1 ABSTRACT

2	The Surgical Patients' Pressure Injury Incidence (SPPII) study: a cohort study of
3	surgical patients and processes of care
4	Background: Surgical patients are at high risk of developing pressure injuries (Pls) due to
5	anaesthesia induced immobility as well as risk factors such as length of surgery and
6	comorbidities. Few Australian studies have investigated the incidence of PIs in surgical
7	patients. This prospective cohort study assessed the incidence of post-surgical PIs and
8	identified gaps in pressure injury prevention (PIP) for elective surgical patients.
9	Methods: Consecutive elective surgery patients at an urban tertiary referral hospital were
10	recruited who had an expected length of stay of >48hours. Baseline PI risk (measured by the
11	Waterlow scale) and PIP strategies implemented at five time points were collected from
12	medical records. Two prospective outcome assessments were conducted at 24 and 48 hours
13	post operatively. Data were analysed descriptively.
14	Results: One patient out of 150 (incidence rate 0.7) developed an intra-operative Stage 1 PI.
15	Four patients developed skin tears. PIP strategies were applied inconsistently throughout the
16	patient journey regardless of risk status.
17	Conclusions: While the incidence of surgically acquired PIs in this study was low, ongoing
18	staff education is needed about the importance of consistent skin and risk assessments and of

19 implementing strategies appropriate for level of pressure injury risk.

21	The Surgical Patients' Pressure Injury Incidence (SPPII) study: a cohort study of
22	surgical patients and processes of care
23	What is already known:
24	• Pressure injuries (PIs) are widely considered to be an adverse event of hospitalisation
25	and are largely preventable.
26	• Surgical patients are at risk of developing a pressure injury primarily due to
27	immobilisation following anaesthesia, length of surgery and comorbidities.
28	• There are few studies on pressure injury incidence and prevention strategies used in
29	the post-operative period.
30	
31	What this manuscript contributes:
32	Although the incidence of post-surgical PIs among elective surgical patients was low, there
33	are gaps in pressure injury prevention for this group of patients, including for those deemed at
34	high risk of pressure injury. There is a need for clinicians to improve documentation of risk
35	assessment and strategies implemented to reduce risk of PI, throughout the surgical patient
36	journey
37	
38	INTRODUCTION
39	Each year, over 2 million surgeries are performed in Australia ¹ during which, the patient is
40	anaesthetised, immobilised and unable to perceive or voice pain and discomfort from
41	unrelieved pressure to the surgical team ² . These factors may lead to the development of a
42	pressure injury (PI) ²⁻⁴ . Pressure injuries (PIs), also known as pressure sores, bed sores and

- 43 decubitus ulcers are defined by the National Pressure Ulcer Advisory Panel as a "localized
- 44 injury to the skin and/or underlying tissue usually over a bony prominence or related to a
- 45 medical or other device"⁵. The financial impact of PIs for hospitals and health systems is

significant, with the annual costs of medical treatment and extended hospitalisations
estimated to be between £1.8 and £2.6 billion in the United Kingdom⁶ and US\$11 billion in
the United States (US)⁷. In Australia, the treatment costs of PIs have been estimated to be
AU\$983 million per annum, representing approximately 1.9% of all public hospital
expenditure⁸.

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Surgical patients have been identified as at elevated risk for PI development⁹. PI development 52 can occur between the first hour and 4-6 hours following sustained pressure¹⁰. Therefore, 53 54 surgeries that are longer than 4 hours have been shown to increase the chance of PI development¹¹⁻¹³. Development of surgery-related PI may result in reduced quality of life^{14,15}, 55 decreased mobility, increased pain, prolonged hospital stay, re-admission and negative 56 psychological consequences^{16,17}. Furthermore, hospital-acquired PIs (HAPIs), including 57 surgery-related PIs, are regarded as a key performance indicator of the quality of care 58 provided by health facilities, particularly of nursing care^{18,19}. In Australia, the National Safety 59 and Quality Health Service Standard 8 requires health service organisations to implement 60 evidence-based systems and guidelines to prevent and manage PIs²⁰. The classification of 61 HAPIs as never events (US) or adverse events (Australia) and the introduction of non-62 payment or financial penalties for HAPIs have placed PIs as a priority for health services. In 63 64 the US, Medicare introduced non-payment for hospital-acquired conditions including PIs in 65 2008, whilst financial penalties were introduced more latterly (2013) in the State of Queensland, Australia^{17, 21-23}. The Australian Commission on Safety and Quality in Health 66 Care (ACSQHC) has developed a national list of 16 hospital acquired complications (HAC) 67 which includes pressure injuries, and developed a range of resources to support adoption of 68 the HAC list²⁴. Depending on the practice setting, the reported incidence and prevalence of 69 HAPIs ranges from 0.0% to 72.5%⁷. For surgery-related PIs, the incidence varies, ranging 70

71 from 1.3% to 66% depending on the study population, the type of surgery and duration of the surgical procedure^{13, 23, 25-27}. Evidence from a recent systematic review of 17 studies found 72 the pooled incidence of surgery-related PIs was 0.15 (95% CI 0.14-0.16; range 0.003-0.574) 73 ²⁸. Of note, none of the included studies were conducted in Australia, highlighting limited 74 research in this area. Indeed, a prospective cohort study at a single-site investigating the 75 incidence of HAPIs remains one of the few studies investigating surgery-related PI incidence 76 in Australia²³. Therefore, our knowledge of PI incidence is predominantly based on studies 77 conducted in other countries and may not be indicative of the true incidence in Australian 78 79 surgical patients.

80

Pressure injury prevention (PIP) is a global quality of care indicator and there are national 81 and international evidence-based clinical guidelines to inform this area of nursing practice²⁹. 82 Conducting risk and skin assessments, coupled with attention to positioning, protecting and 83 padding pressure sensitive and vulnerable areas are primary strategies in PIP for surgical 84 patients³⁰⁻³² are standard PIP processes of care and have the potential to reduce PI 85 incidence³³. However, there are only few studies that provide information on PIP processes of 86 care in relation to surgical patients^{31,34}. Furthermore, these studies are limited as they do not 87 evaluate PIP strategies for at risk patients and there is a need to identify if evidence-based PIP 88 processes of care for surgical patients occurs consistently throughout the entire surgical 89 90 patient journey, including the pre-operative, peri-operative and post-operative phases. This study therefore aimed to determine the incidence of HAPIs among elective surgical patients 91 and to describe the extent to which PIP processes of care were documented as adhered to 92 throughout the surgical patient journey. 93

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95 METHODS

96 Design

97 A one-sample prospective cohort study design.

98

99 Setting

100 This study was conducted in a large public, (402 beds) metropolitan, tertiary referral hospital101 in Sydney, Australia between July 2015 and March 2016.

102

103 **Patients**

104 Eligibility criteria

Patients were eligible for inclusion if they were greater than 18 years of age, scheduled for an 105 elective surgical procedure and had an expected 48-hour minimum hospital stay following 106 107 surgery. This inclusion criterion reflects findings from other studies which suggest that PIs may take up to 48 hours to appear after relief from periods of pressure, friction or 108 shearing^{13,35}. Patients were excluded from the study if they were admitted for emergency 109 surgery, admitted for elective surgery through the emergency department, or admitted into 110 hospital a day or more prior to their elective surgery. These groups were excluded because of 111 the uncertainty about how long they may have been immobile before their transfer to the 112 operating suite. 113

114

115 **Recruitment**

Patients were recruited to the study if they met the inclusion criteria and attended the preadmission clinic prior to surgery. Pre-admission patient lists provided by the admissions unit
were used to identify those patients with an expected length of stay (LOS) of >48 hours.
Using a non-probability sampling method, those patients who met the criteria were
approached by a nurse research assistant (RA) in the pre-admission clinic. Patients were

given verbal and printed information about the study, and if agreeable, signed their consent.
If a patient declined to participate in the study, or was expected to have stay of < 48 hours,

123 the next eligible patient was approached.

124

125 Data collection and outcome assessment

The following information was collected from patients' medical records using a standardised data collection form: demographics, patient's history of PIs in the previous 12 months, comorbidities, length of time in surgery, total time in operating theatre and time in recovery, type of surgery, American Society of Anaesthesiologists (ASA) score, patient transfer method to and from the operating table, patient position and positioning devices and PI

131 prevention strategies implemented pre, intra and post-operatively.

132

Prior to the study commencement, RAs received training in the use of the data collection tool,
the use of the Waterlow scale and the observation and classification, or staging, of PIs
according to the European Pressure Ulcer Advisory Panel and National Pressure Ulcer
Advisory Panel Classification System³⁶. Inter-tester reliability was 92% which is considered
almost perfect agreement³⁷.

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Skin assessments were recorded at five time-points. The first three skin assessments were conducted before, during and after surgery and documented as part of the hospital's standard of care in patients' medical records. At 24 hours and 48 hours post operatively two additional skin assessments were undertaken by the trained RAs as part of the outcome assessment (PI presence) (Figure 1). The number and location of all PIs and any other changes to skin integrity signifying a developing area of PIs were recorded. The staging of any PI that

occurred was verified by the Wound Management Clinical Nurse Consultant (JR). Time to
event (defined as from time in operating suite until development of PI) was also recorded.

147

148 Sample size calculation

Sample size calculations were based on an assumption of PI incidence of 20% as suggested by previous studies of high risk surgical patients^{13,35}. In consultation with a statistician, a sample size of 250 was estimated from tables for 95% confidence intervals with a 5% margin of error. However, the sample size was changed after recruitment of 150 patients and a low detection of PIs.

154

155 Data analysis

Data were entered and analysed using Statistical Package for Social Sciences, version 23 156 (SPSS, Chicago, Illinois). Baseline demographics and clinical characteristics, risk status and 157 processes of care were reported as frequencies and percentages for categorical variables or 158 means and standard deviations for continuous variables. Incidence was calculated using a 159 binomial confidence interval (95%). Mean length of time in the operating suite was 160 calculated from the time the patient entered the surgical unit, including time in the pre-161 operative bay and surgery length), to the time the patient was transferred from the operating 162 suite to either the recovery or ICU. Time in recovery was calculated from the time the patient 163 entered the recovery unit until transfer to ward. 164

165

166 ETHICAL APPROVAL

167 Ethics approval was given by the St Vincent's Hospital Sydney Human Research Ethics

168 Committee (HREC LNR/15/SVH/137). All patients provided written consent to participate.

Patients who declined study participation or were unable to give informed consent wereexcluded.

171

172 **RESULTS**

Two hundred and twenty-three elective surgery patients were assessed for eligibility (Figure
2). Of 206 patients assessed as eligible to participate, 189 consented to take part in the study.
Thirty-nine patients became ineligible following recruitment because their post-operative
length of stay was <48 hours, surgery was cancelled or they were referred to palliative care;
resulting in a final sample of 150.

178

Demographic and baseline characteristics of study participants (Table 1) showed the mean 179 180 age was 60.6 (SD \pm 16.7, range 18.1-87.1), with an average body mass index (BMI) of 28.6 $(SD \pm 6.3, range 18.3-56.4)$ and 63% (n=94) were males. All participants could reposition 181 independently in bed (100%). The majority were continent (n=145; 97%), could ambulate 182 (n=131; 87%) and lived independently (n=138; 92%). In terms of physical health status, as 183 measured by the American Society of Anaesthesiologists (ASA), score, most participants 184 (45%) had mild systemic disease (ASA 2), and 34% moderate systematic disease (ASA3). 185 Over 80% of the sample had one or more co-morbidities such as hypertension (n=57; 38%), 186 cardiovascular disease and heart failure (n=49; 33%) or respiratory disease (n=30; 20%). 187 188 Intra-operative participant characteristics showed that the most common operations were 189

neurology (n=38; 25%), orthopaedic (n=28; 19%) and cardiothoracic (n=21; 14%) (Table 1).

- 191 The average length of time in the operating suite was 4.5 hours (SD±2.35); almost all
- 192 participants received general anaesthetic (n=143; 94%) and over half were placed in a supine
- surgical position (n=87; 59%). A third were either transferred directly to ICU from the

194	operating suite or stayed in recovery for less than 2 hours, or between 2 to 4 hours. The
195	standard hospital operating theatre overlay was used in the majority of participants (71%).
196	

197 **Pressure injury incidence**

One participant was documented as having developed a PI (stage 1) in the left knee during
the intra-operative period. The binomial confidence interval analysis showed the incidence of
PIs was 0.7% (CI 0.0002, 0.037). Four patients (2.6%) had skin tears while in recovery. The
PI and the skin tears resolved within 24 hours post-operatively and no other patient developed
a PI during the study period.

203

204 **Processes of care**

205 PI risk assessment

206 The numbers of documented PI risk assessments decreased during the patient surgical

207 journey. Prior to surgery, 80% (n=120) of participants were assessed using the Waterlow

scale; this decreased to 41% (n=62) intra-operatively and 36% (n=54) post-operatively in

209 recovery (Figure 3). All participants had a Waterlow assessment completed by the RAs at 24

and 48 hours following surgery.

211

The graph below shows that a higher proportion of participants were classified as being at high to very high risk of PI as they progressed along the surgical journey. During the preoperative period only 8% (n=10) of the sample were identified as being at high or very high risk of developing a PI; while at 48 hours post operatively, 59% (n=88) fell into the high to very high-risk category.

217

219 *Post-operative PI preventive strategies and devices*

Documented PI preventive strategies (Table 2) for the post-operative period showed that less
than a quarter of participants who were classified as at high or very high-risk of PI, received a
specialty support surface such as an alternating pressure mattress. Just over a half in this risk
category had documentation of a repositioning regime. Over three quarters of the sample
received patient education and almost all had daily skin inspections.

225

226 **DISCUSSION**

The purpose of this study was to prospectively investigate the incidence of post-surgical PIs among elective surgical patients with a minimum hospital stay of 48 hours and to describe the processes of PI care received. Determining PI incidence, which counts the number of PIs developing after admission, rather than a snapshot of prevalence, provides the strongest evidence of quality of care³⁸. The findings therefore add to the knowledge about PI quality of care for surgical patients, particularly those who have a hospital stay of 48 hours, because this group is generally regarded as being at high risk for developing PIs.

234

In our sample the incidence was low, with only one participant developing a PI (Stage 1) 235 intraoperatively. This was identified and documented in the immediate post-operative period 236 and resolved within 24 hours after surgery. Four patients developed intra-operative skin tears, 237 which also resolved within 24 hours. Given that there is mandatory reporting of the 238 occurrence of PIs in the facility in which the study took place, the likelihood of other PIs in 239 this sample not being documented is low. While some studies have found higher post-240 operative PI incidence rates of up to 27% 34,39-42, others such as a prospective study of 337 241 cardiac surgery reported a PI incidence rate of zero (that is, all patients had intact skin at the 242 time they left the operating theatre)³⁹. Our results were comparable to (albeit lower than) an 243

Australian prospective cohort study comprising 534 patients that reported an immediate postoperative (defined as being within 1 hour of admission to the post anaesthetic care unit) PI incidence rate of $1.3\%^{23}$.

247

Variation in reported incidence across studies may be attributable to the differences in the
time frame between PI occurrence and data collection time during the post-operative period.
Since our aim was to identify PIs attributable to surgery, follow-up to 48 hours postoperatively was selected on the basis that previous research has suggested that the 48 hour
post-operative window is the timeframe within which most PIs due to surgery develop^{13,35,43}.
Incidence of PIs outside this timeframe is considered to be attributable to post-surgical care
and not the surgery itself.

255

Our surgical patient cohort had risk factors for the development of PIs that had been 256 previously identified in the literature. These are, lengthy surgeries between 2-6 hours^{13,35,44-47}; 257 multiple comorbidities including diabetes mellitus⁴⁸; and either low or high BMI¹⁷. In 258 addition, patients in our study underwent a broad range of surgical procedures including 259 cardiac surgery which has been identified in the literature as a risk factor for the development 260 of PIs^{39,46,49}. Several patients in our study, however, had pre-operative characteristics which 261 may have had a protective effect against the development of PIs and therefore contributed to 262 the low incidence of PIs observed. Several PI protective factors were reported in a study of 263 surgical patients, including having healthy skin, being continent, being able to move 264 independently and being admitted from home²³. In our study, 87% of patients could ambulate 265 independently pre-operatively, 97% were continent and 99% were admitted from their own 266 home with only 1 patient admitted from an aged care facility. Therefore, the sample was 267

relatively healthy. In addition, there were a wide range of pressure relieving devices that wereused intra-operatively in the majority of patients such as pillows, gel mats and head rings.

270

Our investigation of documentation of evidence-based PI care throughout the surgical patient 271 journey indicated variability in processes of care. Gaps in documentation of PI were evident 272 with Waterlow completion rates for risk assessments in the intra-operative and immediate 273 post-operative periods as low as 41% and 36% respectively. Such low completion rates could 274 be due to the fast turn-around of patients and the clinical imperative to quickly transfer 275 276 patients to either the recovery or the intensive care unit; thereby making completion of risk assessment unfeasible. Moreover, this information was collected from the patients' medical 277 record, which may reflect a documentation issue rather than a lack of assessments performed. 278 279 Lack of time by nursing staff has been previously reported to be a barrier to completing patient documentation, even though accurate, consistent and appropriate documentation is 280 recognised as a fundamental part of patient care⁵⁰ and essential for monitoring changes in PI 281 risk status throughout the patient admission. Failure to achieve complete documentation at all 282 time periods means that there is high potential for early identification of skin changes and a 283 missed opportunity for instituting preventive strategies. 284

285

Only up to 14% of patients classified as being at high and very high- risk of PI were allocated a pressure-relieving support surface and just over half were documented as having a repositioning regime. This suggests that improvement is urgently needed in the prescription of these interventions for high-risk patients⁵¹ especially given that HAPIs are regarded as a major patient safety issue and that in our sample the numbers classified as being at high risk increased exponentially from admission to 48 hours post-operatively. However, other processes of care documented were well performed, irrespective of risk category, such as

patient education and daily skin inspections. At the study hospital, a multi-strategy approach 293 and patient PIP education has been in place since 2011. Patient education has been proven to 294 be an important component of PI prevention strategies because it provides patients and family 295 with a degree of ownership for their care^{52, 53}. The reasons for strategies that are the 296 cornerstones of evidence based PIP guidelines, such as allocation of pressure-relieving 297 devices and recording of a repositioning regime not being done requires investigation. 298 Another study similarly found that even where formal risk assessment is well-established, 299 this is not necessarily followed up with appropriate PIP^{38} . 300

301

302 Strengths and limitations

This study had a number of strengths. Our study design was a prospective cohort study which is the optimal design to study incidence. We used a combination of data collection methods including medical record documentation for the pre, peri and post-operative periods as well as direct skin observation and assessment for outcome assessment 24 and 48 hrs after surgery. To ensure consistency of reporting, RAs were trained in skin assessment, PI staging and medical record data collection. In addition to capturing PI incidence, this study also reported evidence-based processes of care along the surgical patient journey.

310

Study limitations include firstly, that it was conducted at one large inner-city hospital and the results may not be generalisable to other health facilities, particularly in rural areas. Secondly, only elective surgical patients were recruited and these patients may have been healthier than surgical patients admitted via the emergency department. However, the study sample had comparable general characteristics to those documented in other studies and was representative of patients who undergo surgery requiring a 48 hour stay at the study site facility^{13, 23, 34}. Thirdly, we only followed patients for 48 hours post-operatively and it may be

that PIs developed after this period, particularly for patients that were identified as being at
very high-risk of developing a PI and it may have been useful to continue to follow up these
patients to observe any PI development. However, it is debatable whether PIs developed
more than two days post-operatively could be directly attributable to the surgical procedure.

322

323 CONCLUSIONS

324 Nurses along the health care continuum play an important role in preventing the development of PIs in surgical patients by conducting risk assessments, monitoring skin integrity and 325 326 implementing preventive strategies peri-operatively and in the post-operative period until patients are independent and able to reposition themselves and mobilise. Even where the 327 incidence of PIs is very low, improvements are needed in terms of documenting and 328 329 instituting appropriate PIP for high to very high-risk patients before, during and following surgery. In particular, an understanding of how nurses interpret and use the information from 330 PI risk assessments to make decisions about, and for informing a PIP plan for those at high 331 risk, would be of value for improving practice. 332

333

334 Authors' contributions

CM coordinated the study and contributed to the design, data collection, data analysis and manuscript. EM and JR conceived, designed and assisted in coordinating the study. RP conducted part of the data collection and assisted with coordinating the study and data analysis. AG and PD conducted the main data analysis. All authors contributed towards, drafting and revising the paper and approved the final manuscript.

340

341 CONFLICT OF INTEREST

342 The authors declare no conflicts of interest.

343

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478	Figure legends
479	Figure 1: Study Processes
480	Methods section, Portrait orientation
481	
482	Figure 2: Recruitment of study patients
483	Results section, Portrait orientation
484	

- 485 Figure 3: Waterlow assessment rates pre-operative to 48 hours post-operative (n=150)
- 486 Results section, Landscape orientation