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A controlled pre-post, mixed methods study to determine the effectiveness of a national Delirium Clinical Care Standard to improve the diagnosis and care of patients with delirium in Australian hospitals: a protocol

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Manuscripts

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3 **A CONTROLLED PRE-POST, MIXED METHODS STUDY TO DETERMINE THE**
4 **EFFECTIVENESS OF A NATIONAL DELIRIUM CLINICAL CARE STANDARD**
5 **TO IMPROVE THE DIAGNOSIS AND CARE OF PATIENTS WITH DELIRIUM IN**
6 **AUSTRALIAN HOSPITALS: A PROTOCOL.**
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ABSTRACT

Introduction: Delirium, an acute confusional state, is a significant hospital-acquired condition affecting up to 29% of acute inpatients. The Australian Delirium Clinical Care Standard (the Standard) contains evidence based, multi-component interventions, to identify and reduce delirium. This study aims to: 1) conduct a controlled, before and after study to assess the clinical effectiveness of the Standard to improve diagnosis and treatment of delirium; 2) conduct a cost-effectiveness study of implementing the Standard; and 3) evaluate the implementation process.

Methods and analysis: This study will use a controlled, pre- and post-implementation mixed methods study design, including: medical record reviews, activity based costing analysis, and interviews with staff, patients and their family members. The study population will comprise patients over 65 years admitted to surgical, medical and intensive care wards in five study hospitals for two weeks pre and post Standard implementation. The primary clinical outcome will be the incidence of delirium before, and after, Standard implementation. Secondary outcomes include: length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission rates, and psychotropic drug use data. Cost-effectiveness will be evaluated through activity based costing analysis and outcome data, and the implementation process appraised through the qualitative results.

Ethics and dissemination: Ethics approval has been received for the pilot hospital, additional hospitals have been identified and ethics applications will be submitted once the tools in the pilot study have been tested. The results will be submitted for publication in peer-reviewed journals and presented to national and international conferences. Seminars will provide a quality feedback mechanism for staff and health policy bodies to report results.

Strengths and limitations of this study

- This is the first study in Australia and amongst few internationally to measure both the cost-effectiveness and clinical effectiveness of a National Clinical Care Standard.
- This novel evaluation approach uses a controlled, pre-post design including both quantitative and qualitative data collection, to measure changes in hospital acquired delirium rates.
- The methods outlined in this study have the potential to be applied to the assessment of other Clinical Care Standards.
- Limitations of the study include recruitment in five publicly funding acute care facilities within two States in Australia, and a lack of longer-term follow-up for affected patients.
- The Standard is not mandatory and implementation may be interpreted differently at each facility.

INTRODUCTION

The increasing average age of patients in Australian hospitals is associated with greater levels of cognitive impairment in the inpatient population.¹ Patients in the over 65 years age group, even those with normal cognition, can experience a short-term reduction in their cognitive function and become acutely confused during admission. The term delirium is used to describe this state and is characterized by: its temporary nature, the presence of precipitation factors, and resolution once these factors are removed or treated.² Symptoms and signs of delirium range from patients being agitated and hyperactive, to being sleepy and hypoactive (see Table 1). Common to all manifestations is a decreased attention span and varying levels of confusion.²

Table 1: DSM-5 Definition of Delirium

Diagnostic and Statistical Manual of Mental Disorders (DSM-5), Delirium ²
A. Disturbance in attention (i.e., reduced ability to direct, focus, sustain, and shift attention) and awareness (reduced orientation to the environment).
B. The disturbance develops over a short period of time (usually hours to a few days), represents an acute change from baseline attention and awareness, and tend to fluctuate in severity during the course of a day.
C. An additional disturbance in cognition (e.g. memory deficit, disorientation, language, visuo-spatial ability, or perception).
D. The disturbances in Criteria A and C are not better explained by a pre-existing , established, or evolving neurocognitive disorder, and do not occur in the context of a severely reduced level of arousal such as coma.
E. There is evidence (from the history, physical examination, or laboratory findings) that the disturbance is a direct physiological consequence of another medical condition, substance intoxication or withdrawal (i.e. due to a drug of abuse or to a medication), or exposure to a toxin, or is due to multiple aetiologies.

Delirium is a significant problem in acute care. Using published incidence rates of 3%-29%,³ we estimate delirium affected 116,731 to 1,128,400 inpatients over 65 years of age, applying Australian 2013-14 admissions data.⁴ Higher delirium rates of 47 to 63% have been observed in surgical patients,⁵ and critically ill patients with delirium stay, on average, 6.5 days longer in hospital.⁶ Furthermore, other national Australian data indicate delirium was a principal diagnosis in 11,232 separations (0.29%) of patients over 65 during 2013-14, and that 28% of these patients had existing dementia.⁷ These figures are below the incidence range of 3% to 29% collected from record reviews and targeted assessment,³ but do not include the number of patients developing delirium secondary to other risk factors such as surgery or treatment in

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3 an intensive care unit. Prevalence rates (10%-31%) are higher than for hospital acquired
4 delirium (3%-29%),⁸ with a prospective cohort study (n=10,014) showing on-admission
5 delirium rates of 24.6% for patients over 65 years.⁹ Although delirium is by definition a
6 transient issue, patients developing the condition in hospital are 2.6 times more likely to die
7 during the admission.¹⁰ Patients diagnosed with delirium have a higher risk of developing
8 dementia (adjusted relative risk of 5.7, CI 1.3 to 24.0), and the presence of dementia
9 increases the risk of developing delirium two to five times.^{10 11}

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18 The Australian Commission for Safety and Quality in Health Care (ACSQHC, the national
19 agency for initiatives in this domain) published the National Delirium Clinical Care Standard
20 (the Standard) in 2016,¹² which includes a multi-component intervention for reducing
21 delirium in acute care.¹³ These strategies for preventing and treating delirium were developed
22 in the United States as part of the Hospital Elder Life Program (HELP),¹⁴ and were influential
23 in informing the Delirium Care Pathway developed by the Australian Government in 2011.¹⁵
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HELP targets patients with high risk factors for delirium: existing cognitive impairment,
sleep deprivation, immobility, hearing and visual impairment, and dehydration. The HELP
program has been updated to reflect the guidelines from the National Institute for Health and
Care Excellence (NICE) in the United Kingdom, and includes protocols for medication
reviews, pain management, constipation, infection control, hypoxia, and aspiration
pneumonia.¹⁶ A recent Cochrane review described strong evidence to support a multi-
component approach to reducing delirium in both medical and surgical wards versus usual
care (relative risk (RR) 0.69, 95% CI 0.59 to 0.81),¹⁷ although this strategy was less effective
for those with pre-existing dementia (RR 0.9, 95% CI 0.59 to 1.36). The evidence for
whether these programs reduced the length of a delirium episode was inconclusive.
Despite research on the costs of delirium,¹⁸ and separately on the effectiveness of
interventions,^{19 20} the cost-effectiveness of multi-component interventions in acute care has

been less widely studied.¹⁰ The voluntary nature of the Standard means hospitals need a compelling reason to invest the time, resources, and clinical governance infrastructure required to implement the Standard.²¹

Given the low levels of reported delirium rates,⁷ we hypothesize that introducing the Standard will improve detection rates and enable patients to be more accurately diagnosed and treated. The aims of the study are to: 1) conduct a controlled before and after study to assess the clinical effectiveness of the Standard to improve diagnosis and treatment of delirium in acute inpatients over the age of 65 in Australia; 2) conduct a cost-effectiveness study of implementing the Standard; and 3) evaluate the implementation process. The economic evaluation will include the perspective of patients and their families and carers, as well as the health system. The study design will incorporate both program evaluation and implementation science principles to support the sustainability of the Standard within the acute care health system.²²

METHODS

Study design

The study will use a mixed-methods, controlled, pre-post design, comprising medical record reviews, activity based costing analysis, and interviews with hospital staff, patients, and their carers and relatives (see Table 2).

Table 2: Project timeline for data collection and Standard implementation

Month	Intervention Hospital	Control Hospital
1	<ul style="list-style-type: none"> First medical record review period to measure delirium incidence and secondary outcomes (2 to 4 weeks). First assessment of current status of hospital compliance against 	

	Standard.	
2-3*	<ul style="list-style-type: none"> • <i>Implementation model development</i> • <i>Pre-implementation activities completed</i> 	<i>Note: Standard not implemented in control hospital</i>
4*	<ul style="list-style-type: none"> • <i>Standard implementation</i> 	
5-6	<ul style="list-style-type: none"> • Interviews with nursing and quality control staff • Interviews with patients and their carers and relatives 	
7-8	<ul style="list-style-type: none"> • Second medical review period (2 to 4 weeks) • Second assessment of hospital compliance against Standard 	
9-11	<ul style="list-style-type: none"> • Clinical and cost-effectiveness analyses completed 	
12	<ul style="list-style-type: none"> • Translation activities • Summative report prepared implementation process appraisal 	

- *These activities will be undertaken by the intervention hospitals*

Study population

The study population for the medical record reviews will comprise all patients over 65 years admitted to selected surgical, medical and intensive care wards in five acute care facilities in New South Wales (NSW) and the Australian Capital Territory (ACT) during the medical record review periods. In addition, we will conduct interviews with nursing staff on the study wards (n=10 per hospital), patients who have recovered from an episode of delirium (n=10 per hospital), and their relatives and carers (n=10 per hospital).

Intervention

The Standard comprises a multi-component strategy for detecting and reducing delirium.¹² A key component is the development of a safety and quality pathway (Pathway) for patients

with cognitive impairment (see Table 3 for summary). The Pathway includes patients with delirium and dementia due to the causal relationship between the two clinical states.²³

Table 3: Safety and quality pathway for patients with cognitive impairment in hospital

Step	Actions	Explanation
Step I	Identify patients at high risk for developing delirium, and screen for cognitive impairment	Risk factors include: Age 65 and over Known cognitive impairment Severe illness (risk of dying) Hip fracture Cognitive concerns raised by others
Step II	Identify and monitor risk factors	Falls and pressure injury screening Medicines review Nutrition and dehydration screening Assessment of communication difficulties Identification of treatment not wanted by patient, e.g. through advanced care plans
Step III	Implement individual, integrated prevention and management plans in partnership with patients, carers and family	

Table derived from Standard publications¹²

Comparison

Four of the study hospitals (intervention hospitals) will implement the Standard. Medical record review data from these hospitals will be analysed at the ward and hospital level to compare the level of diagnosis and treatment of delirium before and after implementing the Standard. A fifth hospital, with similar demographics, will act as the control hospital in order to assess underlying trends in delirium recognition and treatment.

Outcomes

For Aim 1 (Clinical effectiveness) the primary clinical outcome will be the incidence of hospital acquired delirium before and after implementing the Standard. Secondary outcomes will include length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission rates, and Standard related indicators.²⁴ Primary and secondary clinical outcomes will be identified using medical record audits and indicator data collected by the hospitals.²⁴ For Aim 2 (Cost-effectiveness) we will use activity based costing analysis to determine the incremental cost of implementing the Standard. We will also assess the change in resource use resulting from improved detection and treatment of delirium.^{18 25}

Recruitment and consent

Medium to large regional and metropolitan public hospitals (n=5) in two jurisdictions (Australian Capital Territory (ACT), and New South Wales (NSW)) will be invited to participate. A waiver of consent for the medical record reviews has been approved for one hospital and will be included in the ethics submission for the remaining hospitals.

Consenting nursing staff (n=10 for each hospital) on the study wards will be invited to participate in the qualitative part of the study to assess their perceptions/views of the treatment and diagnosis of delirium (all hospitals) and implementation process (study hospitals). Patients (n=10 at each hospital), and their relatives and carers (n=10 at each hospital), who had a resolved episode of delirium during their hospital stay will be identified

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3 by the senior nursing staff on the study wards and approached to take part in the study.
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5 Consenting individuals will be interviewed either in person at the hospital, or by phone
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7 following discharge. Additional management, quality, and finance staff at each hospital will
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9 be identified for consent to be interviewed for the costing analysis.
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11 **Sample size calculations**

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13 Our main outcome of interest will be the incidence of delirium. We hypothesize that delirium
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15 may be under diagnosed at baseline,²⁶ and that implementing the Standard protocols will
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17 result in an increased incidence rate. A Cochrane review estimated prevalence rates on
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19 admission of 10%-31%, and hospital acquired incidence of 3%-29%.⁸ We estimate a weekly
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21 admission rate of 0.84 patients over 65 years per bed,⁷ and an average of 18 beds per study
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23 ward over the four study hospitals. Using a study period of four weeks for the first study
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25 hospital, and a two-week period for the remaining 3 study hospitals, we estimate 1506
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27 records will be reviewed (753 records for each of the pre- and post-implementation arms of
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29 the study). This is above the sample size required (345 records per arm) to detect a change in
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31 reported delirium rates of 0.3% to a conservative 3% incidence rate of hospital acquired
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33 delirium using 80% power and 95% CI, for the pooled hospital data.
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38 **DATA COLLECTION**

39 **Medical Record Reviews**

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42 The medical records of all patients over 65 years of age and admitted to the study wards
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44 during the medical record review period (see Table 2) in the pre and post-implementation
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46 phase in each hospital will be included.
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51 Patient demographics, diagnosis and length of stay, in-hospital mortality, delirium risk
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53 factors, and cognitive screening and delirium diagnostic testing will be abstracted from the
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55 records using a purpose-designed tool (See Supplementary File 2).
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Additional data collected for those patients who developed delirium will include: precipitating factors, and the severity and duration of delirium. Data will also be collected to assess compliance with protocols that form part of the Standard indicators. These protocols include: hydration and nutrition, medication reviews, pain management, risk of falls and pressure injuries.²⁷ The medical record review will collect several of the Standard indicators (see Table 4) in the study wards, including falls and pressure injury risk assessments. All the indicators will be collected by the study hospitals as part of each hospital's normal indicator collection.

Table 4: Delirium Clinical Care Standard Indicators²⁴

Indicator	Description
1a	Evidence of local arrangements for cognitive screening of patients presenting to hospital with one or more key risk factors for delirium
1b*	Proportion of older patients undergoing cognitive screening within 24 hours of admission to hospital using a validated test
2a	Evidence of training sessions undertaken by staff in the use of a validated diagnostic tool for delirium
2b*	Proportion of patients who screen positive for cognitive impairment at admission who are assessed for delirium using a validated diagnostic tool
2c*	Rate of delirium among acute admitted patients
2d*	Rate of delirium among acute admitted patients with onset during the hospital stay

3a	Evidence of local arrangements for implementing interventions to prevent delirium for at-risk patients
4a*	Proportion of patients with delirium who have a comprehensive assessment to investigate cause(s) of delirium
4b*	Proportion of patients with delirium who receive a set of interventions to treat the causes of delirium, based on a comprehensive assessment
5a	Evidence of local arrangements for patients with delirium to be assessed for risk of falls and pressure injuries
5b*	Proportion of patients with delirium assessed for risk of falls and pressure injuries
5c*	Proportion of patients with delirium who have had a fall or a pressure injury during their hospital stay
6a	Evidence of local arrangements to ensure that patients with delirium are not routinely prescribed antipsychotic medicines
6b*	Proportion of patients with delirium prescribed antipsychotic medicines in hospital
7a*	Proportion of patients with current or resolved delirium who have an individualised care plan
7b*	Proportion of older patients with current or resolved delirium who are readmitted for delirium within 28 days

- *Indicators collected from the medical record review*

Activity based costing analysis

Each intervention hospital will be responsible for implementing the Standard through development of an implementation model. Such models include the Program Logic Model approach,²⁸ and help identify: a) resources and approvals required, b) implementation

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3 activities such as staff training or physical changes to the wards, c) outputs to measure
4 implementation activities, d) short to medium term outputs in terms of length of stay, and e)
5 indicators to measure impact on longer term patient outcomes. The resources and activities
6 identified in the model will be assessed and costed.
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10 11 **Standard implementation analysis**

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13 To evaluate the implementation process, we will assess each hospital at baseline to determine
14 the level of compliance with the Standard for each Step in the Pathway (Table 2), and
15 compare this with compliance three months after implementation. The implementation
16 process will also be assessed through interviews with nursing staff on the study wards, and
17 with the implementation teams. We will assess this process using the three mechanisms for
18 change outlined in the Standard: 1) establish responsive systems; 2) ensure a skilled and
19 informed workforce; and 3) enable partnerships between clinicians, patients, carers and
20 families.
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31 **Interviews with Staff**

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33 Registered nurses working on the study wards during implementation will be interviewed
34 (n=10 per hospital), in the post-implementation period (months five and six in Table 2).
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36 These interviews will assess the initial and medium-term impact of the Standard on their
37 working practices, their views on the implementation process, and whether implementing the
38 Standard has impacted the diagnosis, treatment, and prognosis of inpatients with delirium.
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40 Questions relating to the Standard will be removed from the interview questionnaire at the
41 control hospital, and replaced with questions relating to current practice about the
42 identification and management of delirium. The interview format and questions are included
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44 in **Supplementary File 1**. Interviews relating to costs will be conducted using an open-
45 ended question format. Question topics will relate to the resources, activities, and indicators
46 identified in the implementation model.
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Interviews with patients, carers, and families

Consenting patients who had a resolved episode of delirium during admission (n=10 per hospital) in the post-implementation phase, and their families and carers (n=10 per hospital) will be interviewed to assess the impact of delirium (see **Supplementary File 1**). Patients, and their relatives and carers, will be identified by the staff and interviewed in person during their stay or by telephone after discharge. The interviews will be electronically recorded, professionally transcribed, de-identified, and analysed with nVIVO software using a framework analysis approach.²⁹

ANALYSIS AND EVALUATION

Aim 1 - Clinical effectiveness

The descriptive statistics from the medical record reviews will be analysed and multi-level modeling techniques used to determine whether implementing the Standard was associated with a change in the incidence of delirium.³⁰ This type of statistical modelling will allow for clustering at the hospital and ward level to account for the differences in implementation strategies and for differences in delirium incidence rates in medical, surgical and ICU environments. The incidence of hospital-acquired delirium will be reported as a percentage of total study admissions both pre- and post-implementation, and by hospital and ward. Hospital acquired delirium will be differentiated from delirium present on admission through the use of the medical record review and condition onset codes. Delirium rates will also be presented on a per patient per day basis due to the evidence linking length of stay and delirium.¹³

Primary and secondary outcomes will be adjusted for variables collected in the medical record review including: demographic data, risk factors for developing delirium, admission ward, and evidence of reduced cognitive function admission.

Aim 2 - Cost-effectiveness

The incremental costs of implementing the Standard, including the changes in resource use resulting from the intervention, will be determined through; analysis of the implementation model, activity based costing analysis, and interviews with hospital management. The impact on patient outcomes will be modelled through the change in discharge disposition, length of stay, and changes in health utilities associated with delirium.¹⁰ Incremental cost-effectiveness ratios (ICERS) will be calculated by dividing the mean incremental costs by the mean difference in outcomes, and a sensitivity analysis will be performed for the main parameters.³¹ Resources and outcomes will be considered within a one-year time frame. Adjustment rates of 5% will be used where costing analysis is performed outside a common one-year period. A sensitivity analysis will be performed using 1%, 5% and 10% changes for the main cost parameters.

Aim 3 - Implementation effectiveness and summative evaluation

The results of the staff interviews and analysis of the implementation model development process will be used to assess the effectiveness of the Standard implementation. A summative evaluation report will be compiled to combine these results and be presented to stakeholders.³² Implementation science techniques and feedback tools will be used to investigate the core challenges in effective translation of the Standard into clinical practice. This will incorporate quantitative measurement of delirium incidence, hospital staff perceptions of implementation challenges. Implementation science components include: broad inclusion criteria, ongoing consumer and stakeholder engagement, a participatory research approach with stakeholders, and the use of process and outcome indicators. The report will provide validation of the generalizability of the results.^{28 33}

IMPLICATIONS OF THIS RESEARCH

Delirium has been shown to have a significant impact on patient outcomes but most importantly delirium is largely preventable using evidence based guidelines for implementing pharmaceutical and physical changes to inpatient care.^{10 34 35} Given the national and international significance of the condition, it is critical to have a better understanding of whether interventions to detect, prevent and treat delirium are effective. We hypothesize that the results of this study will: 1) show an increase in the incidence of delirium due to a higher level of vigilance and screening by trained staff, 2) provide prevalence and incidence rates of delirium in Australian acute care, 3) use process indicators and qualitative analysis to illustrate any issues surrounding implementation of the Standard, and 4) use clinical indicators and cost-effectiveness analysis to determine the longer term impact of the Standard on patient outcomes. This study therefore has important implications for health policy makers, aged care agencies, health quality bodies, and health funding bodies both nationally and internationally. The research will have direct translational impact in terms of assessing the incidence and impact of delirium in the acute care sector.

ETHICS AND DISSEMINATION

Ethics approval has been received for one hospital with permission to waive consent for patients whose medical records are being reviewed (HREC 17-2017 Calvary Public Hospital Bruce). The remaining hospitals have been identified and ethics applications are being submitted.

The results from the study will be submitted for publication in peer-reviewed journals, and to national and international conferences relating to; health policy development and implementation, cognitive function and deterioration, and patient safety and quality. An implementation report will be compiled for each hospital and presented to clinical staff and

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3 management. The summative evaluation report will be presented to the Australian
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5 Commission on Safety and Quality in Health Care.
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8 **ADDITIONAL STATEMENTS**

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11 **Contributors:** JB, JW, CH and VM contributed to the design and development of the study,
12
13 VM and MAK designed the data collection tools and will be involved in data collection, VM
14
15 will conduct the economic evaluation, VM and MAK will conduct the outcomes analysis,
16
17 VM wrote the initial draft of the manuscript, and all authors critically reviewed the
18
19 manuscript and provided substantial input into the submitted manuscript.
20
21

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23
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26 **Competing interests:** No competing interests declared
27

28 **Provenance and peer review:** Peer reviewed, not commissioned
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30 **Data sharing statement:** No additional data available
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Supplementary File 1: Qualitative Interviews

These semi-structured interviews will take approximately 30 minutes each. The interviews will be electronically recorded, and professionally transcribed. Transcript data will be managed using NVivo software. Framework analysis will then be applied to code the data.

A – Patient Interviews

Inclusion/exclusion criteria: The study will include adult patients on study wards with a resolved episode of delirium. Patients with a diagnosis of dementia, or who are unable to give informed consent, or participate in an interview using English language will be excluded.

Background information

Age: ____ (years)

Gender: M/F

Living arrangements, please describe where you live and with whom

What date were you admitted to hospital?

Was your admission planned or was due to an emergency?

What was the main reason/diagnosis for your admission?

Questions:

“We are asking you these questions because you suddenly became confused while you were in hospital. We would like to know about your experience of being confused.”

Please describe what happened to you when you were confused. What do you remember?

What were the things that most helped you during this time?

What do you think caused you to become confused?

Would you like to suggest any changes to your treatment or care that would help others who became disorientated and confused in hospital?

B – Relative/carer survey

Inclusion criteria:

Relatives or carers of patients with delirium, and who were present during the delirium episode.

Background information:

Age: ____ (years)

Gender: M/F

Please state your relationship with patient, e.g. spouse, relative, friend, and/or carer.

Questions:

“We are asking you these questions because a you are related to, or care for, someone who became disoriented and confused during their hospital stay. We would like to know about your experience as a relative/carer.”

- 1) What do you think caused your relative to become confused?
- 2) What information were you given to help you understand what was going on?
- 3) Can you describe anything that you were able to do to help your relative?
- 4) Would you like to suggest any changes to their treatment or care that would help others who became disoriented and confused in hospital?

C – Staff Survey 1: Implementation hospitals

Inclusion criteria: Registered Nurses working on study wards during Standard implementation

Background information

Grade:

Ward:

Years of service:

Have you had any specialist geriatric or psycho geriatric training? Yes/No

Questions:

“We are researching the implementation of the Delirium Clinical Care Standard in your hospital . We would like to know about your experience as a health professional providing care to patients in acute confusional states.”

- 1) What is your experience and opinion of the interventions that have been introduced to reduce delirium on the wards?
- 2) Which of the interventions do you think has been most effective? Why?
- 3) Which of the interventions has been most difficult to implement? Why?
- 4) What has been the most significant change to your nursing practice following implementation of the Standard?
- 5) Do you have any suggestions for improving care for delirious patients?

C – Staff Survey 2: Control hospitals

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3 **Inclusion criteria:** Registered Nurses working on study wards during Standard
4 implementation
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6 **Background information**

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8 Grade:

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10 Ward:

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12 Years of service:

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14 Have you had any specialist geriatric or psycho geriatric training? Yes/No

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16 “We are researching the care of patients with delirium in your hospital. We would like to
17 know about your experience as a health professional providing care to patients in acute
18 confusional states.”

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21 1) What is your experience and opinion of any interventions to reduce delirium that have
22 been introduced on the wards?

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24 2) Which of the interventions do you think has been most effective? Why?

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26 3) Which of the interventions has been most difficult to implement? Why?

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28 4) Do you have any suggestions for improving care for delirious patients?
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Supplementary File 2: Delirium Medical Record Review – Level 1 Questions	
Q1	Patient identifier
Q2	Patient year of birth (yyyy)
Q3	Patient gender
Q4	NESB - Non English speaking background
Q5	Marital status
Q6	Where was the patient living at the time of the admission
Q7	Discharge disposition
Q8	Admission ward
Q9	Reason for admission (please select from list provided)
Q10	Length of stay (days)
Q11	Main Diagnostic codes (please state top five ICD-10 codes)
Q12	If there was a diagnostic code for delirium, was there a condition onset flag for delirium present?
Q13	Did the patient have any of the following risk factors for delirium?
Q14	Was cognitive impairment noted within 24 hours of admission?
Q15	Was cognitive function tested within 24 hours of admission? (<i>If NO, please go to Q22</i>)
Q16	What instrument was used for this test? Please specify the score in the text box
Q17	Who conducted the test?
Q18	Was an additional cognitive function test performed during the admission?
Q19	If cognitive function was tested during admission please give details of the lowest score and days since admission
Q20	If cognitive function was tested during admission please give details of the highest score and days since admission
Q21	If cognitive function was tested during admission please give details of the final score prior to discharge, and days since admission
Q22	Did the patient have any of the additional risk factors for delirium (I)?
Q23	Did the patient have any of the additional risk factors for delirium (II)? - Medications
Q24	Did the patient have any of the additional risk factors for delirium (III)? - Abnormal blood tests. Please specify whether high (h) or low (l)

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Q25 Was the patient prescribed any psychotropic drugs prior to admission? (<i>Please use generic names in lower case</i>)
Q26 Did the patient develop delirium during the admission, or be noted to have delirium on admission? (<i>If NO, please go to Q34</i>)
Q27 Was a delirium screening/diagnostic test performed?
Q28 Which delirium screening/diagnostic test was first performed? Please specify the score
Q29 Were any of the following precipitating factors present?
Q30 How many days did the delirium episode last for?
Q31 Was the patient prescribed any psychotropic drugs in hospital prior to the delirium episode? (<i>Please use generic names in lower case</i>)
Q32 Was the patient prescribed any psychotropic drugs in hospital to treat the delirium episode?
Q33 Which psychotropic drugs was the patient prescribed in hospital to treat the delirium episode? (<i>Please use generic names in lower case</i>)
Q34 Did the patient have a fall in hospital?
Q35 Did the patient develop a hospital acquired pressure injury?
Q36 Was there evidence of compliance with the Delirium Clinical Care Standard?

BMJ Open

A controlled pre-post, mixed methods study to determine the effectiveness of a national Delirium Clinical Care Standard to improve the diagnosis and care of patients with delirium in Australian hospitals: a protocol

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TITLE PAGE

A controlled pre-post, mixed methods study to determine the effectiveness of a national Delirium Clinical Care Standard to improve the diagnosis and care of patients with delirium in Australian hospitals: a protocol

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6 **A controlled pre-post, mixed methods study to determine the effectiveness of a national**
7 **Delirium Clinical Care Standard to improve the diagnosis and care of patients with**
8 **delirium in Australian hospitals: a protocol.**
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13 **ABSTRACT**
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17 *Introduction:* Delirium, an acute confusional state, affects up to 29% of acute inpatients aged
18 65 years and over. The Australian Delirium Clinical Care Standard (the Standard) contains
19 evidence based, multi-component interventions, to identify and reduce delirium. This study
20 aims to: 1) conduct a controlled, before and after study to assess the clinical effectiveness of
21 the Standard to improve diagnosis and treatment of delirium; 2) conduct a cost-effectiveness
22 study of implementing the Standard; and 3) evaluate the implementation process
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30 *Methods and analysis:* The study comprises a controlled, pre- and post-implementation
31 mixed methods study design, including: medical record reviews, activity based costing
32 analysis, and interviews with staff, patients and their family members. The medical record
33 review study population includes patients aged 65 years and over, admitted to surgical,
34 medical and intensive care wards in four intervention hospitals and one control hospital. The
35 primary clinical outcome will be the incidence of delirium. Secondary outcomes include:
36 length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission
37 rates, and use of psychotropic drugs. Cost-effectiveness will be evaluated through activity
38 based costing analysis and outcome data, and the implementation process appraised through
39 the qualitative results.
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51 *Ethics and dissemination:* Ethics approval has been received for the pilot hospital, additional
52 hospitals have been identified and ethics applications will be submitted once the tools in the
53 pilot study have been tested. The results will be submitted for publication in peer-reviewed
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3 journals and presented to national and international conferences. Results seminars will
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5 provide a quality feedback mechanism for staff and health policy bodies.
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7 *Strengths and limitations of this study*

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9 • This is the first study in Australia and amongst few internationally to measure both the
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11 cost-effectiveness and clinical effectiveness of a National Clinical Care Standard.
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14 • This novel evaluation approach uses a controlled, pre-post design including both
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16 quantitative and qualitative data collection, to measure changes in delirium rates in acute
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18 care.
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21 • The methods outlined in this study have the potential to be applied to the assessment of
22
23 other Clinical Care Standards.
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26 • Limitations of the study include recruitment in five publicly funding acute care facilities
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28 within two States in Australia, and a lack of longer-term follow-up for affected patients.
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- 30
31 • The Standard is not mandatory and implementation may be interpreted differently at each
32
33 facility.
34

35 **INTRODUCTION**

36
37 The increasing average age of patients in Australian hospitals is associated with greater levels
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39 of cognitive impairment in the inpatient population.¹ Patients in the 65 years and over age
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41 group, even those with normal cognition, can experience a short-term reduction in their
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43 cognitive function and become acutely confused during admission. The term delirium is used
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45 to describe this state and is generally characterized by: its temporary and variable nature, the
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47 presence of precipitation factors, and resolution once these factors are removed or treated.²
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49 Symptoms and signs of delirium range from patients being agitated and hyperactive, to being
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51 sleepy and hypoactive. Common to all manifestations is a change in attention, awareness, and
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53 cognition and varying levels of confusion.² Delirium is a significant problem in acute care.
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3 Using published incidence rates of 3%-29%,³ we estimate delirium affected 116,731 to
4 1,128,400 inpatients aged 65 years and over, applying Australian 2013-14 admissions data.⁴
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6 Higher delirium rates of 47 to 63% have been observed in surgical patients,⁵ and critically ill
7 patients with delirium stay, on average, 6.5 days longer in hospital.⁶ Furthermore, other
8 national Australian data indicate delirium was a principal diagnosis in 11,232 separations
9 (0.29%) of patients aged 65 years and over during 2013-14, and that 28% of these patients
10 had existing dementia.⁷ These figures are below the incidence range of 3% to 29% collected
11 from record reviews and targeted assessment,³ but do not include the number of patients
12 developing delirium secondary to other risk factors such as surgery or treatment in an
13 intensive care unit. Prevalence rates (10%-31%) are higher than for hospital acquired
14 delirium (3%-29%),⁸ with a prospective cohort study (n=10,014) showing on-admission
15 delirium rates of 24.6% for patients aged 65 years and over.⁹ Although delirium is by
16 definition a transient issue, patients developing the condition in hospital are 2.6 times more
17 likely to die during the admission.¹⁰ Patients diagnosed with delirium have a higher risk of
18 developing dementia (adjusted relative risk of 5.7, CI 1.3 to 24.0), and the presence of
19 dementia increases the risk of developing delirium two to five times.^{10 11}

20
21
22 The Australian Commission for Safety and Quality in Health Care, the national agency for
23 initiatives in this domain, published the National Delirium Clinical Care Standard (the
24 Standard) in 2016.¹² The Standard includes a multi-component intervention for reducing
25 delirium in acute care.¹³ These strategies for preventing and treating delirium were developed
26 in the United States as part of the Hospital Elder Life Program (HELP),¹⁴ and were influential
27 in informing the Delirium Care Pathway developed by the Australian Government in 2011.¹⁵
28
29 HELP targets patients with high risk factors for delirium: existing cognitive impairment,
30 sleep deprivation, immobility, hearing and visual impairment, and dehydration. The HELP
31 program has been updated to reflect the guidelines from the National Institute for Health and
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Care Excellence (NICE) in the United Kingdom, and includes protocols for medication reviews, pain management, constipation, infection control, hypoxia, and aspiration pneumonia.¹⁶ A recent Cochrane review described strong evidence to support a multi-component approach to reducing delirium in both medical and surgical wards versus usual care (relative risk (RR) 0.69, 95% CI 0.59 to 0.81),¹⁷ although this strategy was less effective for those with pre-existing dementia (RR 0.9, 95% CI 0.59 to 1.36). The evidence for whether these programs reduced the length of a delirium episode was inconclusive. Despite research on the costs of delirium,¹⁸ and separately on the effectiveness of interventions,^{19 20} the cost-effectiveness of multi-component interventions in acute care has been less widely studied.¹⁰ The voluntary nature of the Standard means hospitals need a compelling reason to invest the time, resources, and clinical governance infrastructure required to implement the Standard.²¹

Given the low levels of reported delirium rates,⁷ we hypothesize that introducing the Standard will improve detection rates and enable patients to be more accurately diagnosed and treated. The aims of are to: 1) conduct a controlled before and after study to assess the clinical effectiveness of the Standard to improve diagnosis and treatment of delirium in acute inpatients aged 65 years and over in Australia; 2) conduct a cost-effectiveness study of implementing the Standard; and 3) evaluate the implementation process. The economic evaluation will include the perspective of patients and their families and carers, as well as the health system. The study design will incorporate both program evaluation and implementation science principles to support the sustainability of the Standard within the acute care health system.²²

METHODS

Study design

The study will use a mixed-methods, controlled, pre-post design, comprising medical record reviews, activity based costing analysis, and interviews with hospital staff, patients, and their carers and relatives. The study will be conducted during the period 2017-2019

Study population

The study population for the medical record reviews will comprise all patients aged 65 years and over admitted to selected surgical, medical and intensive care wards in five acute care facilities in New South Wales (NSW) and the Australian Capital Territory (ACT) during the medical record review periods (see Table 1). In addition, we will conduct interviews with nursing staff on the study wards (n=10 per hospital), patients who have recovered from an episode of delirium (n=10 per hospital), their relatives and carers (n=10 per hospital), and members of the implementation team and hospital management.

Table 1: Project timeline, study design and data collection periods

Month	Intervention Hospital	Control Hospital
1	<ul style="list-style-type: none"> First medical record review period to measure delirium incidence and secondary outcomes (2 to 4 weeks). First assessment of current status of hospital compliance against Standard. 	
2-3*	<ul style="list-style-type: none"> <i>Implementation model development</i> <i>Pre-implementation activities completed</i> 	<i>Note: Standard not implemented in control hospital</i>
4*	<ul style="list-style-type: none"> <i>Standard implementation</i> 	
5-6	<ul style="list-style-type: none"> Interviews with nursing and quality control staff 	

	<ul style="list-style-type: none"> • <i>Interviews with implementation teams and hospital management*</i> • Interviews with patients and their carers and relatives
7-8	<ul style="list-style-type: none"> • Second medical review period (2 to 4 weeks) • Second assessment of hospital compliance against Standard
9-11	<ul style="list-style-type: none"> • Clinical and cost-effectiveness analyses completed
12	<ul style="list-style-type: none"> • Translation activities • Appraisal of implementation process and preparation of summative report

* *These activities will only be undertaken by the intervention hospitals*

Intervention

The Standard comprises a multi-component strategy for detecting and reducing delirium.¹² A key component is the development of a safety and quality pathway (Pathway) for patients with cognitive impairment (see Table 2 for summary). The Pathway includes patients with delirium and dementia due to the causal relationship between the two clinical states.²³

Table 2: Safety and quality pathway for patients with cognitive impairment in hospital

Step	Actions	Explanation
Step I	Identify patients at high risk for developing delirium, and screen for cognitive impairment	Risk factors include: Age 65 and over Known cognitive impairment Severe illness (risk of dying) Hip fracture Cognitive concerns raised by others
Step II	Identify and monitor risk factors	Falls and pressure injury screening

		Medicines review Nutrition and dehydration screening Assessment of communication difficulties Identification of treatment not wanted by patient, e.g. through advanced care plans
Step III	Implement individual, integrated prevention and management plans in partnership with patients, carers and family	

Table derived from Standard publications¹²

Comparison

Four of the study hospitals (intervention hospitals) will implement the Standard. Medical record review data from these hospitals will be analysed at the ward and hospital level to compare the rates and treatment of delirium before and after implementing the Standard. A fifth hospital, with similar demographics, will act as the control hospital in order to assess underlying trends in delirium recognition and treatment (see Table 1)

Outcomes

For Aim 1 (Clinical effectiveness) the primary clinical outcome will be the incidence of hospital acquired delirium before and after implementing the Standard. Secondary outcomes will include length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission rates, and Standard related indicators.²⁴ Primary and secondary clinical outcomes will be identified using medical record audits and indicator data collected by the hospitals.²⁴

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3 For Aim 2 (Cost-effectiveness) we will use activity based costing analysis to determine the
4 incremental cost of implementing the Standard. We will assess the change in resource use
5 resulting from improved detection and treatment of delirium,^{18 25} and use outcome data and
6 published health utilities relating to delirium to perform a cost-effectiveness analysis.¹⁰
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8 Implementation will be assessed using the RE-AIM framework: reach, effectiveness,
9 adoption, implementation consistency, and maintenance.²⁶
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16 *Recruitment and consent*

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18 Medium to large regional and metropolitan public hospitals (n=5) in two jurisdictions
19 (Australian Capital Territory (ACT), and New South Wales (NSW)) will be invited to
20 participate. A waiver of consent for the medical record reviews has been approved for one
21 hospital and will be included in the ethics submission for the remaining hospitals.
22
23 Consenting nursing staff (n=10 for each hospital) on the study wards will be invited to
24 participate in the qualitative part of the study to assess their perceptions/views of the
25 treatment and diagnosis of delirium (all hospitals) and implementation process (study
26 hospitals). Patients (n=10 at each hospital), and their relatives and carers (n=10 at each
27 hospital), who had a resolved episode of delirium during their hospital stay will be identified
28 by the senior nursing staff on the study wards and approached to take part in the study..
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30 Additional management, quality, and finance staff at each hospital will be identified for
31 consent to be interviewed for the costing analysis.
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44 *Sample size calculations*

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46 Our main outcome of interest will be the incidence of delirium. We hypothesize that delirium
47 may be under diagnosed at baseline,²⁷ and that implementing the Standard protocols will
48 result in an increased incidence rate. A Cochrane review estimated prevalence rates on
49 admission of 10%-31%, and hospital acquired incidence of 3%-29%.⁸ We estimate a weekly
50 admission rate of 0.84 patients aged 65 years and over per bed,⁷ and an average of 18 beds
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per ward over the four intervention hospitals. Using a review period of four weeks for the first intervention hospital, and a two-week period for the remaining 3 intervention hospitals, we estimate 1506 records will be reviewed (753 records for each of the pre- and post-implementation arms of the study). This is above the sample size required (345 records per arm) to detect a change in reported delirium rates of 0.3% to a conservative 3% incidence rate using 80% power and 95% CI, for the pooled hospital data.

DATA COLLECTION

Medical Record Reviews

The medical records of all patients aged 65 years and over and admitted to the study wards during the medical record review period in the pre and post-implementation phase in each hospital will be included (see Table 1). Patient demographics, diagnosis and length of stay, in-hospital mortality, delirium risk factors, and cognitive screening and delirium diagnostic testing will be abstracted from the records using a purpose-designed tool (See **Supplementary File 1**).

Additional data collected for those patients who developed delirium will include: precipitating factors, and the severity and duration of delirium. Data will also be collected to assess compliance with protocols that form part of the Standard indicators. These protocols include: hydration and nutrition, medication reviews, pain management, risk of falls and pressure injuries.²⁸ The medical record review will collect several of the Standard indicators (see Table 3) in the study wards, including falls and pressure injury risk assessments. All the indicators will be collected by the intervention hospitals as part of each hospital's normal indicator collection.

Table 3: Delirium Clinical Care Standard Indicators²⁴

Indicator	Description
1a	Evidence of local arrangements for cognitive screening of patients presenting to hospital with one or more key risk factors for delirium
1b*	Proportion of older patients undergoing cognitive screening within 24 hours of admission to hospital using a validated test
2a	Evidence of training sessions undertaken by staff in the use of a validated diagnostic tool for delirium
2b*	Proportion of patients who screen positive for cognitive impairment at admission who are assessed for delirium using a validated diagnostic tool
2c*	Rate of delirium among acute admitted patients
2d*	Rate of delirium among acute admitted patients with onset during the hospital stay
3a	Evidence of local arrangements for implementing interventions to prevent delirium for at-risk patients
4a*	Proportion of patients with delirium who have a comprehensive assessment to investigate cause(s) of delirium
4b*	Proportion of patients with delirium who receive a set of interventions to treat the causes of delirium, based on a comprehensive assessment
5a	Evidence of local arrangements for patients with delirium to be assessed for risk of falls and pressure injuries
5b*	Proportion of patients with delirium assessed for risk of falls and pressure injuries
5c*	Proportion of patients with delirium who have had a fall or a pressure injury during their hospital stay
6a	Evidence of local arrangements to ensure that patients with delirium are not

	routinely prescribed antipsychotic medicines
6b*	Proportion of patients with delirium prescribed antipsychotic medicines in hospital
7a*	Proportion of patients with current or resolved delirium who have an individualised care plan
7b*	Proportion of older patients with current or resolved delirium who are readmitted for delirium within 28 days

**Indicators collected from the medical record review*

Activity based costing analysis

Each intervention hospital will be responsible for implementing the Standard through development of an implementation model. Such models include the Program Logic Model approach,²⁹ and help identify: a) resources and approvals required, b) implementation activities such as staff training or physical changes to the wards, c) outputs to measure implementation activities, d) short to medium term outputs in terms of length of stay, and e) indicators to measure impact on longer term patient outcomes. The resources and activities identified in the model will be assessed and costed through assessment of the time, grade and numbers of staff involved. Interviews with the hospital management team will be used to measure other costs of implementation.

Standard implementation analysis

We will use the five dimensions of the RE-AIM framework to evaluate the implementation process.²⁶ This will include a pre- and post-implementation audit of each hospital to determine the level of compliance with the Standard for each step of the Pathway (see Table 2) and with Standard Indicators (see Table 3). In addition, the results of the interviews with nursing staff on the intervention hospital wards, and with the implementation teams will be assessed using the three mechanisms for change outlined in the Standard: 1) establish

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3 responsive systems; 2) ensure a skilled and informed workforce; and 3) enable partnerships
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5 between clinicians, patients, carers and families.¹²
6

7 *Interviews with Staff*

8
9 Registered nurses working on the study wards during implementation will be interviewed
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11 (n=10 per hospital), in the post-implementation period (months five and six in Table 1).
12

13 These interviews will assess the initial and medium-term impact of the Standard on their
14
15 working practices, their views on the implementation process, and whether implementing the
16
17 Standard has impacted the diagnosis, treatment, and prognosis of inpatients with delirium.
18

19 Questions relating to the Standard will be removed from the interview questionnaire at the
20
21 control hospital, and replaced with questions relating to current practice about the
22
23 identification and management of delirium. The interview format and questions are included
24
25 in **Supplementary File 2**. Interviews relating to costs will be conducted using an open-ended
26
27 question format. Question topics will relate to the resources, activities, and indicators
28
29 identified in the implementation model.
30
31

32 *Interviews with patients, carers, and families*

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34 Consenting patients who had a resolved episode of delirium during admission (n=10 per
35
36 hospital) in the post-implementation phase, and their families and carers (n=10 per hospital)
37
38 will be interviewed to assess the impact of delirium (**see Supplementary File 2**). Patients,
39
40 and their relatives and carers, will be identified by the staff and interviewed in person during
41
42 their stay or by telephone after discharge. The interviews will be electronically recorded,
43
44 professionally transcribed, de-identified, and analysed with nVIVO software using a
45
46 framework analysis approach.³⁰
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ANALYSIS AND EVALUATION

Aim 1 - Clinical effectiveness

The descriptive statistics from the medical record reviews will be analysed and multi-level modeling techniques used to determine whether implementing the Standard was associated with a change in the incidence of delirium.³¹ This type of statistical modelling will allow for clustering at the hospital and ward level to account for the differences in implementation strategies and for differences in delirium incidence rates in medical, surgical and ICU environments. The incidence of hospital acquired delirium will be reported as a percentage of total study admissions both pre- and post-implementation, and by hospital and ward. Hospital acquired delirium will be differentiated from delirium present on admission through the use of the medical record review and condition onset codes. Delirium rates will also be presented on a per patient per day basis due to the evidence linking length of stay and delirium.¹³

Primary and secondary outcomes will be adjusted for variables collected in the medical record review including: demographic data, risk factors for developing delirium, admission ward, and evidence of reduced cognitive function admission.

Aim 2 - Cost-effectiveness

The incremental costs of implementing the Standard, including the changes in resource use resulting from the intervention, will be determined through analysis of the implementation model, activity based costing analysis, and interviews with hospital management. The impact on patient outcomes will be modelled through the change in discharge disposition, length of stay, and changes in health utilities associated with delirium.¹⁰ Incremental cost-effectiveness ratios (ICERS) will be calculated by dividing the mean incremental costs by the mean difference in outcomes, and a sensitivity analysis will be performed for the main parameters.³² Resources and outcomes will be considered within a one-year time frame.

Adjustment rates of 5% will be used where costing analysis is performed outside a common

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3 one-year period. A sensitivity analysis will be performed using 1%, 5% and 10% changes for
4
5 the main cost parameters.

6 7 *Aim 3 - Implementation effectiveness and summative evaluation*

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9 The results of the staff interviews and analysis of the implementation model development
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11 process will be used to assess the effectiveness of the Standard implementation using the RE-
12
13 AIM framework.²⁶ A summative evaluation report will be compiled to combine these results
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15 and be presented to stakeholders.³³ Implementation science techniques and feedback tools
16
17 will be used to investigate the core challenges in effective translation of the Standard into
18
19 clinical practice. This will incorporate both quantitative measures, e.g medical record review
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21 data, and qualitative outcomes, e.g hospital staff perceptions of implementation challenges.
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23 Implementation science components include: broad inclusion criteria, ongoing consumer and
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25 stakeholder engagement, a participatory research approach with stakeholders, and the use of
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27 process and outcome indicators. The report will provide validation of the generalizability of
28
29 the results.^{29 34}

30 31 32 33 34 **IMPLICATIONS OF THIS RESEARCH**

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37 Delirium has been shown to have a significant impact on patient outcomes but most
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39 importantly up to 30%-4-% of cases are deemed preventable using evidence based guidelines
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41 for implementing changes to inpatient care.^{10 35 36} Given the national and international
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43 significance of the condition, it is critical to have a better understanding of whether
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45 interventions to detect, prevent and treat delirium are effective. We hypothesize that the
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47 results of this study will: 1) show an increase in the incidence of delirium due to a higher
48
49 level of vigilance and screening by trained staff, 2) provide prevalence and incidence rates of
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51 delirium in Australian acute care, 3) use process indicators and qualitative analysis to
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53 illustrate any issues surrounding implementation of the Standard, and 4) use clinical
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3 indicators and cost-effectiveness analysis to determine the longer term impact of the Standard
4 on patient outcomes. This study therefore has important implications for health policy makers,
5 aged care agencies, health quality bodies, and health funding bodies both nationally and
6 internationally. The research will have direct translational impact in terms of assessing the
7 incidence and impact of delirium in the acute care sector.
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13 14 15 **ETHICS AND DISSEMINATION**

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18 Ethics approval has been received for one hospital with permission to waive consent for
19 patients whose medical records are being reviewed (HREC 17-2017 Calvary Public Hospital
20 Bruce). The remaining hospitals have been identified and ethics applications are being
21 submitted.
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27 The results from the study will be submitted for publication in peer-reviewed journals, and to
28 national and international conferences relating to; health policy development and
29 implementation, cognitive function and deterioration, and patient safety and quality. An
30 implementation report will be compiled for each hospital and presented to clinical staff and
31 management. The summative evaluation report will be presented to the Australian
32 Commission on Safety and Quality in Health Care.
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41 42 43 **ADDITIONAL STATEMENTS**

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45 **Contributors:** JB, JW, CH and VM contributed to the design and development of the study,
46 VM and MAK designed the data collection tools and will be involved in data collection, VM
47 will conduct the economic evaluation, VM and MAK will conduct the outcomes analysis,
48 VM wrote the initial draft of the manuscript, and all authors critically reviewed the
49 manuscript and provided substantial input into the submitted manuscript.
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Provenance and peer review: Peer reviewed, not commissioned

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Supplementary File 1: Delirium Medical Record Review	
Q1	Patient identifier
Q2	Patient year of birth (yyyy)
Q3	Patient gender
Q4	NESB - Non English speaking background
Q5	Marital status
Q6	Where was the patient living at the time of the admission
Q7	Discharge disposition
Q8	Admission ward
Q9	Reason for admission (please select from list provided)
Q10	Length of stay (days)
Q11	Main Diagnostic codes (please state top five ICD-10 codes)
Q12	If there was a diagnostic code for delirium, was there a condition onset flag for delirium present?
Q13	Did the patient have any of the following risk factors for delirium?
Q14	Was cognitive impairment noted within 24 hours of admission?
Q15	Was cognitive function tested within 24 hours of admission? <i>(If NO, please go to Q22)</i>
Q16	What instrument was used for this test? Please specify the score in the text box
Q17	Who conducted the test?
Q18	Was an additional cognitive function test performed during the admission?
Q19	If cognitive function was tested during admission please give details of the lowest score and days since admission
Q20	If cognitive function was tested during admission please give details of the highest score and days since admission
Q21	If cognitive function was tested during admission please give details of the final score prior to discharge, and days since admission
Q22	Did the patient have any of the additional risk factors for delirium (I)?
Q23	Did the patient have any of the additional risk factors for delirium (II)? - Medications
Q24	Did the patient have any of the additional risk factors for delirium (III)? - Abnormal blood tests. Please specify whether high (h) or low (l)

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	Q25 Was the patient prescribed any psychotropic drugs prior to admission? (<i>Please use generic names</i>)
	Q26 Did the patient develop delirium during the admission, or be noted to have delirium on admission? (<i>If NO, please go to Q34</i>)
	Q27 Was a delirium screening/diagnostic test performed?
	Q28 Which delirium screening/diagnostic test was first performed? Please specify the score
	Q29 Were any of the following precipitating factors present?
	Q30 How many days did the delirium episode last for?
	Q31 Was the patient prescribed any psychotropic drugs in hospital prior to the delirium episode? (<i>Please use generic names</i>)
	Q32 Was the patient prescribed any psychotropic drugs in hospital to treat the delirium episode?
	Q33 Which psychotropic drugs was the patient prescribed in hospital to treat the delirium episode? (<i>Please use generic names in lower case</i>)
	Q34 Did the patient have a fall in hospital?
	Q35 Did the patient develop a hospital acquired pressure injury?
	Q36 Was there evidence of compliance with the Delirium Clinical Care Standard?

Supplementary File 2: Qualitative Interviews

These semi-structured interviews will take approximately 30 minutes each. The interviews in sections A-C will be electronically recorded, and professionally transcribed. Transcript data will be managed using NVivo software. Framework analysis will then be applied to code the data. Information from section D interviews will be recorded through note taking. All participants will be advised that they may skip any questions they do not wish to answer, the interview can be put on hold, stopped or the participant can withdraw from the research project completely.

A – Patient Interviews

Inclusion/exclusion criteria: The study will include adult patients on study wards with a resolved episode of delirium. Patients with a diagnosis of dementia, or who are unable to give informed consent, or participate in an interview using English language will be excluded.

Background information

Age: _____ (years)

Gender: M/F/Other or not specified

Living arrangements, please describe where you live and with whom

What date were you admitted to hospital?

Was your admission planned or was due to an emergency?

What was the main reason/diagnosis for your admission?

Questions:

“We are asking you these questions because you suddenly became confused while you were in hospital. We would like to know about your experience of being confused.”

Please describe what happened to you when you were confused. What do you remember?

What were the things that most helped you during this time?

What do you think caused you to become confused?

Would you like to suggest any changes to your treatment or care that would help others who become disorientated and confused in hospital?

B – Relative/carer interviews

Inclusion criteria:

Relatives or carers of patients with delirium, and who were present during the delirium episode.

Background information:

Age: _____ (years)

Gender: M/F/Other or Not Specified

Please state your relationship with patient, e.g. spouse, relative, friend, and/or carer.

Questions:

“We are asking you these questions because a you are related to, or care for, someone who became disoriented and confused during their hospital stay. We would like to know about your experience as a relative/carer.”

- 1) What do you think caused your relative to become confused?
- 2) What information were you given to help you understand what was going on?
- 3) Can you describe anything that you were able to do to help your relative?
- 4) Would you like to suggest any changes to their treatment or care that would help others who became disoriented and confused in hospital?

C – Staff Interviews 1: Implementation hospitals

Inclusion criteria: Registered Nurses working on study wards during Standard implementation

Background information

Grade:

Ward:

Years of service:

Have you had any specialist geriatric or psycho geriatric training? Yes/No

Questions:

“We are researching the implementation of the Delirium Clinical Care Standard in your hospital. We would like to know about your experience as a health professional providing care to patients in acute confusional states.”

- 1) What is your experience and opinion of the interventions that have been introduced to reduce delirium on the wards?
- 2) Which of the interventions do you think has been most effective? Why?
- 3) Which of the interventions has been most difficult to implement? Why?
- 4) What has been the most significant change to your nursing practice following implementation of the Standard?
- 5) Do you have any suggestions for improving care for delirious patients?

C – Staff Interviews 2: Control hospital

Inclusion criteria: Registered Nurses working on study wards during Standard implementation in implementation hospitals

Background information

Grade:

Ward:

Years of service:

Have you had any specialist geriatric or psycho geriatric training? Yes/No

“We are researching the care of patients with delirium in your hospital. We would like to know about your experience as a health professional providing care to patients in acute confusional states.”

- 1) What is your experience and opinion of any interventions to reduce delirium that have been introduced on the wards?
- 2) Which of the interventions do you think has been most effective? Why?
- 3) Which of the interventions has been most difficult to implement? Why?
- 4) Do you have any suggestions for improving care for delirious patients?

D – Implementation Team and Management Interviews

“We are researching the implementation of the Delirium Clinical Care Standard in your hospital. This involves estimating the costs of implementation and assessing the resource impact of better diagnosis and treatment. We would like to ask you some questions relating to the costs and resource use of implementing the Standard.”

- 1) Details of the resources and activities relating to the implementation model
- 2) Details of the number and grades of staff involved in these activities and the time involved in these activities, including any preparation or travel time
- 3) External expenditure relating to the Standard implementation
- 4) Infrastructure and other costs (ie IT costs)
- 5) Ongoing costs relating to the Standard

BMJ Open

A controlled pre-post, mixed methods study to determine the effectiveness of a national Delirium Clinical Care Standard to improve the diagnosis and care of patients with delirium in Australian hospitals: a protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019423.R2
Article Type:	Protocol
Date Submitted by the Author:	18-Dec-2017
Complete List of Authors:	Mumford, Virginia; Macquarie University, Australian Institute of Health Innovation Kulh, Mary ; Calvary Public Hospital Hughes, Clifford; Macquarie University, Australian Institute of Health Innovation Braithwaite, Jeffrey; Macquarie University, Australian Institute of Health Innovation Westbrook, Johanna; Macquarie University, Australian Institute of Health Innovation
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health economics, Health policy, Geriatric medicine
Keywords:	Delirium & cognitive disorders < PSYCHIATRY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, GERIATRIC MEDICINE, HEALTH ECONOMICS, Clinical governance < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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TITLE PAGE

A controlled pre-post, mixed methods study to determine the effectiveness of a national Delirium Clinical Care Standard to improve the diagnosis and care of patients with delirium in Australian hospitals: a protocol

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6 **A controlled pre-post, mixed methods study to determine the effectiveness of a national**
7 **Delirium Clinical Care Standard to improve the diagnosis and care of patients with**
8 **delirium in Australian hospitals: a protocol.**
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13 **ABSTRACT**
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17 *Introduction:* Delirium, an acute confusional state, affects up to 29% of acute inpatients 65
18 years and over. The Australian Delirium Clinical Care Standard (the Standard) contains
19 evidence based, multi-component interventions, to identify and reduce delirium. This study
20 aims to: 1) conduct a controlled, before and after study to assess the clinical effectiveness of
21 the Standard to improve diagnosis and treatment of delirium; 2) conduct a cost-effectiveness
22 study of implementing the Standard; and 3) evaluate the implementation process
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30 *Methods and analysis:* This will use a controlled, pre- and post-implementation mixed
31 methods study design, including: medical record reviews, activity based costing analysis, and
32 interviews with staff, patients and their family members. The study population will comprise
33 patients 65 years and over, admitted to surgical, medical and intensive care wards in four
34 intervention hospitals and one control hospital. The primary clinical outcome will be the
35 incidence of delirium. Secondary outcomes include: length of stay, severity and duration of
36 delirium, in-hospital mortality rates, re-admission rates, and use of psychotropic drugs. Cost-
37 effectiveness will be evaluated through activity based costing analysis and outcome data, and
38 the implementation process appraised through the qualitative results.
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50 *Ethics and dissemination:* Ethics approval has been received for two hospitals, additional
51 hospitals have been identified and ethics applications will be submitted once the tools in the
52 pilot study have been tested. The results will be submitted for publication in peer-reviewed
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3 journals and presented to national and international conferences. Results seminars will
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5 provide a quality feedback mechanism for staff and health policy bodies.
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7 *Strengths and limitations of this study*
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- 10 • This is the first study in Australia and amongst few internationally to measure both the
11 cost-effectiveness and clinical effectiveness of a National Clinical Care Standard.
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 - 13 • This novel evaluation approach uses a controlled, pre-post design including both
14 quantitative and qualitative data collection, to measure changes in delirium rates in acute
15 care.
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17 care.
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 - 19 • The methods outlined in this study have the potential to be applied to the assessment of
20 other Clinical Care Standards.
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 - 23 • Limitations of the study include recruitment in five publicly funding acute care facilities
24 within two States in Australia, and a lack of longer-term follow-up for affected patients.
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 - 27 • The Standard is not mandatory and implementation may be interpreted differently at each
28 facility.
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INTRODUCTION

The increasing average age of patients in Australian hospitals is associated with greater levels of cognitive impairment in the inpatient population.¹ Patients in the 65 years and over age group, even those with normal cognition, can experience a short-term reduction in their cognitive function and become acutely confused during admission. The term delirium is used to describe this state and is generally characterized by: its temporary and variable nature, the presence of precipitation factors, and resolution once these factors are removed or treated.² Symptoms and signs of delirium range from patients being agitated and hyperactive, to being sleepy and hypoactive. Common to all manifestations is a change in attention, awareness, and cognition and varying levels of confusion.² Delirium is a significant problem in acute care. Using published incidence rates of 3%-29%,³ we estimate delirium affected 116,731 to 1,128,400 inpatients aged 65 years and over, applying Australian 2013-14 admissions data.⁴ Higher delirium rates of 47 to 63% have been observed in surgical patients,⁵ and critically ill patients with delirium stay, on average, 6.5 days longer in hospital.⁶ Furthermore, other national Australian data indicate delirium was a principal diagnosis in 11,232 separations (0.29%) of patients aged 65 years and over during 2013-14, and that 28% of these patients had existing dementia.⁷ These figures are below the incidence range of 3% to 29% collected from record reviews and targeted assessment,³ but do not include the number of patients developing delirium secondary to other risk factors such as surgery or treatment in an intensive care unit. Prevalence rates (10%-31%) are higher than for hospital acquired delirium (3%-29%),⁸ with a prospective cohort study (n=10,014) showing on-admission delirium rates of 24.6% for patients aged 65 years and over.⁹ Although delirium is by definition a transient issue, patients developing the condition in hospital are 2.6 times

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3 more likely to die during the admission.¹⁰ Patients diagnosed with delirium have a higher risk
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5 of developing dementia (adjusted relative risk of 5.7, CI 1.3 to 24.0), and the presence of
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7 dementia increases the risk of developing delirium two to five times.^{10 11}
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10 The Australian Commission for Safety and Quality in Health Care (ACSQHC, the national
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12 agency for initiatives in this domain) published the National Delirium Clinical Care Standard
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14 (the Standard) in 2016,¹² which includes a multi-component intervention for reducing
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16 delirium in acute care.¹³ These strategies for preventing and treating delirium were developed
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18 in the United States as part of the Hospital Elder Life Program (HELP),¹⁴ and were influential
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20 in informing the Delirium Care Pathway developed by the Australian Government in 2011.¹⁵
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22 HELP targets patients with high risk factors for delirium: existing cognitive impairment,
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24 sleep deprivation, immobility, hearing and visual impairment, and dehydration. The HELP
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26 program has been updated to reflect the guidelines from the National Institute for Health and
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28 Care Excellence (NICE) in the United Kingdom, and includes protocols for medication
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30 reviews, pain management, constipation, infection control, hypoxia, and aspiration
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32 pneumonia.¹⁶ A recent Cochrane review described strong evidence to support a multi-
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34 component approach to reducing delirium in both medical and surgical wards versus usual
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36 care (relative risk (RR) 0.69, 95% CI 0.59 to 0.81),¹⁷ although this strategy was less effective
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38 for those with pre-existing dementia (RR 0.9, 95% CI 0.59 to 1.36). The evidence for
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40 whether these programs reduced the length of a delirium episode was inconclusive.
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44 Despite research on the costs of delirium,¹⁸ and separately on the effectiveness of
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46 interventions,^{19 20} the cost-effectiveness of multi-component interventions in acute care has
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48 been less widely studied.¹⁰ The voluntary nature of the Standard means hospitals need a
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50 compelling reason to invest the time, resources, and clinical governance infrastructure
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52 required to implement the Standard.²¹
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3 Given the low levels of reported delirium rates,⁷ we hypothesize that introducing the
4 Standard will improve detection rates and enable patients to be more accurately diagnosed
5 and treated. The aims of are to: 1) conduct a controlled before and after study to assess the
6 clinical effectiveness of the Standard to improve diagnosis and treatment of delirium in acute
7 inpatients aged 65 years and over in Australia; 2) conduct a cost-effectiveness study of
8 implementing the Standard; and 3) evaluate the implementation process. The economic
9 evaluation will include the perspective of patients and their families and carers, as well as the
10 health system. The study design will incorporate both program evaluation and
11 implementation science principles to support the sustainability of the Standard within the
12 acute care health system.²²

23 24 25 **METHODS**

26 27 28 *Study design*

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30 The study will use a mixed-methods, controlled, pre-post design, comprising medical record
31 reviews, activity based costing analysis, and interviews with hospital staff, patients, and their
32 carers and relatives. The study will be conducted during the period 2017-2019

33 34 35 36 37 *Study population*

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39 The study population for the medical record reviews will comprise all patients aged 65 years
40 and over admitted to selected surgical, medical and intensive care wards in five acute care
41 facilities in New South Wales (NSW) and the Australian Capital Territory (ACT) during the
42 medical record review periods (see Table 1). In addition, we will conduct interviews with
43 nursing staff on the study wards (n=10 per hospital), patients who have recovered from an
44 episode of delirium (n=10 per hospital), their relatives and carers (n=10 per hospital), and
45 hospital management.
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54 55 ***Table 1: Project timeline, study design and data collection periods***

Month	Intervention Hospital	Control Hospital
1	<ul style="list-style-type: none"> • First medical record review period to measure delirium incidence and secondary outcomes (2 to 4 weeks). • First assessment of current status of hospital compliance against Standard. 	
2-3*	<ul style="list-style-type: none"> • <i>Implementation model development</i> • <i>Pre-implementation activities completed</i> 	<i>Note: Standard not implemented in control hospital</i>
4*	<ul style="list-style-type: none"> • <i>Standard implementation</i> 	
5-6	<ul style="list-style-type: none"> • Interviews with nursing and quality control staff • <i>Interviews with implementation teams and hospital management*</i> • Interviews with patients and their carers and relatives 	
7-8	<ul style="list-style-type: none"> • Second medical review period (2 to 4 weeks) • Second assessment of hospital compliance against Standard 	
9-11	<ul style="list-style-type: none"> • Clinical and cost-effectiveness analyses completed 	
12	<ul style="list-style-type: none"> • Translation activities • Appraisal of implementation process and preparation of summative report 	

* *These activities will only be undertaken by the intervention hospitals*

Intervention

The Standard comprises a hospital-wide, multi-component strategy for detecting and reducing delirium.¹² A key component is the development of a safety and quality pathway (Pathway) for patients with cognitive impairment (see Table 2 for summary). The Pathway

includes patients with delirium and dementia due to the causal relationship between the two clinical states.²³

Table 2: Safety and quality pathway for patients with cognitive impairment in hospital

Step	Actions	Explanation
Step I	Identify patients at high risk for developing delirium, and screen for cognitive impairment	Risk factors include: Age 65 and over Known cognitive impairment Severe illness (risk of dying) Hip fracture Cognitive concerns raised by others
Step II	Identify and monitor risk factors	Falls and pressure injury screening Medicines review Nutrition and dehydration screening Assessment of communication difficulties Identification of treatment not wanted by patient, e.g. through advanced care plans
Step III	Implement individual, integrated prevention and management plans in partnership with patients, carers and family	

Table derived from Standard publications¹²

Comparison

Four of the study hospitals (intervention hospitals) will implement the Standard. Medical record review data from these hospitals will be analysed at the ward and hospital level to compare the level of diagnosis and treatment of delirium before and after implementing the Standard. A fifth hospital, with similar demographics, will act as the control hospital in order to assess underlying trends in delirium recognition and treatment (see Table 1)

Outcomes

For Aim 1 (Clinical effectiveness) the primary clinical outcome will be the incidence of hospital acquired delirium before and after implementing the Standard. Secondary outcomes will include length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission rates, and Standard related indicators.²⁴ Primary and secondary clinical outcomes will be identified using medical record audits and indicator data collected by the hospitals.²⁴

For Aim 2 (Cost-effectiveness) we will use activity based costing analysis to determine the incremental cost of implementing the Standard. We will assess the change in resource use resulting from improved detection and treatment of delirium,^{18 25} and use outcome data and published health utilities relating to delirium to perform a cost-effectiveness analysis.¹⁰

Implementation will be assessed using the RE-AIM framework: reach, effectiveness, adoption, implementation consistency, and maintenance.²⁶

Recruitment and consent

Medium to large regional and metropolitan public hospitals (n=5) in two jurisdictions (Australian Capital Territory (ACT), and New South Wales (NSW)) will be invited to participate. A waiver of consent for the medical record reviews has been approved for two hospitals and will be included in the ethics submission for the remaining hospitals.

Consenting nursing staff (n=10 for each hospital) on the study wards will be invited to participate in the qualitative part of the study to assess their perceptions/views of the

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3 treatment and diagnosis of delirium (all hospitals) and implementation process (study
4 hospitals). Patients (n=10 at each hospital), and their relatives and carers (n=10 at each
5 hospital), who had a resolved episode of delirium during their hospital stay will be identified
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7 by the senior nursing staff on the study wards and approached to take part in the study.
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9 Additional management, quality, and finance staff at each hospital will be identified for
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11 consent to be interviewed for the costing analysis.
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15 *Sample size calculations*

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17 Our main outcome of interest will be the incidence of delirium. We hypothesize that delirium
18 may be under diagnosed at baseline,²⁷ and that implementing the Standard protocols will
19 result in an increased incidence rate. A Cochrane review estimated prevalence rates on
20 admission of 10%-31%, and hospital acquired incidence of 3%-29%.⁸ We estimate a weekly
21 admission rate of 0.84 patients aged 65 years and over per bed,⁷ and an average of 18 beds
22 per ward over the four intervention hospitals. Using a review period of four weeks for the
23 first intervention hospital, and a two-week period for the remaining 3 intervention hospitals,
24 we estimate 1506 records will be reviewed (753 records for each of the pre- and post-
25 implementation arms of the study). This is above the sample size required (345 records per
26 arm) to detect a change in reported delirium rates of 0.3% to a conservative 3% incidence rate
27 using 80% power and 95% CI, for the pooled hospital data.
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43 **DATA COLLECTION**

44 *Medical Record Reviews*

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46 The medical records of all patients aged 65 years and over and admitted to the study wards
47 during the medical record review period in the pre- and post-implementation phase in each
48 hospital will be included (see Table 1). Patient demographics, diagnosis and length of stay,
49 in-hospital mortality, delirium risk factors, and cognitive screening and delirium diagnostic
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testing will be abstracted from the records using a purpose-designed tool (See **Supplementary File 1**).

Additional data collected for those patients who developed delirium will include: precipitating factors, and the severity and duration of delirium. Data will also be collected to assess compliance with protocols that form part of the Standard indicators. These protocols include: hydration and nutrition, medication reviews, pain management, risk of falls and pressure injuries.²⁸ The medical record review will collect several of the Standard indicators (see Table 3) in the study wards, including falls and pressure injury risk assessments. All the indicators will be collected by the intervention hospitals as part of each hospital's normal indicator collection.

Table 3: Delirium Clinical Care Standard Indicators²⁴

Indicator	Description
1a	Evidence of local arrangements for cognitive screening of patients presenting to hospital with one or more key risk factors for delirium
1b*	Proportion of older patients undergoing cognitive screening within 24 hours of admission to hospital using a validated test
2a	Evidence of training sessions undertaken by staff in the use of a validated diagnostic tool for delirium
2b*	Proportion of patients who screen positive for cognitive impairment at admission who are assessed for delirium using a validated diagnostic tool
2c*	Rate of delirium among acute admitted patients
2d*	Rate of delirium among acute admitted patients with onset during the hospital stay
3a	Evidence of local arrangements for implementing interventions to prevent

	delirium for at-risk patients
4a*	Proportion of patients with delirium who have a comprehensive assessment to investigate cause(s) of delirium
4b*	Proportion of patients with delirium who receive a set of interventions to treat the causes of delirium, based on a comprehensive assessment
5a	Evidence of local arrangements for patients with delirium to be assessed for risk of falls and pressure injuries
5b*	Proportion of patients with delirium assessed for risk of falls and pressure injuries
5c*	Proportion of patients with delirium who have had a fall or a pressure injury during their hospital stay
6a	Evidence of local arrangements to ensure that patients with delirium are not routinely prescribed antipsychotic medicines
6b*	Proportion of patients with delirium prescribed antipsychotic medicines in hospital
7a*	Proportion of patients with current or resolved delirium who have an individualised care plan
7b*	Proportion of older patients with current or resolved delirium who are readmitted for delirium within 28 days

**Indicators collected from the medical record review*

Activity based costing analysis

Each intervention hospital will be responsible for implementing the Standard through development of an implementation model. Such models include the Program Logic Model approach,²⁹ and help identify: a) resources and approvals required, b) implementation activities such as staff training or physical changes to the wards, c) outputs to measure

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3 implementation activities, d) short to medium term outputs in terms of length of stay, and e)
4 indicators to measure impact on longer term patient outcomes. The resources and activities
5 identified in the model will be assessed and costed through assessment of the time, grade and
6 numbers of staff involved. Interviews with the hospital management team will be used to
7 measure other costs of implementation.
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13 *Standard implementation analysis*

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15 To evaluate the implementation process we will use the five dimensions of the RE-AIM
16 framework (reach, efficacy, adoption, implementation, and maintenance).²⁶ The RE-AIM
17 checklist will provide a structured approach to analyzing the implementation through
18 discussions with the implementation team.²⁶ This will include a pre- and post audit of each
19 hospital to determine the level of compliance with the Standard for each step of the Pathway
20 (see Table 2) and with Standard Indicators (see Table 3. In addition, the results of the
21 interviews with nursing staff on the intervention hospital wards, and with the implementation
22 teams will be assessed using the three mechanisms for change outlined in the Standard: 1)
23 establish responsive systems; 2) ensure a skilled and informed workforce; and 3) enable
24 partnerships between clinicians, patients, carers and families.¹²
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38 *Interviews with Staff*

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40 Registered nurses working on the study wards during implementation will be interviewed
41 (n=10 per hospital), in the post-implementation period (months five and six in Table 1).
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43 These interviews will assess the initial and medium-term impact of the Standard on their
44 working practices, their views on the implementation process, and whether implementing the
45 Standard has impacted the diagnosis, treatment, and prognosis of inpatients with delirium.
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47 Questions relating to the Standard will be removed from the interview questionnaire at the
48 control hospital, and replaced with questions relating to current practice about the
49 identification and management of delirium. The interview format and questions are included
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3 in **Supplementary File 2**. Interviews relating to costs will be conducted using an open-ended
4 question format. Question topics will relate to the resources, activities, and indicators
5 identified in the implementation model.
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8 9 *Interviews with patients, carers, and families*

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11 Consenting patients who had a resolved episode of delirium during admission (n=10 per
12 hospital) in the post-implementation phase, and their families and carers (n=10 per hospital)
13 will be interviewed to assess the impact of delirium (**see Supplementary File 2**). Patients,
14 and their relatives and carers, will be identified by the staff and interviewed in person during
15 their stay or by telephone after discharge. The interviews will be electronically recorded,
16 professionally transcribed, de-identified, and analysed with nVIVO software using a
17 framework analysis approach.³⁰
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28 **ANALYSIS AND EVALUATION**

29 30 *Aim 1 - Clinical effectiveness*

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32 The descriptive statistics from the medical record reviews will be analysed and multi-level
33 modeling techniques used to determine whether implementing the Standard was associated
34 with a change in the incidence of delirium.³¹ This type of statistical modelling will allow for
35 clustering at the hospital and ward level to account for the differences in implementation
36 strategies and for differences in delirium incidence rates in medical, surgical and ICU
37 environments. The incidence of hospital acquired delirium will be reported as a percentage of
38 total study admissions both pre- and post-implementation, and by hospital and ward. Hospital
39 acquired delirium will be differentiated from delirium present on admission through the use
40 of the medical record review and condition onset codes. Delirium rates will also be presented
41 on a per patient per day basis due to the evidence linking length of stay and delirium.¹³
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55 Primary and secondary outcomes will be adjusted for variables collected in the medical
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3 record review including: demographic data, risk factors for developing delirium, admission
4 ward, and evidence of reduced cognitive function admission. Under the terms of the Standard,
5 each hospital will determine the most appropriate tests to screen and diagnose delirium. We
6 will collect the scores for these tests and construct severity scores for those tests that have
7 been validated to assess severity.
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13 *Aim 2 - Cost-effectiveness*

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15 The incremental costs of implementing the Standard, including the changes in resource use
16 resulting from the intervention, will be determined through analysis of the implementation
17 model, activity based costing analysis, and interviews with hospital management. The impact
18 on patient outcomes will be modelled through the change in discharge disposition, length of
19 stay, and changes in health utilities associated with delirium.¹⁰ Incremental cost-effectiveness
20 ratios (ICERS) will be calculated by dividing the mean incremental costs by the mean
21 difference in outcomes, and a sensitivity analysis will be performed for the main
22 parameters.³² Resources and outcomes will be considered within a one-year time frame.
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24 Adjustment rates of 5% will be used where costing analysis is performed outside a common
25 one-year period. A sensitivity analysis will be performed using 1%, 5% and 10% changes for
26 the main cost parameters.
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40 *Aim 3 - Implementation effectiveness and summative evaluation*

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42 The results of the staff interviews and analysis of the implementation model development
43 process will be used to assess both the resources required to design the individual
44 components of the Standard, and the overall effectiveness of the Standard implementation,
45 using the RE-AIM framework and checklist.²⁶ A summative evaluation report will be
46 compiled to combine these results and be presented to stakeholders.³³ Implementation
47 science techniques and feedback tools will be used to investigate the core challenges in
48 effective translation of the Standard into clinical practice. This will incorporate both
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3 quantitative measures, e.g medical record review data, and qualitative outcomes, e.g
4 hospital staff perceptions of implementation challenges. Implementation science components
5 include: broad inclusion criteria, ongoing consumer and stakeholder engagement, a
6 participatory research approach with stakeholders, and the use of process and outcome
7 indicators. The report will provide validation of the generalizability of the results.^{29 34}
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13 14 **IMPLICATIONS OF THIS RESEARCH**

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18 Delirium has been shown to have a significant impact on patient outcomes but most
19 importantly up to 30%-40% of cases are deemed preventable using evidence based guidelines
20 for implementing changes to inpatient care.^{10 35 36} Given the national and international
21 significance of the condition, it is critical to have a better understanding of whether
22 interventions to detect, prevent and treat delirium are effective. We hypothesize that the
23 results of this study will: 1) show an increase in the incidence of delirium due to a higher
24 level of vigilance and screening by trained staff, 2) provide prevalence and incidence rates of
25 delirium in Australian acute care, 3) use process indicators and qualitative analysis to
26 illustrate any issues surrounding implementation of the Standard, including identifying
27 criteria within the Standard that have been more challenging to implement, and 4) use clinical
28 indicators and cost-effectiveness analysis to determine the longer term impact of the Standard
29 on patient outcomes. This study therefore has important implications for health policy makers,
30 aged care agencies, health quality bodies, and health funding bodies both nationally and
31 internationally. The research will have direct translational impact in terms of assessing the
32 incidence and impact of delirium in the acute care sector.
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ETHICS AND DISSEMINATION

Ethics approval has been received for two hospitals with permission to waive consent for patients whose medical records are being reviewed (HREC 17-2017 Calvary Public Hospital Bruce). The remaining hospitals have been identified and ethics applications are being submitted.

The results from the study will be submitted for publication in peer-reviewed journals, and to national and international conferences relating to; health policy development and implementation, cognitive function and deterioration, and patient safety and quality. An implementation report will be compiled for each hospital and presented to clinical staff and management. The summative evaluation report will be presented to the Australian Commission on Safety and Quality in Health Care.

ADDITIONAL STATEMENTS

Contributors: JB, JW, CH and VM contributed to the design and development of the study, VM and MAK designed the data collection tools and will be involved in data collection, VM will conduct the economic evaluation, VM and MAK will conduct the outcomes analysis, VM wrote the initial draft of the manuscript, and all authors critically reviewed the manuscript and provided substantial input into the submitted manuscript.

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Competing interests: No competing interests declared

Provenance and peer review: Peer reviewed, not commissioned

Data sharing statement: Once the study is completed we will publish all relevant aggregated results.

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Supplementary File 1: Delirium Medical Record Review

Q1 Patient identifier _____

Q2 Patient year of birth (yyyy)_____

Q3 Patient gender

- Male
- Female
- Not specified

Q4 NESB – Non-English speaking background

- Yes
- No
- Not specified

Q5 Marital status

- Married
- Widowed
- Divorced
- Separated
- Never married

Q6 Where was the patient living at the time of the admission

- At home
- Assisted living
- Residential care
- Not specified

Q7 Discharge disposition

- Discharged to pre-admission place of living
- Discharged to a higher level of care
- Died in hospital
- Not specified
- Transferred to another hospital

Q8 Admission wards

- Medical ward 1
- Medical ward 2
- Surgical ward 1
- Surgical ward 2
- ICU/CCU
- Emergency department
- Short stay ward

1
2
3 Q9 Reason for admission
4

5 Q10 Length of stay (days)

6 Q11 Main Diagnostic codes (please state top five ICD-10 codes)

- 7
8 • Code 1 _____
9 • Code 2 _____
10 • Code 3 _____
11 • Code 4 _____
12 • Code 5 _____
13

14 Q12 If there was a diagnostic code for delirium, was there a condition onset flag for delirium present?

- 15 • Yes
16 • No
17

18 Q13 Did the patient have any of the following risk factors for delirium?

- 19 • Known cognitive impairment or dementia (1)
20 • Severe illness/risk of dying (2)
21 • Hip fracture (3)
22 • Cognitive concerns raised by others (4)
23
24

25 Q14 Was cognitive impairment noted within 24 hrs of admission?

- 26 • Yes
27 • No or not specified
28

29 Q15 Was cognitive function tested within 24 hrs of admission?

- 30 • Yes
31 • No or not specified
32

33 *Skip To: Q18 If Was cognitive function tested within 24 hrs of admission? = No or not specified*

34 Q16 What instrument was used for this test? Please specify the score in the text box

- 35
36 • ACER _____
37 • AMTS _____
38 • CAM _____
39 • CAM-ICU _____
40 • MOCA _____
41 • RUDAS _____
42 • SMMSE _____
43 • 4AT _____
44 • Other (please specify) _____
45
46

47 Q17 Who conducted the test?

- 48 • Allied Health
49 • Geriatrician (Consultant or Senior Registrar)
50 • Nursing staff
51 • Other medical staff
52 • Psychiatrist or Psychogeriatrician
53
54
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2
3 Q18 Was an additional cognitive function test performed during the admission?

- 4 • Yes
5 • No

6 *Skip To: Q22 If Was an additional cognitive function test performed during the admission? = No*

7
8
9 Q19 If cognitive function was tested during admission please give details of the **lowest** score and days since admission

- 10
11 • Test used _____
12 • Score _____
13 • Days since admission _____

14
15 Q20 If cognitive function was tested during admission please give details of the **highest** score and days since admission

- 16
17 • Test used _____
18 • Score _____
19 • Days since admission _____

20
21 Q21 If cognitive function was tested during admission please give details of the **final** score prior to discharge, and days since admission

- 22
23 • Test used _____
24 • Score _____
25 • Days since admission _____

26
27
28 Q22 Did the patient have any of the additional risk factors for delirium (I)?

- 29 • Depression
30 • Diminished activities of daily living
31 • Hearing impairment
32 • High alcohol use
33 • Immobility
34 • Previous history of delirium
35 • Previous history of cognitive impairment
36 • Visual impairment

37
38
39 Q23 Did the patient have any of the additional risk factors for delirium (II)? - Medications

- 40 • Polypharmacy (five or more prescription drugs)
41 • Benzodiazepine use
42 • Opioid analgesic use

43
44
45 Q24 Did the patient have any of the additional risk factors for delirium (III)? - Abnormal blood tests.
46 Please specify whether high (h) or low (l)

- 47 • Sodium _____
48 • Potassium _____
49 • Glucose _____
50 • Albumin _____

1
2
3 Q25 Was the patient prescribed any psychotropic drugs prior to admission? Please use generic names in
4 lower case

- 5
- 6 • Anti-convulsants _____
 - 7 • Anti-cholinergics _____
 - 8 • Anti-dementia drugs _____
 - 9 • Anti-parkinsonian drugs _____
 - 10 • Anti-psychotics _____
 - 11 • Benzodiazepines _____
 - 12 • Lithium _____
 - 13 • Melatonin _____
 - 14 • SNRIs _____
 - 15 • SSRIs _____
 - 16 • Stimulants _____
 - 17 • TCAs _____
 - 18 • Others _____
- 19
20
21

22 Q26 Did the patient develop delirium during the admission, or be noted to have delirium on admission?

- 23
- 24 • Yes
 - 25 • No

26 *Skip To: Q34 If Did the patient develop delirium during the admission, or be noted to have delirium on admission?*
27 *= No*

28
29 Q27 Was a delirium screening/diagnostic test performed?

- 30
- 31 • Yes
 - 32 • No

33
34 Q28 Which delirium screening/diagnostic test was first performed? Please specify the score

- 35
- 36 • CAM _____
 - 37 • DSM V _____
 - 38 • ICD10 _____
 - 39 • 4AT _____
 - 40 • Other (please specify) (5) _____

41 Q29 Were any of the following precipitating factors present?

- 42
- 43 • Central line
 - 44 • Evidence of dehydration
 - 45 • Evidence of malnutrition
 - 46 • Evidence of multiple bed moves (>2 wards)
 - 47 • General anaesthetic given
 - 48 • Indwelling urinary catheter
 - 49 • Three or more medications added to medications on admission
 - 50 • Use of physical restraints
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3 Q30 How many days did the delirium episode last for?

- 4 • Number of days _____
5 • Not specified
6 • Not resolved prior to discharge or transfer
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10 Q31 Was the patient prescribed any psychotropic drugs in hospital prior to the delirium episode? Please
11 use generic names in lower case

- 12 • Anti-convulsants _____
13 • Anti-cholinergics _____
14 • Anti-dementia drugs _____
15 • Anti-parkinsonian drugs _____
16 • Anti-psychotics _____
17 • Benzodiazepines _____
18 • Lithium _____
19 • Melatonin _____
20 • SNRIs _____
21 • SSRIs _____
22 • Stimulants _____
23 • TCAs _____
24 • Others _____
25
26

27
28 Q32 Was the patient prescribed any psychotropic drugs in hospital to treat the delirium episode?

- 29 • Yes
30 • No
31

32
33 Q33 Which psychotropic drugs was the patient prescribed in hospital to treat the delirium episode? Please
34 use generic names in lower case

- 35 • Anti-convulsants _____
36 • Anti-cholinergics _____
37 • Anti-dementia drugs _____
38 • Anti-parkinsonian drugs _____
39 • Anti-psychotics _____
40 • Benzodiazepines _____
41 • Lithium _____
42 • Melatonin _____
43 • SNRIs _____
44 • SSRIs _____
45 • Stimulants _____
46 • TCAs _____
47 • Others _____
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51 Q34 Did the patient have a fall in hospital?

- 52 • Pre-delirium episode
53 • During or post delirium episode
54 • Not specified
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3 Q35 Did the patient develop a hospital acquired pressure injury?

- 4
- 5 • Pre-delirium episode
 - 6 • During or post delirium episod
 - 7 • Not specified (3)
- 8
9

10 Q36 Was there evidence of compliance with the Delirium Clinical Care Standard? Please click all that
11 apply

- 12
- 13 • Patient was identified as high risk for developing delirium
 - 14 • Patient was identified as high risk and appropriate screening was carried out
 - 15 • A comprehensive assessment was made to investigate the cause of delirium
 - 16 • The patient was assessed for risk of falls
 - 17 • The patient was assessed for risk of pressure injuries
 - 18 • The patient was given an individualised care plan
 - 19 • The patient was re-admitted with delirium within 28 days
 - 20 • The patient was re-admitted for any other reason within 28 days
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Supplementary File 1: Qualitative Interviews

These semi-structured interviews will take approximately 30 minutes each. The interviews in sections A-C will be electronically recorded, and professionally transcribed. Transcript data will be managed using NVivo software. Framework analysis will then be applied to code the data. Information from section D interviews will be recorded through note taking. All participants will be advised that they may skip any questions they do not wish to answer, the interview can be put on hold, stopped or the participant can withdraw from the research project completely.

A – Patient Interviews

Inclusion/exclusion criteria: The study will include patients aged 65 years and over on study wards with a resolved episode of delirium. Patients will be excluded if: 1) they have a documented diagnosis of dementia in their clinical record; 2) the qualitative researcher deems the patient unable to give informed consent, or 3) the patient is not able to participate in an interview using English language

Background information

Age: _____ (years)

Gender: M/F/Other or not specified

Living arrangements, please describe where you live and with whom

What date were you admitted to hospital?

Was your admission planned or was due to an emergency?

What was the main reason/diagnosis for your admission?

Questions:

“We are asking you these questions because you suddenly became confused while you were in hospital. We would like to know about your experience of being confused.”

Please describe what happened to you when you were confused. What do you remember?

What were the things that most helped you during this time?

What do you think caused you to become confused?

Would you like to suggest any changes to your treatment or care that would help others who become disorientated and confused in hospital?

B – Relative/carer interviews

Inclusion criteria:

1
2
3 Relatives or carers of patients with delirium, and who were present during the delirium
4 episode.
5

6 **Background information:**

7 Age: ____ (years)

8 Gender: M/F/Other or Not Specified

9 Please state your relationship with patient, e.g. spouse, relative, friend, and/or carer.

10 **Questions:**

11 “We are asking you these questions because a you are related to, or care for, someone who
12 became disoriented and confused during their hospital stay. We would like to know about
13 your experience as a relative/carer.”

- 14 1) What do you think caused your relative to become confused?
15 2) What information were you given to help you understand what was going on?
16 3) Can you describe anything that you were able to do to help your relative?
17 4) Would you like to suggest any changes to their treatment or care that would help others
18 who became disoriented and confused in hospital?
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30 **C – Staff Interviews 1: Implementation hospitals**

31 **Inclusion criteria:** Registered Nurses working on study wards during Standard
32 implementation
33

34 **Background information**

35 Grade:

36 Ward:

37 Years of service:

38 Have you had any specialist geriatric or psycho geriatric training? Yes/No
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46 **Questions:**

47 “We are researching the implementation of the Delirium Clinical Care Standard in your
48 hospital. We would like to know about your experience as a health professional providing
49 care to patients in acute confusional states.”

- 50 1) What is your experience and opinion of the interventions that have been introduced to
51 reduce delirium on the wards?
52 2) Which of the interventions do you think has been most effective? Why?
53 3) Which of the interventions has been most difficult to implement? Why?
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3 4) What has been the most significant change to your nursing practice following
4 implementation of the Standard?
5

6 5) Do you have any suggestions for improving care for delirious patients?
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10 **C – Staff Interviews 2: Control hospital**

11 **Inclusion criteria:** Registered Nurses working on control wards during Standard
12 implementation in implementation hospitals
13

14 **Background information**

15 Grade:
16

17 Ward:
18

19 Years of service:
20

21 Have you had any specialist geriatric or psycho geriatric training? Yes/No
22
23
24

25 “We are researching the care of patients with delirium in your hospital. We would like to
26 know about your experience as a health professional providing care to patients in acute
27 confusional states.”
28

29 1) What is your experience and opinion of any interventions to reduce delirium that have
30 been introduced on the wards?
31

32 2) Which of the interventions do you think has been most effective? Why?
33

34 3) Which of the interventions has been most difficult to implement? Why?
35

36 4) Do you have any suggestions for improving care for delirious patients?
37
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41 **D – Implementation Team and Management Interviews**

42 “We are researching the implementation of the Delirium Clinical Care Standard in your
43 hospital. This involves estimating the costs of implementation and assessing the resource
44 impact of better diagnosis and treatment. We would like to ask you some questions relating to
45 the costs and resource use of implementing the Standard.”
46
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51 1) Details of the resources and activities relating to the implementation model

52 2) Details of the number and grades of staff involved in these activities and the time involved
53 in these activities, including any preparation or travel time

54 3) External expenditure relating to the Standard implementation

55 4) Infrastructure and other costs (ie IT costs)

56 5) Ongoing costs relating to the Standard
57
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