in having the bottom and groin swabs taken. We anticipate that there are no other risks of injury or illness involved in participating in this research.

9 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, you will be informed right away. This new information may mean you can no longer participate in this research. If this occurs, the persons supervising the research will stop you taking part. In all cases, you will be offered all available care to suit your medical needs and medical condition.

10 What if I withdraw from this research project?

If you decide you wish to withdraw from this research project, please notify a member of the research team If you do withdraw your consent during the research project, the study nurse will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by up to the time you withdraw will form part of the research project results.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form, you consent to the study nurse and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The information will be kept in a locked filing cabinet in a locked room at Royal Brisbane and Women's Hospital. The information will only be available to the Principal researcher and the research assistant. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. After the research is finished, the information will be stored for 15 years at QUT in a locked room. After that it will be shredded and destroyed.

Information about you may be obtained from your health records held at this service for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. No individual information will be published; the results will be published as combined information.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 Who is organising and funding the research?

The research project is being conducted by Jill Campbell – Principal Investigator. The research is being funded by a grant from the Royal Brisbane and Women's Hospital Foundation.

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Royal Brisbane and Women's Hospital. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 Further information or any problems

If you need any more information or if you have any problems about this project, you can contact any of the researchers.

Clinical contact person

Name	Jill Campbell
Position	Principal Investigator
Telephone	Mobile 0419735144
Email	Jill_Campbell@health.qld.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Royal Brisbane and Women's Hospital
Telephone	07 3646 5490
Email	RBWH_Ethics@health.qld.gov.au

RBWH HREC Office contact

Position	Assistant Research Governance Officer
Telephone	07 3646 2377
Email	Anitha_Dinesh@health.qld.gov.au

QUT UHREC Office contact

Position	Research Ethics Advisor
Telephone	07 3138 3837
Email	c.windsor@qut.edu.au

Consent Form

Title; Incontinence-associated dermatitis and Candida detection; A pilot prospective observational study in the acute care setting.

Protocol Number HREC/13/QRBW/394

Coordinating Principal Investigator Jill Campbell

Associate Investigators Associate Professor Fiona Coyer
Dr Sonya Osborne
Dr Alison Mudge
Dr Ivan Robertson

Location Royal Brisbane and Women's Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)

Signature Date

Declaration by Study Nurse/ Principal Investigator

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Nurse/ Principal Investigator (please print)

Signature Date

Form for Withdrawal of Participation - Adult providing own consent

Title; Incontinence-associated dermatitis and Candida detection; A pilot prospective observational study in the acute care setting.

Protocol Number; HREC/13/QRBW/394
Coordinating Principal Investigator/Principal Investigator; Jill Campbell
Associate Investigator(s) Associate Professor Fiona Coyer
Dr Sonya Osborne
Dr Alison Mudge
Dr Ivan Robertson

Location; Royal Brisbane and Women's Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me, or my relationship with Royal Brisbane and Women's Hospital.

Name of Participant (please print)

Signature Date

In the event that the participant's decision to withdraw is communicated verbally, the Principal Investigator will need to provide a description of the circumstances below.

Declaration by Principal Investigator

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Principal Investigator (please print)

Signature Date

Appendix L: Patient information and consent form, Person Responsible, Study 2

Royal Brisbane and Women's Hospital
Metro North Health Service District

Patient Information Sheet/Consent Form
Person Responsible

Royal Brisbane and Women's Hospital (RBWH)

Title	Incontinence-associated dermatitis and *Candida* detection; A pilot prospective observational study in the acute care setting.
Protocol Number	HREC/13/QRBW/394
Project Sponsor	RBWH Foundation and RBWH Research Advisory Committee
Coordinating Principal Investigator/ Principal Investigator	Jill Campbell, Clinical Nurse Skin Integrity RBWH, PhD Candidate.
Associate Investigator(s)	Associate Professor Fiona Coyer Director Academic Programs, Queensland University of Technology.
	Dr Sonya Osborne, Senior Lecturer, Queensland University of Technology.
	Dr Alison Mudge, Clinical Director, Research and Education, Department of Internal Medicine and Aged Care, RBWH;
	Dr Ivan Robertson, Director of Dermatology RBWH
Location	Internal Medicine Service Line, RBWH

Part 1 What does participation involve?

The patient is invited to take part in a research project. This patient information document contains detailed information about this research project. Its purpose is to explain to you openly and clearly all the procedures involved in this project before deciding if the patient can take part.

The project is called, Incontinence-associated dermatitis and *Candida* detection; A pilot prospective study in the acute care setting.

1 Purpose and Background

Being incontinent may cause a condition known as incontinence-associated dermatitis, a painful skin irritation that is caused by urine and faeces coming into contact with skin. This is similar to the condition known as nappy rash that develops in infants. Thrush may be present on moist skin such as genital region. It may live on the skin without causing any symptoms or problems. In some cases, having thrush on the skin can cause some symptoms. A thrush infection can be a common complication of incontinence-associated dermatitis.
The purpose of this project is to determine if thrush infections are associated with the development of incontinence-associated dermatitis.

This Patient Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if the patient can take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether the patient can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish the patient to take part, they do not have to. They will receive the best possible care whether or not they take part.

If you decide you want the patient to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:
• Understand what you have read
• Consent for the patient to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of the patient's health information as described.

You will be given a copy of this Patient Information and Consent Form to keep.

The results of this research will be used by the main investigator Jill Campbell, a Registered Nurse to obtain a Doctor of Philosophy (PhD) degree, being undertaken and supervised at the Queensland University of Technology (QUT).
This research has been initiated by Jill Campbell, and has been funded by the Royal Brisbane and Women's Hospital Foundation.

2 What does participation in this research involve?

Patients from medical wards at Royal Brisbane and Women's Hospital are being invited to participate.
Agreeing to take part in the study means the patient is willing to do the following things:
1. Have a swab of the their bottom and groin collected by the study nurse within 48 hours of admission and then every Monday and Friday until they leave the hospital

or until day 30 of their admission, whichever comes first. The swabs will be examined for the presence of thrush.
2 .Provide answers to questions (taking approximately 10 minutes) about factors that may be associated with thrush or the development of the condition known as incontinence-associated dermatitis. You or the patient will be asked questions about medications, particularly antibiotics, current illnesses and if the patient is continent or not.
3. Consent to the research staff accessing the patient's hospital records to obtain information on their health status and medications which are relevant to thrush and incontinence-associated dermatitis.

You will be asked to sign a consent form prior to any study assessments being performed.

.

There are no costs associated with participating in this research project, nor will the patient be paid.

3 What does the patient have to do?

There is nothing specific the patient has to do to fully participate in the study beyond that outlined in section 2

4 Other relevant information about the research project

This study is only being done at the Royal Brisbane and Women's Hospital. We are expecting to recruit approximately 80 patients.

5 Does the patient have to take part in this research project?

Participation in any research project is voluntary. If you do not wish the patient to take part, they do not have to. If you decide they can take part and later change your mind, you are free to withdraw from the study at any stage.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. You may also want to discuss the project with the patient's doctor or relative. Sign the consent form only after you have had a chance to ask your questions and received satisfactory answers.

If you do decide the patient can take part, you will be given this Patient Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether the patient can or cannot take part ,or to take part and then withdraw, will not affect the patient's routine treatment, their relationship with those treating them or their relationship with the Royal Brisbane and Women's Hospital.

6 What are the alternatives to participation?

The patient does not have to take part in this research project to receive treatment at this hospital. If you decide the patient will not take part in the study, you can access information about thrush and incontinence-associated dermatitis from their ward nurse, the Skin Integrity specialist nurses at the Royal Brisbane and Women's Hospital or their medical team.

7 What are the possible benefits of taking part?

All patients will be given the same high level of care that is routinely given to patients at the RBWH. Participation in this study will in no way interfere with current of future treatments and care provided to the patient by their doctors. While there are no direct benefits to the patient, the research will result in a better understanding of thrush on the genital skin and if there is an association between this and the development of incontinence-associated dermatitis. It will help us to design more effective prevention and treatment measures. This may mean fewer people develop incontinence-associated dermatitis.

8 What are the possible risks and disadvantages of taking part?

There is a very low risk of minor discomfort involved in having the bottom and groin swabs taken. We anticipate that there are no other risks of injury or illness involved in participating in this research.

9 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, you will be informed right away. This new information may mean the patient can no longer take part in this research. If this occurs, the persons supervising the research will stop the patient taking part. In all cases the patient will be offered all available care to suit their medical needs and medical condition.

10 What if the patient withdraws from this research project?

If you decide you wish to withdraw the patient from this research project, please notify a member of the research team. If you do withdraw your consent during the research project, the study nurse will not collect additional personal information from the patient, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that patient data collected by up to the time you withdraw will form part of the research project results.

Part 2 How is the research project being conducted?

11 What will happen to information about the patient?

By signing the consent form you consent to the study nurse and relevant research staff collecting and using personal information about the patient for the research project. Any information obtained in connection with this research project that can identify the patient will remain confidential. The information will be kept in a locked filing cabinet in a locked room at Royal Brisbane and Women's Hospital. The information will only be available to the Principal researcher and the research assistant. Patient information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. After the research is finished, the information will be stored for 15 years at QUT in a locked room. After that, it will be shredded and destroyed.
Information about the patient may be obtained from their health records held at this service for the purpose of this research. By signing the consent form you agree to the research team accessing their health records if they are relevant to participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the patient cannot be identified, except with your permission. No individual information will be published; the results will be published as combined information.

.
Information about participation in this research project may be recorded in the patient's health records.

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about the patient. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access to the patient's information.

Any information obtained for the purpose of this research project that can identify the patient will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12 Who is organising and funding the research?

The research project is being conducted by Jill Campbell – Principal Investigator. The research is being funded by a grant from the Royal Brisbane and Women's Hospital Foundation.

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Royal Brisbane and Women's Hospital. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 Further information or any problems

If you need any more information or if you have any problems about this project, you can contact any of the researchers.

Clinical contact person

Name	Jill Campbell
Position	Principal Investigator
Telephone	Mobile 0419735144
Email	Jill_Campbell@student.qut.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Royal Brisbane and Women's Hospital
Telephone	07 3646 5490
Email	RBWH_Ethics@health.qld.gov.au

RBWH RGO office contact

Position	Research Governance Officer
Telephone	07 3646 8579
Email	RBWH-RGO@health.qld.gov.au

Consent Form - Person Responsible

Title; Incontinence-associated dermatitis and Candida detection; A pilot prospective observational study in the acute care setting.
Protocol Number; HREC/13/QRBW/394
Coordinating Principal Investigator; Jill Campbell
Associate Investigators; Associate Professor Fiona Coyer
Dr Sonya Osborne
Dr Alison Mudge
Dr Ivan Robertson

Location; Royal Brisbane and Women's Hospital

Declaration by person responsible for the patient

I have read the Patient Information Sheet or someone has read it to me in a language that I understand.
I understand the purposes, procedures and risks of the research described in the project.
I have had an opportunity to ask questions and I am satisfied with the answers I have received.
I freely agree for the patient to take part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future health care.
I understand that I will be given a signed copy of this document to keep.

Name of Patient (please print)

Name of person responsible

Relationship to patient

Signature Date

Name of Witness* to Patient's Signature (please print)

Signature Date

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Nurse/Principal Investigator

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the patient has understood that explanation.

Name of Study Nurse/ Principal Investigator† (please print)

Signature Date

Form for Withdrawal of Participation – Person Responsible

Title Incontinence-associated dermatitis and Candida detection; A pilot prospective observational study in the acute care setting.

Protocol Number HREC/13/QRBW/394
Coordinating Principal Investigator/
Principal Investigator Jill Campbell

Associate Investigator(s) Associate Professor Fiona Coyer
Dr Sonya Osborne
Dr Alison Mudge
Dr Ivan Robertson

Location Royal Brisbane and Women's Hospital

Declaration by person responsible

I wish to withdraw the patient from taking part in the above research project and understand that such withdrawal will not affect their routine treatment, their relationship with those treating them or their relationship with Royal Brisbane and Women's Hospital.

Name of Patient (please print)

Name of person responsible

Relationship to patient

Signature Date

In the event that the patient's decision to withdraw is communicated verbally, the Study Nurse/Principal Investigator r will need to provide a description of the circumstances below.

Declaration by Study Nurse/Principal Investigator

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the person responsible has understood that explanation.

Name of Study Nurse/Principal Investigator† (please print)

Signature Date

Appendix M: Ethical approval notification from Royal Brisbane and Women's Hospital Human Research Ethics Committee for Study 2

Queensland Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Enquiries to: Ann-Maree Gordon
A/Coordinator
Telephone: 07 3646 5490
Facsimile: 07 3646 5849
File Ref: HREC/13/QRBW/394
Email: RBWH-Ethics@health.qld.gov.au

Ms Jill Campbell
15 Kulindi Place
Carseldine Q 4034

Dear Ms Campbell,

Re: Ref Nº: HREC/13/QRBW/394: Incontinence-associated dermatitis and Candida detection; A pilot prospective observational study in the acute care setting

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) **(EC00172)** at its meetings held on 18 November, 2013 and 16 December, 2013.

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating site for this project is:

- Royal Brisbane & Women's Hospital, Qld

This letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the CEO or Delegate of the Royal Brisbane & Women's Hospital under whose auspices the research will be conducted.

The approved documents include:

Document	*Version*	*Date*
Covering Letter		20 October 2013
Application: NEAF *(Submission Code: AU/1/7E05112)*	2.0 (2008)	23 October 2013
Case Report Form	1	19 October 2013

Royal Brisbane & Women's Hospital
Level 7 Block 7
Butterfield Street, Herston Qld 4029
Australia

Telephone +61 7 3646 5490
Facsimile +61 7 3646 5849
www.health.qld.gov.au/rbwh/research/hrec.asp

Document	Version	Date
Curriculum Vitae of Jill Campbell		October 2013
Response to Request for Further Information		25 November 2013
InTACt Study Protocol	2	23 November 2013
RBWH Participant Information Sheet & Consent Form - Self	2	23 November 2013

Approval of this project from the RBWH HREC is valid from **19.12.2013** to **19.12.2016** subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at http://www.health.qld.gov.au/rbwh/research/hrec.asp.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at http://www.health.qld.gov.au/rbwh/research/hrec.asp.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **19.12.2014** and a final report is to be submitted on completion of the study. These instructions can be found at http://www.health.qld.gov.au/ohmr/html/regu/reporting_templates.asp.
- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at http://www.health.qld.gov.au/rbwh/research/hrec.asp.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by the Coordinating Principal Investigator to the Research Governance Office at the Royal Brisbane & Women's Hospital

in a timely manner to enable the institution to authorise the commencement of the project at its site.

- Should you have any queries about the RBWH HREC's consideration of your project please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/rbwh/research/hrec.asp.

The RBWH HREC wishes you every success in your research.

Yours sincerely,

Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
19.12.2013

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review research proposals have been certified by the National Health and Medical Research Council.

Appendix N: Administrative Review Approval Notification from Queensland University of Technology Human Research Ethics Committee Unit Approval for Study 2

Dear A/Prof Fiona Coyer and Ms Jill Campbell

Project Title: Incontinence associated dermatitis and Candida detection: A prospective observational study in the acute care setting (InTACt Study)

Ethics category Human - Administrative Review
QUT approval number: 1400000048 (As per Royal Brisbane and Women's Hospital Human Resarch Ethics Committee., Approval number: HREC/13/QRBW/394)
QUT clearance until: 19/12/2016

We are pleased to advise that your application has been reviewed and administratively approved by the Chair, University Human Research Ethics Committee (UHREC) based on the approval gained from the responsible HREC. We note this HREC has awarded the project ethical clearance until 19/12/2016.

CONDITIONS OF APPROVAL
Please ensure you and all other team members read through and understand all UHREC conditions of approval prior to commencing any data collection:
- Standard: Please see attached or www.research.qut.edu.au/ethics/humans/stdconditions.jsp
- Specific: None apply

Projects approved through an external organisation may be subject to that organisation's review arrangements. Researchers must immediately notify the QUT Research Ethics Unit if their project is selected for investigation / review by an external organisation.

VARIATIONS
All variations must first be approved by the responsible HREC before submission to QUT for ratification. Once approval has been obtained please submit this to QUT using our online variation form:
www.research.qut.edu.au/ethics/humans/var/

MONITORING
Please ensure you also provide QUT with a copy of each adverse event report and progress report submitted to the responsible HREC.

Administrative review decisions are subject to ratification at the next available UHREC meeting. You will only be contacted again in relation to this matter if UHREC raises additional questions or concerns.

Please don't hesitate to contact us if you have any queries.

We wish you all the best with your research.

Kind regards

Janette Lamb on behalf of the Chair UHREC
Research Ethics Unit | Office of Research | Level 4 88 Musk Avenue
Kelvin Grove | Queensland University of Technology
p: +61 7 3138 5123 | e: ethicscontact@qut.edu.au | w: www.research.qut.edu.au/ethics/

Appendix O: Queensland Civil and Administrative Tribunal Notification of Approval for Study 2

QCAT

Queensland Civil and Administrative Tribunal

Our Reference:CRL005-14
Contact Name:Trisha Rushby
Contact Number:07 3227 8188
Facsimile: (07) 3247 5879

3 June 2014

Dr Jill Campbell
15 Kulindi Place
CARSELDINE QLD 4034

Dear Dr Campbell

Re: Application for approval of Clinical Research QCAT Ref: CRL005-14

I am pleased to advise that the Tribunal approves the clinical research:

" Incontinence-associated dermatitis and Candida detection; A pilot prospective observational study in the acute care setting"

I **enclose** a copy of the Tribunal's Order dated 2 June 2014 and wish you every success with your research.

Please contact me on 07 3227 8188 if you require further information.

Yours sincerely,

Trisha Rushby
Human Rights Senior Case Manager 1
Queensland Civil and Administrative Tribunal

For more information on QCAT
Call 1300 753 228 or visit www.qcat.qld.gov.au
GPO Box 1639, Brisbane Qld 4001 Fax: 07 3221 9156
Email: enquiries@qcat.qld.gov.au ABN: 13 846 673 994

QCAT

Queensland Civil and Administrative Tribunal

DECISION

Case number:	**CRL005-14**
Applicant:	**Jill Campbell**
Before:	**Senior Member Endicott**
Date:	**2 June 2014**
Proceeding Type:	**On-Papers Hearing**

IT IS THE DECISION OF THE TRIBUNAL THAT:

1. The study "Incontinence-associated dermatitis and Candida detection: A pilot prospective observational study in the acute care setting" is approved.

2. This approval remains to 31 December, 2016 or until revocation or expiry of ethics approval, whichever is the sooner.

Signed

Senior Member Endicott
Queensland Civil and Administrative Tribunal

For more information on QCAT
Call 1300 753 228 or visit www.qcat.qld.gov.au
GPO Box 1639, Brisbane Qld 4001 Fax: 07 3221 9156
Email: enquiries@qcat.qld.gov.au ABN: 13 846 673 994

Appendix P: Statement of Contribution of Co-Authors for the Thesis by Publication

QUT

RESEARCH STUDENTS CENTRE
Examination Enquiries: 07 3138 1839
Email: research.examination@qut.edu.au

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of this chapter: 2

Publication title and date of publication or status: The Skin Safety Model: Reconceptualising Skin Vulnerability in Older Patients. Published. Journal of Nursing Scholarship; 2016 48(1):14-22.

	Statement of contribution*
Jill Campbell Signature 8/6/16 Date	Conducted literature review. Conceived and developed conceptual framework, wrote manuscript.
Fiona Coyer	Review of conceptual framework and manuscript
Sonya Osborne	Review of conceptual framework and manuscript

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer — Name
Signature
8/6/2016 — Date

RESEARCH STUDENTS CENTRE
Examination Enquiries: 07 3138 1839
Email: research.examination@qut.edu.au

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of this chapter: 4

Publication title and date of publication or status: Incontinence-associated dermatitis: a cross sectional prevalence study in the Australian acute care hospital setting. Published International Wound journal, June 2014 doi:10.1111/iwj.12322

Contributor	Statement of contribution*
Jill Campbell Signature 8/6/16 Date	Study concept and design, data acquisition, analysis and interpretation, wrote manuscript.
Fiona Coyer	Review of study concept and design. Assisted with data interpretation. Manuscript review
Sonya Osborne	Assisted with data interpretation. Manuscript review

Principal Supervisor Confirmation
I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer (Name) — Signature — Date 8/6/2016

RESEARCH STUDENTS CENTRE
Examination Enquiries: 07 3138 1839
Email: research.examination@qut.edu.au

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of this chapter: 5

Publication title and date of publication or status: Combining pressure injury and incontinence-associated dermatitis prevalence surveys; An effective protocol? Accepted 27.5.16 for publication, Wound Practice and Research.

Contributor	Statement of contribution*
Jill Campbell Signature Date 8/6/16	Study concept and design, data acquisition, analysis and interpretation, wrote manuscript.
Sandra Gosley	Assisted with data acquisition and interpretation. Manuscript review and revision
Kerrie Coleman	Manuscript review and revision
Fiona Coyer	Review of study concept and design. Manuscript review and revision

Principal Supervisor Confirmation
I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer
Name

Signature

Date 8/6/2016

RESEARCH STUDENTS CENTRE
Examination Enquiries: 07 3138 1839
Email: research.examination@qut.edu.au

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of this chapter: 7

Publication title and date of publication or status: *Candida Albicans* colonisation, incontinence-associated dermatitis and continence status in the acute care setting; A pilot study. Under review.

Contributor	Statement of contribution*
Jill Campbell Signature Date 8/6/16	Study concept and design, data acquisition, analysis and interpretation, wrote manuscript.
Fiona Coyer	Review of study concept and design. Assisted with data interpretation. Manuscript review and revision
Alison Mudge	Review of study concept and design. Assisted with data interpretation. Manuscript review and revision
Ivan Roberston	Review of study concept and design. Manuscript review
Sonya Osborne	Manuscript review and revision

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer (Name) — Signature — 8/6/2016 (Date)

RESEARCH STUDENTS CENTRE
Examination Enquiries: 07 3138 1839
Email: research.examination@qut.edu.au

Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the suggested format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the Australasian Research Online database consistent with any limitations set by publisher requirements.

In the case of this chapter: 8
Publication title and date of publication or status: Risk factors for *Candida* colonisation at the perianal and inguinal sites in patients admitted to acute medical wards. Under review

Contributor	Statement of contribution*
Jill Campbell Signature Date 8/6/16	Study concept and design, data acquisition, analysis and interpretation, wrote manuscript.
Fiona Coyer	Review of study concept and design. Assisted with data interpretation. Manuscript review and revision
Alison Mudge	Review of study concept and design. Assisted with data interpretation. Manuscript review and revision
Sonya Osborne	Manuscript review and revision

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Fiona Coyer — Name
Signature
8/6/2016 — Date