Formal title: A pilot randomised controlled trial using prophylactic dressings to minimise sacral pressure injuries in high risk hospitalised patients.

Running head: **P**ressure **I**njury **P**revention **P**ilot **S**tudy (PIPPS)

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**ABSTRACT**

This pilot randomised controlled trial examined the effect of prophylactic dressings to minimise sacral pressure injuries in high-risk hospitalised patients and assessed feasibility criteria to inform a larger study. Eighty patients were recruited at admission points (the Emergency Department and Surgical Care Unit) or directly from participating wards in the general medical surgical setting following assessment of high risk for sacral pressure injury. Participants were randomised into either the routine care or routine care and silicone foam border dressing group. Outcome assessment comprised digital photographs of each participant's sacrum every 72 hours for evaluation by a blind-to-intervention assessor. Sixty-seven participants had at least one sacral photograph taken and assessed by a blind-to-intervention assessor. Three participants were assessed as having a Stage I pressure injury. While the use of photography was effective, feasibility criteria identified challenges related to bias, blinding, weight assessment, preparation of nursing staff and sample size estimation.

## INTRODUCTION

General medical-surgical patients are at risk of hospital acquired pressure injuries (PI) during their admission (Brindle & Wegelin, 2012; Chaiken, 2012; Jenkins & O'Neal, 2010; Meyers, 2010). These may lead to increased length of stay due to complications such as pain, impaired immobility and infection (Lyder et al., 2012; VanGilder, MacFarlane, Meyer, & Lachenbruch, 2009). Prevention of PI remain a national and international priority in terms of quality patient outcomes; however PI continue to be a persistent challenge and economic burden for health services and the wider community (Centre for Healthcare Improvement, 2012; Graves, Birrell, & Whitby, 2005; Mulligan, Prentice, & Scott, 2011). This paper follows an earlier published protocol outlining the methods used in this study (Walker, Aitken, Huxley, & Juttner, 2015).

### Background

Valid and reliable evidence regarding the effectiveness of dressings to prevent PI is vital. Available published data is limited due to design and/or methodological limitations (Brindle & Wegelin, 2012; Chaiken, 2012; Moore & Webster, 2011; Santamaria et al., 2013; Schulz, 2008). Some studies have reported silicone foam border wound dressings as effective in reducing the incidence of PI in very high-risk critical care or high dependency patient populations (Brindle & Wegelin, 2012; Chaiken, 2012; Santamaria et al., 2013; Walsh et al., 2012). The study used the silicone foam border wound dressings described in these published studies. The dressings are specifically designed for the sacral area and are highly adaptable, comfortable and hypoallergenic. Advice from the manufacturer indicates: the silicone layer ensures the dressing can be changed without damaging the wound or surrounding skin, reducing the risk of additional pain and maceration; the dressing is moisture proof so can

remain insitu during hygiene cares and can remain in place for several days where appropriate (Mölnlycke Health Care, Gothenburg Sweden).

PI are a significant problem in acutely ill general medical-surgical patients and it is not clear if outcomes reported in published studies can be replicated in this population. Although the acute care population experiences many of the same risk factors as the critical care population, such as infection, pressure injury, delirium, and venous thromboembolism, they often do not experience the same extent of immobility, nutritional deficiency and altered consciousness. Consequently, it is imperative that the effectiveness of silicone foam border wound dressings is tested specifically in the general medical-surgical population.

## THE STUDY

### Aims

The objective of this study was to assess the feasibility of conducting a randomised controlled trial (RCT) using pre-determined feasibility criteria comprising recruitment, retention, management of research personnel and data and intervention fidelity; use pilot data to refine the intervention protocol and research strategies; test the effectiveness of blind assessment and data collection and enable sample size estimations for a larger subsequent study. This sits within a larger programme of research designed to reduce the prevalence and severity of PI in high-risk hospitalised patients.

### Design

The study used a parallel group randomised controlled design, as per the Good Clinical Practice and Consolidated Standards of Reporting Trials (CONSORT) guidelines (Moher et al., 2010), over a five month period from February to July 2014.

*Participants*

Non-probability consecutive sampling was used to recruit adult patients admitted to specific admission entry points (the Surgical Care Unit and the Emergency Department) or through participating medical and orthopedic surgical wards.

Potentially eligible patients were screened against study inclusion and exclusion criteria (Table 1), and 50% (153/306) of screened patients (or their family member or legal guardian) were approached for further information about their eligibility at an appropriate time during their admission. If eligible and wanting further information about the study, patients or their proxy were provided with sufficient time to read the patient information form, consider their participation and provide informed consent.

**Table 1** Inclusion and exclusion criteria

| |
|---|
| Inclusion criteria |
| • ≥18 years of age (the study venue is an adult-focused tertiary health facility);<br>• Able to provide written informed consent either in person or via their family member or legal guardian (National Health and Medical Research Council 2007). Approval to seek proxy consent was granted by the Queensland Civil and Administrative Tribunal.<br>• Assessed as being at high risk or greater of PI (as per a risk assessment score of 15+ using the Waterlow Scale) on hospital admission to the medical or surgical study wards.<br>• Expected hospital length of stay ≥72hrs following recruitment; |
| Exclusion criteria |
| • Suspected or actual spinal injury which prevented the patient being repositioned;<br>• Lower back surgery (lumbar spine) which prevented the application of a sacral dressing;<br>• Existing sacral PI, injury or allergy in the sacral area at the time of hospital admission;<br>• Faecal incontinence at the time of hospital admission;<br>• Unable to speak or understand English with no interpreter present |

One hundred and twenty-five patients (41%) of screened patients met the eligibility criteria to participate in the study. From these, 80 patients provided informed consent and were recruited, 38 were eligible but declined to participate and seven were eligible but consent could not be obtained in a timely manner. Refer to the Consolidated Standards of

Reporting Trials (CONSORT) diagram for the study, Figure 1. Patient's reasons for declining to participate were due to a general lack of interest in the study (n = 15), or stress associated with their admission (n =12). Other reasons included: allergies to wound dressings or sensitive skin (n = 5), family advice against participation (n = 2), pre-exiting knowledge about preventing "bed sores" (n = 2), and not liking the look or feel of the dressing (n = 2).

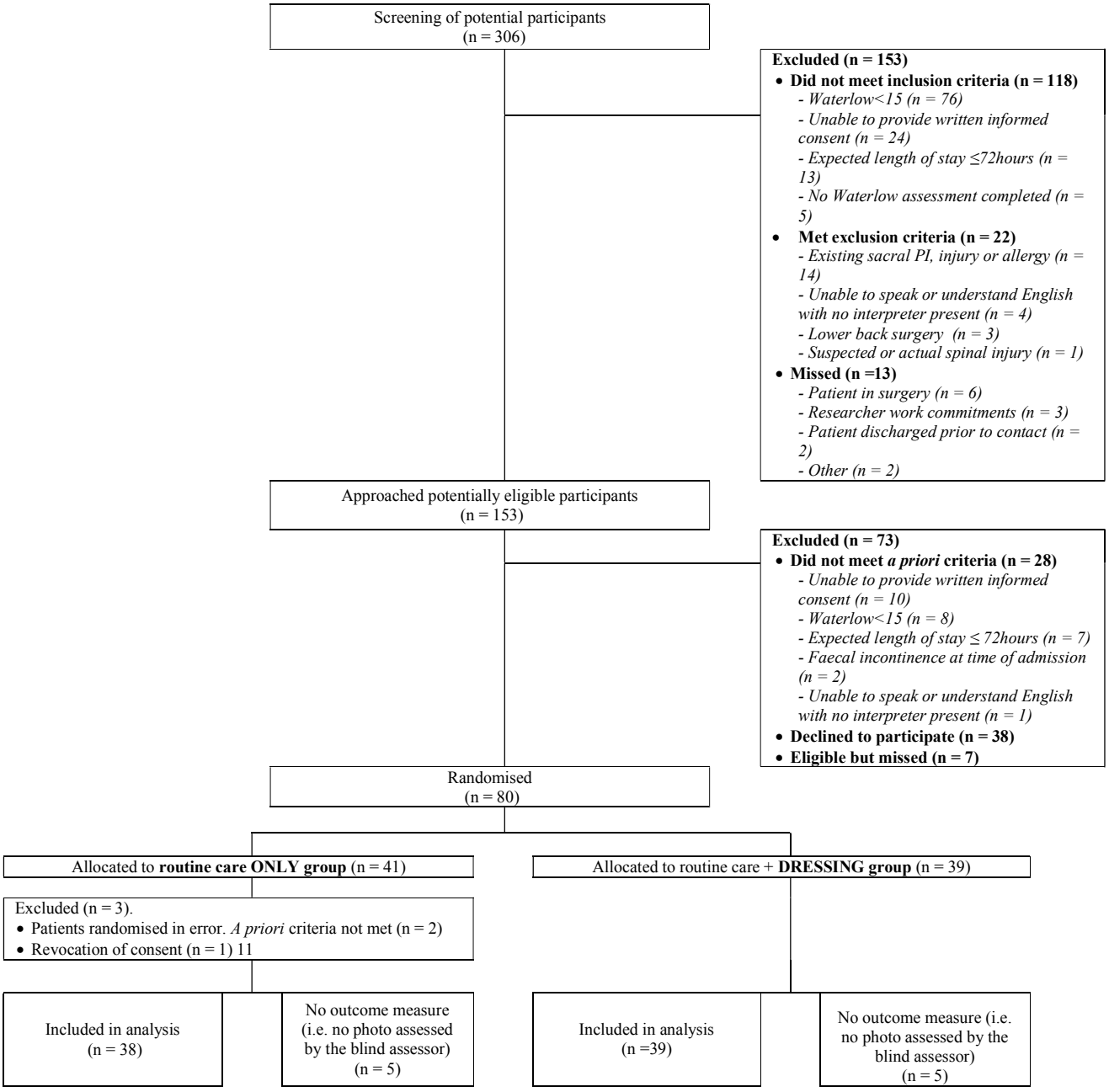

**Figure 1** The CONSORT diagram

*Intervention*

Study participants had demographic and health status characteristics recorded (age, gender, diagnosis or surgery, source of admission, mobility status, body mass index, health comorbidities, current smoking status, Waterlow score, existing PI (other than sacral) and history of PI), and a high resolution digital photograph taken of their sacrum as a baseline reference point. The Waterlow assessment relies on the rating of categories including build and weight for height measured using a body mass index assessment (BMI), visual assessment of the skin, age, gender, continence, mobility, measure of malnutrition and a number of 'special risk factors' such as tissue malnutrition, neurological deficits, major surgery and certain medications (Webster, Gavin, Nicholas, Coleman, & Gardner, 2010).

Participants allocated to the dressing group then had a silicone foam border dressing applied to their sacrum by the Research Nurse (ResN). Regardless of their intervention group allocation, all study participants continued to receive routine care, as per hospital policy. This consisted of regular skin observation and nursing care including use of a pressure distribution overlay on a standard mattress, or removal of a standard mattress and replacement with a pressure redistributing mattress, possible multi-disciplinary review and second hourly repositioning.

Instruction regarding correct application of the 18 x 18 cm dressings was sourced through the manufacturer's website (Mölnlycke Health Care, Gothenburg Sweden), and expert clinician advice. All participants enrolled in the study had their sacrum skin integrity and/or dressing assessed at least once a day by the ResN or Registered Nurses (RNs) caring for them as per hospital policy recommendations. For participants in the dressing group, the dressing was replaced every 3 days or sooner if it became loose or soiled, in accordance with

protocols from previous studies (Brindle, 2010; Brindle & Wegelin, 2012; Chaiken, 2012; Walsh et al., 2012).

*Data analyses*

Analysis of data was conducted according to the statistical analyses plan previously reported (Walker et al., 2015). An intention-to-treat strategy was used to include all randomised participants in their allocated group regardless of the treatment they received (Polit & Beck, 2012). Although intention-to-treat analysis may underestimate the effects of the treatment, it is considered a true reflection of the 'real world' and therefore allows for greater generalizability (Fergusson, Aaron, Guyatt, & Hébert, 2002; Polit & Beck, 2012). A permissible exception to this was the post-randomisation exclusion of patients mistakenly recruited (Chan, Robioneck, & Joensson, 2008; Fergusson et al., 2002).

*Randomisation*

Random allocation of patients to either the routine care group or the dressing group was achieved using an on-line clinical trials coordinating website accessed by the ResN using a smart phone or tablet. A stratified approach was used to ensure even distribution of participants' diagnostic category (medical and surgical), as well as a 1:1 ratio with random block sizes. Of the 80 patients recruited, 39 (49%) were admitted to the Division of Medicine and 41 (51%) to the Division of Surgery.

*Blinding*

Although participants and clinicians could not be blinded to treatment group allocation, sacral assessment was undertaken by a suitably qualified blind-to-intervention ("blinded") nurse assessor. This role was separate from that of the ResNs who had a direct relationship with study participants. The blinded-to-intervention nurse assessor was located

off-site and evaluated high resolution photographs every third day coinciding with dressing removal in intervention participants and/or on discharge from the ward. Photography offers a practical and validated solution to the challenges associated with blinding (Baumgarten et al., 2009; Defloor & Schoonhoven, 2004). The study procedure manual identified the process for taking photographs including consistent camera settings for resolution, color and size and, use of a disposable 10cm paper ruler with the participant's study ID and date to measure the sacrum and wound if present. Prior to commencement of the study, ResNs practiced taking photographs with the high resolution digital camera to establish appropriate distances from which to photograph the sacral area. Assessment of the photographs was guided by The National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel pressure injury and staging classification system (National Pressure Ulcer Advisory Panel, 2009), as reported in the Pan Pacific Clinical Practice Guideline for the Prevention and Management of Pressure Injury (Australian Wound Management Association, 2012).

**Ethical considerations**

This pilot RCT was conducted in accordance with the Helsinki Declaration (2008) and [Australian] National Health and Medical Research Council's National Statement Guidelines (2007). Ethical approval was granted by the health service and university human research ethics committees, and where patients were unable to provide informed consent, proxy consent by family member and/or legal guardian was approved by the Queensland Civil and Administrative Tribunal. As previously reported (Walker et al., 2015), the study was registered with the Australian and New Zealand Clinical Trials Registry: ACTRN12613001328763 http://www.ANZCTR.org.au/ACTRN12613001328763.aspx

**RESULTS**

*Participant recruitment and retention*

As illustrated in the CONSORT diagram (Figure 1), 80 participants were recruited into the main study with 3 participants excluded immediately post randomisation due to randomisation error (n = 2), and revoked consent (n = 1). Seventy-seven participants were included in the analyses as per the intention-to-treat principle. Only 67 participants (84%) had an outcome measure, that is; had a least one sacral photograph taken after the baseline photograph, assessed by the "blinded" assessor. For those 10 participants (13%) who did not have an outcome measure, reasons included early discharge from the ward (< 72 hours), lumbar spinal block or spinal surgery preventing the application of a sacral dressing, or dressing removed by patient due to reported discomfort.

The majority of patients were screened in the Surgical Care Unit, although only 24% of screened patients were recruited. Only 2 patients were recruited from 6 screened in the Emergency Department. This small number of screened/recruited patients in the Emergency Department was predicted due to the National Emergency Access Target (National Health Performance Authority, 2012), which aims to admit presenting patients to hospital, refer them to another hospital for treatment or discharge them home within four hours. As a result, 183/306 patients were screened (60%), and 50/80 participants (63%) were recruited directly from the participating wards.

The median age of participants was 75 years (IQR: 49-91), with more female participants (n = 54, 70%) than males (n = 23, 30%). The median Waterlow score on admission was 17 (IQR: 15-24). A score of 15 or above is accepted as the cut-off point for high risk of PI and a score of 20 or above as very high risk (Princess Alexandra Hospital, 2014; Webster et al., 2010). For those participants who had a BMI assessment undertaken on admission (n = 38), the majority were in the obese range (a score $\geq 30$ kg/m$^2$). Where participants could not have a formal BMI assessment, the ResN made a clinical judgment of

weight (by visual inspection alone). This method of assessment resulted in a more equal distribution of weight between the four categories (Table 2).

**Table 2** *Comparison* between groups for demographic and clinical characteristics

| **Characteristic** | | | **Total** | **Routine Care ONLY** | **Routine care + DRESSING** | |
|---|---|---|---|---|---|---|
| | | | **n = 77** | **n = 38** | **n = 39** | ***p* value** |
| Age | *Median, IQR* | | 75 (49 -91) | 72 (56 -87) | 77 (55 - 90) | 0.21 |
| Hospital Length of stay - Admit to discharge | *Median, IQR* | | 6 (2 - 18) | 6 (3 - 12) | 6 (3 - 14) | 0.64 |
| Gender | *n, (%)* | Female | 54 (70%) | 31 (82%) | 23 (59%) | 0.03 |
| | | Male | 23 (30%) | 7 (18%) | 16 (41%) | |
| Time from hospital admission to recruitment - hours | *Median, IQR* | | 13.4 (1.7 - 41.6) | 6.8 (1.5 - 40.9) | 19.8 (1.6 - 50.3) | 0.12 |
| Time from recruitment to discharge (hours) | *Median, IQR* | | 121 (79 – 172) | 122 (88 – 198) | 121 (73 – 171) | 0.91 |
| Time from admission to discharge (hours) | *Median IQR* | | 149 (104 – 201) | 149 (102 -198) | 149 (111 – 134) | 0.91 |
| Waterlow score | *Median, IQR* | | 17 (15 - 24) | 17 (15-23) | 17 (15-21) | 0.74 |
| Body Mass Index (kg/m$^2$) | *Median, IQR* | | 33 (23 - 56) | 34 (23 44) | 31 (25 -35) | 0.33 |
| BMI Category | *n, (%)* | Underweight | 3 (8%) | 3 (14%) | 0 | 0.09 |
| | | Normal weight | 6 (16%) | 1 (5%) | 5 (29%) | |
| | | Overweight | 6 (16%) | 3 (15%) | 3 (18%) | |
| | | Obese | 23 (61%) | 14 (67%) | 9 (3%) | |
| | | Missing data | 39 | 17 | 22 | |
| Clinical judge. of weight | *n, (%)* | Underweight | 10 (26%) | 5 (29%) | 5 (24%) | 0.98 |
| | | Normal weight | 10 (26%) | 4 (24%) | 6 (29%) | |
| | | Overweight | 11 (29%) | 5 (29%) | 6 (29%) | |
| | | Obese | 7 (18%) | 3 (18%) | 4 (19%) | |
| | | Missing data | 39 | 21 | 18 | |
| Health history | *n, (%)* | None relevant | 42 (55%) | 17 (45%) | 25 (66%) | 0.22 |
| | | Diabetes | 28 (37%) | 18 (47%) | 10 (26%) | |
| | | Vascular disease | 3 (4%) | 1 (3%) | 2 (5%) | |
| | | Previous PI | 3 (4%) | 2 (5%) | 1 (3%) | |
| | | Missing data | | | 1 | |
| Mobility status | *n, (%)* | Independent | 19 (25%) | 10 (26%) | 10 (24%) | 0.80 |
| | | Assist x 1 | 17 (22%) | 10 (26%) | 7 (18% | |
| | | Assist x 2 | 14 (18%) | 6 (16%) | 8 (21%) | |
| | | Full assist | 26 (34%) | 12 (32%) | 14 (37%) | |
| | | Missing data | | | 1 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Smoking status | *n, (%)* | Non-smoker | 70 (92%) | 34 (89%) | 36 (95%) | 0.40 |
| | | Current smoker | 6 (8%) | 4 (11%)) | 2 (5%) | |
| | | Missing data | | | 1 | |
| Existing PI (other than sacral) | *n (%)* | Yes | 7 (8) | 4 (11) | 3 (8) | |
| | | Missing data | 1 | | | |
| Site of existing PI | | Shoulder | 2 | 1 | 1 | |
| | | Heel | 3 | 2 | 1 | |
| | | Toe | 1 | 0 | 1 | |
| | | Other | 1 | 1 | 0 | |
| Reason for admission | *n, (%)* | Medical | 36 (47%) | 16 (42%) | 20 (51%) | 0.59 |
| | | Elective Surg. | 30 (39%) | 17 (45%) | 13 (33%) | |
| | | Trauma | 11 (14%) | 5 (13%) | 6 (15%) | |

P values calculated using $\chi^2$ or Fishers exact tests of independence for categorical data and Wilcoxon rank-sum tests for continuous data; BMI – Body Mass Index

*Management of research personnel and data*

Considerable time was spent with the ResNs and blind assessor prior to the commencement of the study to familiarise them with the study protocol and procedure manual. The Principal Investigator was also available via telephone and email for specific queries during the study. The experience was described by the ResNs as 'a wonderful experience to be part of'; 'information provided was useful and easy to understand'; 'we were supported at every step'.

Assessment of a participant's sacrum and/or dressing was conducted by ResNs on 208 occasions (74%) or RNs on 72 occasions (26%), with the majority of assessments taking place on the morning shift (81%), and decreasing during the afternoon (42%) and evening (12%). Patient self-assessment of dressing comfort was sought and documented on 131 occasions. Ninety-five percent of patient self-assessments (125 occasions) reported the dressing as comfortable with only six (5%) reporting dressing discomfort. Dressings were immediately removed for participants who found the dressing uncomfortable as per the study protocol (Walker et al., 2015).

The median (IQR) number of days sacral dressings remained in situ was two days (1-3) or 49 hours (24-69). Reasons for dressing dislodgement and removal prior to the routine

day-three change included: non-adherence due to the dressing becoming wet during hygiene cares (usually during a shower) or its edges rolling up during physical movement, removal because of faecal incontinence, reported discomfort, and/or lumbar spinal surgery or spinal block.

*Intervention fidelity (suitability of site, time and resources, preparation of nursing staff)*

Eight to 12 months were allocated for screening and the recruitment of 80 participants in this pilot study. The sample was achieved in five months indicating an over-estimation of time allocation. The study budget covered the casual salaries for the blind assessor and ResNs, as well as the purchase of the study dressings. The median time provided to each recruited participant was estimated as two hours and 10 minutes. The cost of the study dressings (30 boxes x five dressings) was $AUD 1,339.

Prior to the commencement of screening and recruitment, a series of in-service sessions were provided to nursing staff in the participating wards and admission points over four weeks to prepare them for the study. Flyers and reminders from nurse leaders in the participating wards and admission points were also used to keep clinicians informed about the study. Following the completion of the recruitment phase, nursing staff were anonymously surveyed to assess the effectiveness of preparation and training provided. Of the 63 nurses who completed the survey, only 32 (51%) reported having any knowledge of the pilot study before it commenced, and only 25 (40%) found the preparatory/training session about the study effective (useful/helpful). Forty-nine of the surveyed nurses (78%) felt well supported by the researchers during the study.

*Blind assessment of pressure injury and inter-rater reliability*

A qualified staff member from the Stomal Therapy and Wound Management Department assessed 20 day-three sacral photographs (30%) to enable the estimation of inter-rater reliability. This independent assessor also blinded-to-intervention, agreed with the blinded assessor's evaluation in 95% of cases. Inter-rater reliability analysis using the Cohen's kappa statistic was performed to determine consistency between assessors. A result of 0.77 indicated an acceptable degree of agreement between assessors.

The blinded assessor reported observing atraumatic markings on the skin in the shape of the dressing which reduced blinding to intervention. As a result the blinded assessor correctly identified the allocated group for 20 of the 34 patients in the intervention group and all 33 patients in the control (routine care only) group. Despite attempts to ensure a period of time between dressing removal and photograph of the sacral area to allow these marking to dissipate, it was often not possible due to patient comfort concerns.

Three participants were assessed as having a Stage I PI. Details regarding diagnostic category, allocated group and significant health history of those assessed as developing a Stage 1 PI are reported (Table 3).

**Table 3** Assessment of Pressure Injury according to blinded-to-intervention photographic assessment

| | Allocated group | Gender | Age | Health history | Clinical judge of weight | Inter-rater assessment of stage 1 pressure injury |
|---|---|---|---|---|---|---|
| 1 | Routine care | F | 74 | Dementia<br>Diabetes | Underweight | Agree. Stage I PI |
| 2 | Dressing | F | 72 | Dementia<br>Previous PI | Overweight | Agree. Stage I PI |
| 3 | Dressing | M | 80 | Vascular disease | Overweight | Disagree. No pressure injury |

*Suitability of data collection tools*

Both ResNs and the blind assessor found the protocol and procedure manual instructions easy to understand and suitable for the context. The ResN collection tools

(screening tool and case report form) and blinded assessment form were also positively evaluated with some minor suggestions for layout modification.

The 'end of bed' data collection tool was included with the patients' chart to record assessment of the patient's sacrum and/or dressing, the date, time and reason for dressing changes. Forty-four nurses from the participating ward anonymously completed a survey regarding the suitability of this data collection tool. Only 11 (25%) reported using the 'end-of-bed' data collection tool.

*Sample size*

The sample size calculation based on the occurrence of Stage 1 PI between study groups, had an overall difference of 3%. Based on the Group 1 proportion of 0.061 (2 PI from n = 33, as assessed by the blind assessor) and Group 2 proportion of 0.029 (1 PI from n = 34, as assessed by the blind assessor), and using a Fisher's exact test with a two-sided significance level of 0.05 and power of 80%, a sample size of 1500 (750 in each group) would be required to test the effectiveness of this intervention.

## DISCUSSION

This pilot study was completed within the resources allocated and in less time than predicted. Feasibility outcomes suggest further refinement of the protocol and research strategies in relation to reducing bias, the use of photography, assessment of weight, preparation of nursing staff, better utilisation of bedside paperwork and blinding.

The low prevalence of PI assessed during this study may have been influenced by existing state and hospital policies regarding PI screening, assessment, prevention and management, on-going staff education, and regular point prevalence audits (Princess Alexandra Hospital, 2014; Webster et al., 2010), as per the National Safety and Quality

Health Service Standards for Preventing and Managing Pressure Injuries (Australian Commission on Safety and Quality in Health Care (ACSQHC), 2011). Additionally all registered and enrolled nurses at the study venue undertake annual pressure injury assessment training. A Hawthorne Effect, where subjects' awareness of the study affects the dependent variable (Polit & Beck, 2012), may also have contributed to the low prevalence of PI. Nursing staff caring for study participants quickly became aware of patients' participation in the study which may have encouraged closer attention to PI assessment and prevention strategies.

The use of digital photography provided a practical solution for the independent assessment of sacral skin integrity during the study (Baumgarten et al., 2009). Inter-rater reliability between the assessors was acceptable suggesting this method of blinding could be extended to a larger study with the inclusion of additional measures to improve its accuracy. These might include utilising a panel of three or more independent blind assessors to provide peer-reviewed, real-time skin assessments, or the use of a third blind assessor in instances where two assessors had conflicting evaluations. These measures would need to ensure skin assessment was undertaken in a timely manner to safeguard participants' health and safety.

Assessment of weight is an important assessment criterion in the screening of patients at risk of PI. PI risk assessment tools such as the Waterlow Scale require the rating of eight categories including build and weight for height (Webster et al., 2010). In this study there was a clear difference in assessment of participant's weight by clinicians in 51% of cases where a formal BMI assessment had not been performed. A formal weight assessment is considered standard practice for all admitted patients due to its importance in medication prescribing, skin integrity management, manual handing and nutritional status (Evans, 2012; Goutelle, Bourguignon, Bertrand-Passeron, Jelliffe, & Maire, 2009). Compliance in obtaining a formal assessment of body weight in health settings remains poor (Evans, 2012; Goutelle et

al., 2009), which has serious ramifications for appropriate PI prevention strategies. In situations where a formal weight assessment of patients is not possible due to a lack of suitable weight assessment equipment or complications such as pain, injury, immobility and/or cognitive impairment (Goutelle et al., 2009), a visual estimation of weight is used. The practice of visual assessment is cited by researchers as consistently inaccurate (Corbo, Canter, Grinberg, & Bijur, 2005; Hall, Larkin, Trujillo, Hinds, & Delaney, 2004; Kahn, Oman, Rudkin, Anderson, & Sultani, 2007), particularly when assessing underweight and obese patients (Determann et al., 2007; Kahn et al., 2007). Some recommendations to improve weight estimation include beds with built-in scales or scale devices that can be easily used between beds, (Kahn et al., 2007), reliance on patient self-assessment of weight where they are conscious, cognitively alert and able to communicate (Corbo et al., 2005), or visual assessment by a three -person panel (Goutelle et al., 2009).

The ResNs and blind assessor enjoyed their participation in the research process and contributed to the building of research capacity within the profession. There were challenges in securing nursing staff in the participating wards and units to prepare them for the study and evaluate their experience. Only 63 from approximately 188 registered and enrolled nurses from the participating wards and units evaluated the study, with 40% of these respondents reporting having no knowledge of the project prior to its commencement. This was despite a six month program of information sharing with nurse leaders in the participating wards and admission points, and implementation of fortnightly nurse leader meetings for the duration of the study period to report project progress. Additionally, colour posters were placed in participating wards to inform staff of the study commencement data and one month prior to the commencement of the study, nursing staff in the participating wards were invited to education sessions during working hours for information about the study.

Clinicians in health settings are a workforce in constant motion, with elevated rates of staff variability, skill and experience. The high degree of part-time employment for Australian nurses and the movement within, across and out of the profession can be attributed to decreasing rates of staff retention and overall working hours, as well as higher rates of secondment (the temporary transfer to other positions), extended leave, short-term contracts, and short to medium term migration from Australia (Australian Institute of Health and Welfare (AIHW), 2013; Health Workforce Australia (HWA), 2015). This transience in the clinical setting can make it difficult to be informed about and participate in research activities.

Documentation fatigue may also have impacted nurses' motivation to be involved with the research process. Involvement usually means more paperwork which is described as the burden of contemporary nursing practice (Lomas, 2012); hence nurses may have been reluctant to allocate valuable time to the study. The ResNs therefore attempted to support nursing staff in the management of these patients by developing a daily routine of checking-in with participants and their nurses, inspecting participant's sacral dressing or skin integrity and documenting these observations in the 'end-of-bed' data collection tool. Greater time to prepare nurses in the pre-study phase, over a period of three to six months for example, may have had improved awareness of the study in the participating wards and increased awareness and use of the 'end of bed' data collection tool. A larger time investment during the post-study evaluation period may also have led to a better response rate. Support of nurses by the ResNs appears to have been the most effective method of insuring study fidelity.

Only three of the 67 participants were assessed by the blinded assessor as having a Stage I PI, with one case disputed by the inter-rater assessor. Two of the three participants (including the participant with contested Stage I PI assessment) were allocated to the dressing group and all three participants had significant chronic comorbidities such as vascular disease

(n = 1), diabetes and advanced dementia (n = 1) and advanced dementia (n = 1). All were over the age of 70. While the use of prophylactic silicone foam border dressings reduced the incidence of PI in critical care or high dependency patients (Brindle & Wegelin, 2012; Chaiken, 2012; Santamaria et al., 2013; Walsh et al., 2012), they may not have been as effective in a hospitalised general medical-surgical population where patients are generally awake, and have greater mobility. As reported, two of the main reasons for dressing dislodgement and removal prior to the routine day-three change were due to saturation during hygiene cares or edges of the dressing rolling-up during physical movement.

Blinding is a considerable challenge for this type of research. Efforts were made to reduce bias by blinding the skin assessor to group allocation. Initial attempts were also made to remove the dressing 10-15 minutes before the sacral photograph was taken to allow atraumatic marking on the skin (where the dressing had relaxed into the folds of the skin of the lower back and buttocks) to dissipate. It quickly became apparent that this was often not possible due to patient comfort concerns, particularly for those patients with acute orthopaedic injuries or chronic illnesses. A sham dressing, consisting only of the dressing boarder may have left similar atraumatic markings on the lower back and buttocks of control group participants, thereby lowering the number of correctly identified group allocations by the blind assessor and reducing bias. While sham procedures and devices are used for control groups in clinical trials investigating the effectiveness of wound treatments (Bergin & Wraight, 2006; Malin et al., 2013; Nelson, Hillman, & Thomas, 2014; Serena et al., 2009), there is no evidence in the literature of a sham dressing as described. Ethical and patient safety issues associated with a sham dressing would need to be to be carefully considered and tested prior to implementation.

**Limitations**

Due to the small sample size within a single healthcare setting, results from this pilot study are not generalizable and should not be considered for their effect. Study limitations include participant attrition due to early discharge, spinal block or lower back surgery which prevented dressing application. Protocol inconsistency was evident due to disparity in body weight assessment and probable mattress variation. A pragmatic approach was adopted when training the ResNs and clinicians in the application of the silicone foam border dressings. This was achieved using the manufacturer's website and expert clinician advice. While companies that manufacture dressings offer the potential for additional training, this is not available on a 24/7 basis and therefore is unlikely to be available to every clinician using specific dressings. For those participants who were assessed as obese following a formal BMI, a larger silicone foam border dressing (23 x 23 cm) may have made a difference to the overall average dressing wear time. At the time this study was conducted, this larger dressing was unavailable.

## CONCLUSION

While the sample size needed to test the effectiveness of the prophylactic silicone border foam border dressings for hospitalised general medical-surgical population would require significant time and financial resources, results from this pilot study indicate a large multi-site RCT, including the use photography for blind assessment of skin integrity, is feasible.

**NOTES**

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