

BMJ Open Evaluation of the effectiveness of a comprehensive care plan to reduce hospital acquired complications in an Australian hospital: protocol for a mixed-method preimplementation and postimplementation study

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ABSTRACT

Introduction A new healthcare standard (Standard 5: Comprehensive Care) has been introduced by the Australian Commission on Safety and Quality in Healthcare. Standard 5 advocates for organisational leadership to develop and maintain systems and processes to deliver patient-centred comprehensive care plans that include appropriate screening to identify and mitigate risks associated with hospitalisation. The aim of this study is to evaluate the effectiveness and cost effectiveness of a comprehensive care and risk evaluation (Comprehensive Assessment and Risk Evaluation (CARE)) plan to reduce hospital acquired complications (HACs) in an Australian hospital network.

Methods and analysis This study will comprise a mixed-method pre and post implementation concurrent triangulation evaluation design. The primary clinical outcome will assess the reduction of routinely reported HACs (pressure care and falls), selected based on the likely reliability of routinely collected data prior to implementation. Secondary clinical outcomes will include length of stay and activity-based costing data for each episode, in-hospital mortality, expected and unplanned readmissions within 28 days, compliance with CARE plan completion and referrals for at risk patients, staff satisfaction, patient satisfaction and barriers and enablers to implementation. We expect that the incidence of other HACs (malnutrition, delirium, violence and aggression, and suicide and self-harm) may increase as routine methods for assessing risk were not in place prior to implementation of the CARE plan. We will therefore collect data on incidence of these HACs as tertiary outcomes. Our primary cost-effectiveness outcome will be calculation of an incremental cost-effectiveness ratio.

Ethics and dissemination Ethics approval has been received from Northern Health Low Risk Ethics Committee. The results of this study will be published in peer-reviewed journals and presented at conferences.

INTRODUCTION

The provision of safe and appropriate health-care is an ongoing challenge for health service providers. In the face of increasing

Strengths and limitations of this study

- A key strength of this study is the measurement of both the clinical effectiveness and the cost effectiveness associated with implementing a comprehensive care plan embedded in a hospital service in response to recent changes to the Australian National Safety and Quality Health Service Standards.
- This comprehensive approach to evaluation uses a mixed methods pre-post design to measure both the changes in the incidence of hospital acquired complications, impacts on patients and staff, and the cost-effectiveness of the plan, relative to the benefit.
- Limitations include that this study is being conducted in only one hospital network, and results may not be generalisable to other hospital services.
- As the study design is not experimental, this study may be impacted by threats to internal validity.

pressure from an ageing population,^{1 2} growth in chronic and preventable diseases,³ increasing inflationary pressures and workforce shortages,⁴⁻⁸ and changing community expectations,^{9 10} there is a need for health-care providers to ensure that they provide effective care, which uses resources in the most efficient way to deliver the best possible outcomes for patients.

In 2018, the Australian Commission on Safety and Quality in Healthcare in collaboration with Australian Government, states and territories, the private sector, clinical experts and patients and carers, launched their second edition of the National Safety and Quality Health Service Standards.¹¹ These standards aim to protect patients from harm and improve the quality-of-care

provision. They form the basis through which health services are assessed to achieve accreditation, with the aim of ensuring that all Australian health services have appropriate systems in place to minimise the risk of harm and ensure quality care delivery.

As part of the latest standards, a new standard has been introduced, Standard 5: Comprehensive Care¹¹ (the Standard). The standard advocates for organisational leadership to develop and maintain systems and processes to deliver patient-centred comprehensive care plans. The standard includes a minimising patient harm criterion that advocates for appropriate screening to identify and mitigate risks associated with hospitalisation, specifically the six hospital-acquired complications (HACs) of falls, pressure injury, delirium, malnutrition, violence and aggression, and suicide and self-harm.

Falls are common in acute care, affecting an estimated 2% of hospital stays,^{12 13} with around 25% resulting in injury and 2% resulting in fractures.¹³ Pressure ulcers prevalence in hospitals creates a significant financial burden to the health system. Studies have estimated that the cost of treating pressure ulcers per patient per day range from €2.65 to €87.57 (\$A4.28 to \$A141.39)¹⁴ and that the care of patients with pressure ulcers accounts for between 1.9% and 4% of healthcare expenditure.^{15 16} Delirium impacts an estimated 3%–29% of hospitalised inpatients, with affected patients 2.6 times more likely to die during an admission.^{17 18} Malnutrition is estimated to affect up to 40% of hospitalised individuals and is often poorly documented.¹⁹ Malnutrition may be present on admission or develop during a patient stay, but it is almost always associated with longer lengths of hospital stay and has been associated with a 31%–55% increase in hospital costs when compared with well-nourished patients.²⁰ Often malnourished patients, and/or patients with delirium, are also at much higher risk of other HACs including falls^{21–23} and pressure injury.^{24 25}

Occupational violence is common in healthcare settings and includes verbal and physical abuse. The number of Code Grey (emergency management response for a non-armed act of aggression) responses in inner metropolitan health services in Melbourne in 2015–2016 was 7634²⁶; however, it is estimated that only 20% of all events are reported.²⁷ Suicide of a patient in an inpatient unit is 1 of 10 core events on the Australian Sentinel events list.²⁸ While they occur relatively infrequently, sentinel events may ‘indicate hospital system and process deficiencies that compromise quality and safety’ and are ‘an indicator of governments’ objective to deliver public hospital services that are safe and of high quality.’²⁹

This study has two aims:

Aim 1 is to assess the clinical effectiveness of the implementation of a comprehensive care plan to (1) improve the identification of risk of falls, pressure injury, malnutrition, delirium and aggression, suicide and self-harm; (2) reduce the incidence and improve the management of falls and pressure injuries, which were previously assessed

for as part of earlier standard requirements and are the most reliably coded HACs.

Aim 2 is to conduct a cost-effectiveness study determining the value of implementing the Comprehensive Assessment and Risk Evaluation (CARE) plan relative to the costs.

METHODS

Study design

This study will comprise a mixed-method preimplementation and postimplementation concurrent triangulation evaluation design. Routinely collected data will be used to evaluate the effectiveness of the CARE plan in reducing the incidence of HACs. Audits and surveys will collect further quantitative and qualitative information to fill the gaps of current routinely collected data sources, including measuring time and resources required to implement and use the CARE record, patient and staff satisfaction with the CARE plan, and auditing compliance with completion of each component of the plan. To assess the cost effectiveness of the CARE plan, we will calculate an incremental cost-effectiveness ratio to provide a ratio of extra cost (staffing and resource use) per extra unit of health effect (reduction in HACs).

Study population

Northern Health (NH) is the major provider of acute, subacute and ambulatory specialist services in Melbourne’s north and provides a comprehensive range of primary, secondary and tertiary healthcare services. The hospital network consists of a 410-bed acute hospital (including mental health, intensive care unit, special care nursery and short stay), two subacute hospital sites with 134 and 87 beds, and an outpatient, day procedure site. The NH catchment is located in one of Australia’s fastest growing areas, with the population projected to grow from 350 000 in 2016 to more than 570 000 by 2031.³⁰ Residents originate from more than 184 countries and speak more than 106 languages, with the top five languages spoken after English being Arabic, Italian, Assyrian, Turkish and Greek. Residents in the NH catchment have lower levels of income, educational attainment and health literacy and higher rates of unemployment than state averages.^{31 32}

Intervention

The CARE plan was developed at NH to address the requirements of Standard 5. Hospital standard 5 subcommittees were established for each component of the CARE plan (pressure injury, falls, malnutrition, delirium, violence and aggression, suicide and self-harm) in early 2018 with the overall aim of minimising patient harm as per the National Standard of Safety and Quality Health Service (NSQHS) Standard 5. Terms of reference, membership requirements, outcomes, objectives and Key Performance Indicators (KPIs) for reporting were established for each subcommittee (available on request). The membership of each subcommittee consists of Nursing

Executive, Nurse Unit Managers, Allied Health Managers, Medical Staff, Quality Managers, Clinical Risk Managers and Consumers. The subcommittees were tasked with reviewing the literature related to their component of the CARE plan, and to identify validated risk screens and assessment tools for inclusion in the CARE plan.

The final CARE plan includes:

- ▶ The Northern Hospital (TNH) Stratify Falls Risk assessment, a locally developed and validated risk screen that has been in place at NH since 2011.³³
- ▶ The Braden pressure injury risk assessment³⁴ a validated risk screen which will replace the NH-Pressure Ulcer Point Prevalence (PUPP) assessment, a locally developed and validated risk assessment screening tool which has been in place since 2011.³⁵
- ▶ The Malnutrition Screening Tool, a validated malnutrition risk screen which has been used at NH since 2015.³⁶
- ▶ The Confusion Assessment Method validated delirium risk assessment screen³⁷ which, if delirium risk identified, will lead to the 4AT Part 1 and 2, a rapid delirium detection screen assessment.³⁸
- ▶ The Broset Violence Checklist, a validated violence and aggression risk screen.³⁹
- ▶ The Columbia-Suicide Severity Rating Scale, a validated suicide and self-harm risk screen.⁴⁰

Where patients are identified as 'at risk', the CARE plan requires the patient receive risk mitigation strategies in line with risk screen recommendations and best practice clinical care standards endorsed by the NSQHS, and that these be reviewed at predetermined intervals.

Implementation of the CARE plan will involve a comprehensive education process for nursing staff. All staff will attend a 1 hour presentation, followed by bedside training, referred to as 'bedside CARE simulation'. To ensure consistency of method, a single senior nurse, the 'implementation officer' will conduct all training on all wards. The implementation officer will deliver all lectures and provide one-to-one bedside training to a minimum of 70% of staff on each ward. A train-the-trainer method will be used so that these staff can provide training for the remaining ward staff.

Comparator

The CARE plan will be implemented in the inpatient wards health service wide over a period of 8 months (table 1). Data routinely reported on HACs, combined with medical record review data, will provide historical performance of NH prior to the implementation of the CARE plan for comparative purposes. Further detail of the process of evaluating the implementation of the CARE plan is provided in the Analysis and evaluation section.

Outcomes

The primary, secondary and tertiary outcomes have been selected based on the likely reliability of the data source and the incident rate, thus ensuring the likelihood of identifying an effect that can be attributed to the CARE

plan implementation. It is likely that some measures are under-reported (malnutrition) while other measures have not been in place prior to the CARE plan implementation (delirium, violence and aggression, suicide and self-harm). We therefore expect for these HACs that the implementation of the CARE plan may lead to an increase in the number of *reported* incidents, as opposed to an increase in the number of incidents. Thus, the primary clinical outcomes are based on incident types that are either reported in routinely collected administrative datasets and/or those which are known to be consistently and reliably reported on voluntary risk management reporting systems.⁴¹

Primary outcomes

To address aim 1 (clinical effectiveness), the primary clinical outcome will be the effectiveness of the CARE plan in reducing incidence of hospital-acquired falls and pressure injury. These will be reported as number of events per 10 000 episodes where possible, or as the proportion of total episodes when the calculation of incident rates is not possible.

To address aim 2 (cost effectiveness), activity-based costing data and direct and indirect staffing costs will be used to determine the incremental cost of implementing the CARE plan. We will perform an incremental cost-effectiveness ratio using changes in resource use (expected and unplanned readmissions within 28 days, length of stay) for falls and pressure injuries preimplementation and postimplementation implementation of the CARE plan.

Secondary outcomes

To address aim 1 (clinical effectiveness), the following secondary outcomes will also be recorded and reported:

- ▶ In-hospital and in-ward compliance with completion of the CARE plan and associated management plans, including referrals on to appropriate services (eg, allied health).
- ▶ Staff satisfaction with the CARE plan.
- ▶ Patient satisfaction with care during stay following implementation of CARE plan, including prereview and post review of results on Victorian Patient Satisfaction Survey.⁴²
- ▶ Barriers and enablers to implementation and adherence to CARE plan.

Tertiary outcomes

To address aim 1 (clinical effectiveness), the following tertiary outcomes will also be recorded and reported:

- ▶ In-ward clinical incidents where delirium has been identified as a contributing factor.
- ▶ In-hospital and in-ward incidents where malnutrition is identified as a contributing factor.
- ▶ In-hospital and in-ward incidents where violence and aggression is identified as a contributing factor.
- ▶ In-hospital and in-ward incidents of suicide and self-harm.



Table 1 Comprehensive Assessment and Risk Evaluation plan implementation and evaluation plan timeframe

Month	March	April	May	June	July	August	September	October	November	December	January	February
Ward 1				Med. record audits	Patient interviews							Implementation workshops Staff Survey
		Ward 2			Medical record audits	Patient interviews						Implementation workshops Staff Survey
			Ward 3 Ward 4		Medical record audits	Patient interviews						Implementation workshops Staff Survey
				Ward 5		Medical record audits	Patient interviews					Implementation workshops Staff Survey
					Ward 6 Ward 7 Ward 8			Medical record audits	Patient interviews			Implementation workshops Staff Survey
						Ward 9 Ward 10			Medical record audits	Patient interviews		Implementation workshops Staff Survey
							Ward 11 Ward 12			Medical record audits	Patient interviews	Implementation workshops Staff Survey
								Ward 13 Ward 14		Medical record audits	Patient interviews	Implementation workshops Staff Survey

Sample size calculations

Hospital administrative data

The sample size calculations for the preincidence and post incidence of HACs are based on the most reliably coded HACs of falls and pressure injuries and take into account the likely number of inpatient episodes over a 12-month period and the observed rates of the primary (and tertiary) outcomes. Thus, given that the sample size is fixed, we provide an indication of the effect size that will be able to be detected with 80% power.

Based on an observed 80 000 episodes in 2017/2018, and an observed rate of in-hospital falls of 1.75%, 12 months of data pre/post the implementation of the CARE plan will provide the ability to detect a change to 1.5% when considering overall TNH episodes. The reduction in the rate of falls will need to be greater (tending towards 1.4% for detecting across acute and subacute areas). The rate of falls may vary by ward, but larger effect sizes are required to detect a statistically significant reduction in in-hospital falls. For pressure injuries, with an observed rate of 2.3% over the 2-year period from 1 July 2016 to 30 June 2018, the sample size will provide an ability to detect a reduction to 2.0%. The observed rate for the secondary outcomes is lower than those reported for in-hospital falls and pressure injuries, but these calculations provide an indication of the order of reduction/change required to detect a statistically significant improvement.

Audits

The evaluation of the audits will also be limited to a sample size of 50 medical records, prior to and post implementation. This sample size will provide the ability to detect a minimum difference of 25% in the proportion completion of each component of the CARE plan and the appropriate pre-CARE plan form, assuming an independent two-sample proportion test with alpha value of 0.05 and beta of 0.2 (80% power).

Implementation focus groups

Four focus groups with 8–10 participants in each group will be conducted with the development and implementation teams. The number of participants has been chosen based on the scientific literature, which recommends 5–8 participants per group for non-commercial focus groups. Numbers larger than this may not allow all participants to actively participate.⁴³

Staff survey

In terms of the staff survey, based on results from previous health service wide surveys, we expect a response rate between 5% and 20%. The total inpatient staff population at NH is approximately 3000, so the expected range of our sample size for the staff survey will be between 150 and 600. We will send out two reminder emails midway through and a few days before the end of the survey period with the aim of maximising response.

Interviews with patients, carers and families

We will interview 140 recently discharged patients (10 from each ward). The decision on sample size was pragmatic and based on the resources available to undertake these interviews.

Patient and public involvement

Patients representatives have been involved in the development of this protocol. A patient representative has provided feedback on the protocol and participated in the development of the patient interview questions that will be used in this study.

DATA SOURCES AND COLLECTION

Hospital administrative data

Hospital administrative data (Victorian Admitted Episodes Dataset) will be sought over a 5-year period (1 January 2016 to 31 December 2020), to provide at least 3 years of data prior to the implementation of the CARE plan and at least 18 months post implementation.

Given that the CARE plan implementation will be conducted over the March–September 2019 period, the data will be reported at an episode level with patient, clinical and healthcare utilisation variables to be collected. Patient demographic variables will include age, sex, country of birth, indigenous status, language spoken, marital status and usual place of residence. Clinical details will include admission type (emergency, elective), primary, associated and in-hospital complication diagnoses (using the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10-AM) codes)⁴⁴ and discharge destination. Healthcare utilisation variables will include admission and discharge dates (to indicate length of stay) and activity-based costing data for each episode. Outcomes linked to each episode will also be sought, including: in-hospital mortality, expected and unplanned readmissions within 28 days (including costs of readmissions).

The ICD-10-AM codes will be used to identify patient episodes of care with hospital acquired pressure injuries and falls with injury. These data will be merged with other datasets to confirm the hospital-acquired pressure injuries and falls with injury, supplemented by the voluntary reported data in the Victorian Health Incident Management System (VHIMS). VHIMS will be used to identify episodes of care with malnutrition, delirium, violence and aggression, and suicide and self-harm. Code grey and workers compensation will also be used to identify episodes of care with violence and aggression.

Audits

Three months after implementation within a ward, a random sample of 50 medical records (from across the 3 months) will be reviewed using a purpose designed tool (online supplementary file 1) to determine completion performance of the CARE plan and compliance with associated evidence-based management plans (table 1).

Completion rates will be compared with a random sample of completion of admission forms from 50 medical records from each ward preimplementation.

Implementation focus groups

The Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework will be used to evaluate the implementation process for the CARE plan.⁴⁵ RE-AIM is a framework that uses a mixed-method approach to evaluating the translation of research into practice. The framework incorporates both implementation and impact evaluation and provides a structured approach to analysing an implementation process, a valuable step when considering scalability.

Four focus groups will be conducted with the development and implementation teams. Email invitations will be sent to all group members and participants will be purposely selected to provide representation across disciplines and divisions. The aim of these focus groups will be to reach saturation of ideas, specifically the barriers and enablers associated with implementation of the CARE plan, and key learnings from the process. The outcomes from these workshops will be combined with quantitative and qualitative data (staff surveys and patient interviews) to identify whether the CARE plan delivers comprehensive care and avoids potential areas of failure (in accordance with Standard 5) by:

- ▶ Providing continuous and collaborative care.
- ▶ Working in partnership with patients, carers and families to adequately identify, assess and manage patients' clinical risks, and find out their preferences for care.
- ▶ Ensuring effective communication and teamwork (between members of the healthcare team).¹¹

Staff survey

An invitation to participate will be sent to all clinical staff organisation wide via email from the office of the Chief Executive Officer and will be administered electronically using Qualtrics^{XM} software. The survey was developed by a working group of experts from the standard subcommittees. This survey will assess the level of confidence staff feel in completing the CARE plan, time required to complete, as well as how useful they feel the CARE plan has been in reducing duplication of assessments and improving care (survey available as online supplementary file 2). Specifically, the questions on the survey will aim to identify whether there is any relationship between discipline and years of experience and:

- ▶ How long the CARE plan takes to complete.
- ▶ How satisfactory staff felt the level of education they received at implementation.

The survey will also identify:

- ▶ The extent to which staff felt that the CARE plan reduced duplication and time spent on admission with forms and processes.
- ▶ Whether staff felt that the CARE plan led to clinicians feeling they knew more about their patients.

- ▶ Whether staff felt that the CARE plan has achieved its objectives to improve safety and comprehensive care.
- ▶ Whether staff felt that the CARE plan led to improved communication between disciplines, and if so, which disciplines.
- ▶ Whether staff felt that the CARE plan led to increased involvement of patients and families in care and decisions.
- ▶ How easy/hard staff found the screening/assessment tools.
- ▶ How useful staff found each of the individual management plans for each HAC.

The internal validity and acceptability of the survey will be pilot tested on 10 staff using the 'think aloud' method to ensure that the meaning of the questions is interpreted as intended.

Interviews with patients, carers and families

Once the CARE plan has been in place on a ward for a period of 4 months (table 1), a series of semistructured interviews with patients (using a questionnaire) will be conducted. Ten patients will be randomly selected via computer-generated stratified random sampling to ensure selection of patients across wards, age, gender and reason for admission (health condition). Inclusion criteria will be patients who were hospitalised in the previous month on the index ward, who are over the age of 18, speak English, Arabic, Italian, Assyrian, Turkish, Greek, Macedonian, Mandarin/Cantonese, Persian, Vietnamese or Croatian. The first 10 patients identified on the randomisation will be invited to participate in semistructured interview by phone. If a patient declines participation, the next patient on the list will be approached, until a total of 10 patients are identified on each ward, with a total of 140 patients interviewed across the hospital. If a participant speaks a language other than English, the semistructured interview with a questionnaire will be conducted by an interpreter over the phone. The aim of these interviews will be to identify how effective the CARE plan was in improving communication, and any actions that might improve patient access to quality care during their hospital stay (interview questions available in online supplementary file 3). The interview questionnaire was developed by a small working group consisting of three clinicians and a patient. The interviews will be conducted by a trained clinician or interpreter who was not part of the patient's care team during their hospital stay.

ANALYSIS AND EVALUATION

Aim 1: clinical effectiveness

The linked and merged dataset across the various quantitative data sources will be assessed as a pre-post intervention analysis, with 12 months of data used in each period. As the CARE plan will be implemented on each unit/ward on different start dates, different 12-month periods pre and post will be considered for each unit/ward, so

that the performance of the CARE plan can be evaluated NH wide.

The data will be reported as either the proportion of total episodes for each outcome, or expressed as an incident rate (eg, 2.5 falls with injury per 10 000 patient episodes or per patient bed days). Data will be presented at the hospital level and stratified by acute/subacute. It will not be possible or appropriate to stratify by discharge unit/ward due to the likelihood of restrictions due to sample size (see below), and the likelihood that a patient will be discharged from a different unit/ward to where the in-hospital incident/complication occurred. That is, while observed events can be assigned to units/wards, it will not be possible to calculate a rate given that a patient may be transferred through many units/wards during their stay. While a small number of patients are likely to be counted twice in some outcome measures as they are transferred to/from acute and subacute areas, no bias in the evaluation is expected, as these transfers will be consistent preintervention and post intervention.

The rate of each primary outcome will be compared between the preperiod and post period, using categorical models (ie, logistic regression) and/or parametric or non-parametric models (linear regression or Poisson regression) for continuous variables. We will stratify falls according to severity (those resulting in injury vs those without) and pressure injuries according to stage (both at diagnosis and most severe stage during admission).

The provision of data for 36 months prior to the start of the CARE plan implementation will enable an assessment of quarterly rates of each primary (and possibly secondary outcomes), with data available extracted to 2020 enabling an assessment of rates following the intervention as well. If increasing/decreasing trends are identified in the data either immediately prior to the preperiod or as a result of the implementation, then a washout period may be explored to remove any change that may occur over 2 months as the CARE plan is being implemented on each unit/ward. Time series analysis techniques may be used, although this is unlikely given the likelihood of the effects of other interventions implemented at NH over the 2–3 years leading up to the implementation of the CARE plan.

Data will be collated in Microsoft Excel with statistical analyses conducted using Stata V.15.1 (StataCorp, College Station, Texas, USA). A two-sided *p* value of less than 0.05 will be used to indicate statistical significance.

Response data from the staff survey will be presented using descriptive statistics. All the interview and focus group transcripts will be managed using NVivo software. Thematic analysis will then be used to code and interpret the data. Two investigators will independently code the data from the focus groups and patient interviews using an iterative constant comparative method and results will be fed back to participants for respondent validation.⁴⁶

Aim 2: cost effectiveness

The costs associated with implementing the CARE plan, including staff and resource use, will be determined

through analysis of the staff survey results (time to complete the plan), activity-based costing analysis and relevant data from implementation focus groups. The impact of the CARE plan on patient outcomes will be modelled through changes in length of stay, discharge destinations and readmissions. Incremental cost-effectiveness ratios will be calculated by dividing the mean incremental costs by the mean difference in outcomes.⁴⁷ A 1%, 5% and 10% change for the main cost parameters will be used to perform a sensitivity analysis.

CONSENT

Patient health records and audits

The data collected is for the purpose of identifying changes in events preimplementation and post implementation of the CARE plan and identifying areas for improvement in routinely collected information. Any data collected in this process will not be linked to individuals. Use of this data does not require individual patient level of consent, and will be collected, stored and used in adherence to the National Statement on Ethical Conduct in Human Research (2007), the Privacy Act (1988) and the Health Records Act 2001 (Vic).⁴⁸

Implementation focus groups

The invitation to participate in the implementation focus groups will include that participation is voluntary. Informed consent will be obtained on attendance at the focus groups, and will include a description of the method for transcribing the data (all data will be transcribed as anonymous) and participants will be informed that they will have a week following the focus groups to withdraw from participation.

Staff survey

Responses to this survey will be anonymous and staff will be informed that responses to the survey will not impact on their employment. A response to the survey will be considered implied consent to participate. This has been made explicit in the survey preamble (explanatory statement).

Interviews with patients, carers and families

Informed consent (either in person or verbal, if conducted over the phone) will be gained from all patient participants. Participants will be informed that their responses will not impact on future care received at NH. Patients can withdraw their consent to participate during and up to 1 week following their interview, after which time the transcribed data will be deidentified. This has been made explicit on the patient information and consent form. Family members of the participants may participate in the interview.

IMPLICATIONS

HACs have a significant impact on patient outcomes, resulting in increased risk of additional complications,

increased lengths of hospital stay, delays in surgical intervention, potentially preventable restraint and/or tranquilisation, increased risk of admission to a residential care facility following discharge, and increased risk of mortality.⁴⁹ These complications also result in substantial costs incurred by hospitals⁵⁰ associated with the additional care required to manage these patients. Given the current emphasis placed on the prevention of these complications by the standard, it is vital that health services measure the effectiveness of any interventions implemented aimed at reducing occurrence. There are also significant opportunity costs associated with undertaking comprehensive risk assessments on every hospitalised patient, so an understanding of the benefit of these assessments relative to the costs is critical prior to widespread uptake. The outcomes of this study will therefore have important implications for hospitals both nationally and internationally and will have direct translational impact with the findings influencing the ongoing management of patients at NH.

ETHICS AND DISSEMINATION

Ethics approval has been received from NH Low Risk Ethics Committee. The results of this study will be published in peer-reviewed journals and presented conferences.

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REFERENCES

- Andrews GR. Promoting health and function in an ageing population. *BMJ* 2001;322:728–9.
- Ageing HJ. *Thirroul*. NSW: Spinney Press, 2008.
- Australian Institute of Health and Welfare. *Risk factors contributing to chronic disease*. Canberra: AIHW, 2012.
- Gordon B. Solving the workforce shortage. *Health Progress* 2003;84:59.
- Del Mar C. New investments in primary care in Australia. *BMC Health Serv Res* 2011;11:39.
- Brooks PM, Robinson L, Ellis N. Options for expanding the health workforce. *Aust Health Rev* 2008;32:156–60.
- Buchan JM, Naccarella L, Brooks PM. Is health workforce sustainability in Australia and New Zealand a realistic policy goal? *Aust Health Rev* 2011;35:152–5.
- Productivity Commission Research Report. *Health workforce*. Canberra: Australian Government Productivity Commission, 2005.
- Hill S, Wiley ET, Wiley I. *The knowledgeable patient: communication and participation in health*. Hoboken, NJ: Wiley-Blackwell, 2011.
- Strategic NH. *Health participation: achieving greater public participation and accountability in the Australian health care system*. Melbourne: National Health Strategy, 1993.
- Australian Commission on Safety and Quality in Healthcare. *National safety and quality health service standards*. 2 edn. Sydney: ACSQHC, 2017.
- Morse JM. Enhancing the safety of hospitalization by reducing patient falls. *Am J Infect Control* 2002;30:376–80.
- Rubenstein LZ, Josephson KR. The epidemiology of falls and syncope. *Clin Geriatr Med* 2002;18:141–58.
- Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. *Infect Control Hosp Epidemiol* 2005;26:293–7.
- Bennett G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. *Age Ageing* 2004;33:230–5.
- Nguyen K-H, Chaboyer W, Whitty JA. Pressure injury in Australian public hospitals: a cost-of-illness study. *Aust Health Rev* 2015;39:329–36.
- Australian Commission on Safety and Quality in Health Care. *A better way to care: safe and high-quality care for patients with cognitive impairment (dementia and delirium) in hospital - actions for clinicians*. Sydney: ACSQHC, 2014.
- National Institute for Health and Clinical Excellence. *Delirium: diagnosis, prevention and management (clinical guidelines 103)*. London: National Institute for Health and Clinical Excellence, 2010.
- Rasmussen HH, Kondrup J, Staun M, et al. Prevalence of patients at nutritional risk in Danish hospitals. *Clin Nutr* 2004;23:1009–15.
- Curtis LJ, Bernier P, Jeejeebhoy K, et al. Costs of hospital malnutrition. *Clin Nutr* 2017;36:1391–6.
- Bauer JD, Isenring E, Torma J, et al. Nutritional status of patients who have fallen in an acute care setting. *J Hum Nutr Diet* 2007;20:558–64.
- Vivanti A, Ward N, Haines T. Nutritional status and associations with falls, balance, mobility and functionality during hospital admission. *J Nutr Health Aging* 2011;15:388–91.
- Lakatos BE, Capasso V, Mitchell MT, et al. Falls in the general hospital: association with delirium, advanced age, and specific surgical procedures. *Psychosomatics* 2009;50:218–26.
- Banks M, Bauer J, Graves N, et al. Malnutrition and pressure ulcer risk in adults in Australian health care facilities. *Nutrition* 2010;26:896–901.
- Pendlebury ST, Lovett NG, Smith SC, et al. Observational, longitudinal study of delirium in consecutive unselected acute medical admissions: age-specific rates and associated factors, mortality and re-admission. *BMJ Open* 2015;5:e007808.
- Department of Health and Human Services. *Expert review of health services' occupational violence and aggression responses: final report*. Apex Consulting, 2017.
- Griffiths D, Morphet J, Innes K. *Occupational violence in health care: final report*. VIC Australia: Institute for Safety, Compensation and Recovery Research, 2015.
- Australian Commission on Safety and Quality in Health Care. *Australian sentinel events list (version 2)*. Sydney: ACSQHC, 2018.
- Productivity Commission. *Chapter 11: public hospitals. Report on government services 2016*. Melbourne: Productivity Commission, 2016.
- Northern Health Melbourne. Annual report 2017–18, 2018. Available: <https://www.nh.org.au/media-centre/publications/annual-report/>
- Australian Bureau of Statistics. Socioeconomic index for areas, 2016. Available: <http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifa>
- Jessup RL, Osborne RH, Beauchamp A, et al. Differences in health literacy profiles of patients admitted to a public and a private hospital in Melbourne, Australia. *BMC Health Serv Res* 2018;18:134.

- 33 Barker A, Kamar J, Graco M, *et al*. Adding value to the stratify falls risk assessment in acute hospitals. *J Adv Nurs* 2011;67:450–7.
- 34 Bergstrom N, Braden BJ, Laguzza A, *et al*. The Braden scale for predicting pressure sore risk. *Nurs Res* 1987;36:205–10.
- 35 Page KN, Barker AL, Kamar J. Development and validation of a pressure ulcer risk assessment tool for acute hospital patients. *Wound Repair Regen* 2011;19:31–7.
- 36 Ferguson M, Capra S, Bauer J, *et al*. Development of a valid and reliable malnutrition screening tool for adult acute hospital patients. *Nutrition* 1999;15:458–64.
- 37 Inouye SK, van Dyck CH, Alessi CA, *et al*. Clarifying confusion: the confusion assessment method. A new method for detection of delirium. *Ann Intern Med* 1990;113:941–8.
- 38 Bellelli G, Morandi A, Davis DHJ, *et al*. Validation of the 4AT, a new instrument for rapid delirium screening: a study in 234 hospitalised older people. *Age Ageing* 2014;43:496–502.
- 39 Almvik R, Woods P. The Brøset violence checklist: sensitivity, specificity, and interrater reliability. *J Interpers Violence* 2000;15:1284–96.
- 40 Posner K, Brent D, Lucas C, *et al*. *Columbia-suicide severity rating scale (C-SSRS)*. New York, NY: Columbia University Medical Center, 2008.
- 41 Barker AL, Morello RT, Wolfe R, *et al*. 6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial. *BMJ* 2016;352:h6781.
- 42 Draper M, Hill S. *The role of patient satisfaction surveys in a national approach to hospital quality management*. Canberra: AGPS, 1996.
- 43 Krueger RA, Casey MA. *Focus groups: a practical guide for applied research*. Sage publications;, 2014.
- 44 Australian Consortium for Classification Development. *ICS-10-AM/ACHI/ACS*. 11 edn. Sydney: Independent Hospital Pricing Authority, 2019.
- 45 Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1322–7.
- 46 Glaser BG. The constant comparative method of qualitative analysis. *Soc Probl* 1965;12:436–45.
- 47 Gray AM, Clarke PM, Wolstenholme JL, *et al*. *Applied methods of cost-effectiveness analysis in healthcare*. Oxford: Oxford University Press, 2011.
- 48 National Health and Medical Research Council. *Ethical considerations in quality assurance and evaluation activities*. Canberra: NHMRC, 2014.
- 49 Long SJ, Brown KF, Ames D, *et al*. What is known about adverse events in older medical hospital inpatients? A systematic review of the literature. *Int J Qual Health Care* 2013;25:542–54.
- 50 Fuller RL, McCullough EC, Bao MZ, *et al*. Estimating the costs of potentially preventable Hospital acquired complications. *Health Care Financ Rev* 2009;30:17.