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:	*BMJ Open*
Manuscript ID	bmjopen-2017-019423
Article Type:	Protocol
Date Submitted by the Author:	01-Sep-2017
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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

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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Key words: Delirium, economic evaluation, hospital acquired conditions, quality improvement

Document data
Abstract word count: 263
Main Document word count: 3417 including tables, 2738 excluding tables.
Number of references: 35
Number of tables: 4
Number of supplementary files: 2

Key words
Delirium and cognitive disorders, Health economics, Protocols and guidelines, Geriatric medicine, Quality in health care, Clinical governance

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

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 over 65 years.[9] Although delirium is by definition a transient issue, patients developing the condition in hospital are 2.6 times more likely to die during the admission.[10] Patients diagnosed with delirium have a higher risk of developing dementia (adjusted relative risk of 5.7, CI 1.3 to 24.0), and the presence of dementia increases the risk of developing delirium two to five times.[10 11]

The Australian Commission for Safety and Quality in Health Care (ACSQHC, the national agency for initiatives in this domain) published the National Delirium Clinical Care Standard (the Standard) in 2016,[12] which includes a multi-component intervention for reducing delirium in acute care.[13] These strategies for preventing and treating delirium were developed in the United States as part of the Hospital Elder Life Program (HELP),[14] and were influential in informing the Delirium Care Pathway developed by the Australian Government in 2011.[15] 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 Heath 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	• 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*	• *Implementation model development* • *Pre-implementation activities completed*	*Note: Standard not implemented in control hospital*
4*	• *Standard implementation*	
5-6	• Interviews with nursing and quality control staff • Interviews with patients and their carers and relatives	
7-8	• Second medical review period (2 to 4 weeks) • Second assessment of hospital compliance against Standard	
9-11	• Clinical and cost-effectiveness analyses completed	
12	• 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 publications[12]

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

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

Sample size calculations

Our main outcome of interest will be the incidence of delirium. We hypothesize that delirium may be under diagnosed at baseline,[26] and that implementing the Standard protocols will result in an increased incidence rate. A Cochrane review estimated prevalence rates on admission of 10%-31%, and hospital acquired incidence of 3%-29%.[8] We estimate a weekly admission rate of 0.84 patients over 65 years per bed,[7] and an average of 18 beds per study ward over the four study hospitals. Using a study period of four weeks for the first study hospital, and a two-week period for the remaining 3 study 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 of hospital acquired delirium using 80% power and 95% CI, for the pooled hospital data.

DATA COLLECTION

Medical Record Reviews

The medical records of all patients over 65 years of age and admitted to the study wards during the medical record review period (see Table 2) in the pre and post-implementation phase in each hospital will be included.

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 2)**.

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 Indicators[24]

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

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.

Standard implementation analysis

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

Interviews with Staff

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

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

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.

Funding: Funding for this research was provided by the NSW Ministry of Health, under the NSW Health Early-Mid Career Fellowships Scheme.

Competing interests: No competing interests declared

Provenance and peer review: Peer reviewed, not commissioned

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

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

"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?

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? *(If NO, please go to Q22)*
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)

Q25 Was the patient prescribed any psychotropic drugs prior to admission? *(Please use generic names in lower case)*
Q26 Did the patient develop delirium during the admission, or be noted to have delirium on admission? *(If NO, please go to Q34)*
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? *(Please use generic names in lower case)*
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? *(Please use generic names in lower case)*
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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-019423.R1
Article Type:	Protocol
Date Submitted by the Author:	02-Nov-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

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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Key words: Delirium, economic evaluation, hospital acquired conditions, quality improvement

Document data
Abstract word count: 255
Main Document word count: 2873
Number of references: 36
Number of tables: 3
Number of supplementary files: 2

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.

ABSTRACT

Introduction: Delirium, an acute confusional state, affects up to 29% of acute inpatients aged 65 years and over. 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: The study comprises 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 medical record review study population includes patients aged 65 years and over, admitted to surgical, medical and intensive care wards in four intervention hospitals and one control hospital. The primary clinical outcome will be the incidence of delirium. Secondary outcomes include: length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission rates, and use of psychotropic drugs. 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. Results seminars will provide a quality feedback mechanism for staff and health policy bodies.

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 delirium rates in acute care.
- 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 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 more likely to die during the admission.[10] Patients diagnosed with delirium have a higher risk of developing dementia (adjusted relative risk of 5.7, CI 1.3 to 24.0), and the presence of dementia increases the risk of developing delirium two to five times.[10 11]

The Australian Commission for Safety and Quality in Health Care, the national agency for initiatives in this domain, published the National Delirium Clinical Care Standard (the Standard) in 2016.[12] The Standard includes a multi-component intervention for reducing delirium in acute care.[13] These strategies for preventing and treating delirium were developed in the United States as part of the Hospital Elder Life Program (HELP),[14] and were influential in informing the Delirium Care Pathway developed by the Australian Government in 2011.[15] 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 Heath 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 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	• 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*	• *Implementation model development* • *Pre-implementation activities completed*	*Note: Standard not implemented in control hospital*
4*	• *Standard implementation*	
5-6	• Interviews with nursing and quality control staff	

	• *Interviews with implementation teams and hospital management** • Interviews with patients and their carers and relatives
7-8	• Second medical review period (2 to 4 weeks) • Second assessment of hospital compliance against Standard
9-11	• Clinical and cost-effectiveness analyses completed
12	• 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 publications[12]

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]

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 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 by the senior nursing staff on the study wards and approached to take part in the study.. Additional management, quality, and finance staff at each hospital will be identified for consent to be interviewed for the costing analysis.

Sample size calculations

Our main outcome of interest will be the incidence of delirium. We hypothesize that delirium may be under diagnosed at baseline,[27] and that implementing the Standard protocols will result in an increased incidence rate. A Cochrane review estimated prevalence rates on admission of 10%-31%, and hospital acquired incidence of 3%-29%.[8] We estimate a weekly admission rate of 0.84 patients aged 65 years and over per bed,[7] and an average of 18 beds

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 Indicators[24]

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

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

Interviews with Staff

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

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 2).** 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.[30]

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

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 using the RE-AIM framework.[26] A summative evaluation report will be compiled to combine these results and be presented to stakeholders.[33] 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 both quantitative measures, e.g medical record review data, and qualititative outcomes, e.g 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.[29 34]

IMPLICATIONS OF THIS RESEARCH

Delirium has been shown to have a significant impact on patient outcomes but most importantly up to 30%-4-% of cases are deemed preventable using evidence based guidelines for implementing changes to inpatient care.[10 35 36] 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 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.

Funding: Funding for this research was provided by the NSW Ministry of Health under the NSW Health Early-Mid Career Fellowships Scheme.

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
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? *(If NO, please go to Q22)*
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)

Q25 Was the patient prescribed any psychotropic drugs prior to admission? *(Please use generic names)*
Q26 Did the patient develop delirium during the admission, or be noted to have delirium on admission? *(If NO, please go to Q34)*
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? *(Please use generic names)*
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? *(Please use generic names in lower case)*
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:	*BMJ Open*
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

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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Key words: Delirium, economic evaluation, hospital acquired conditions, quality improvement

Document data
Abstract word count: 255
Main Document word count: 2964
Number of references: 36
Number of tables: 3
Number of supplementary files: 2

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.

ABSTRACT

Introduction: Delirium, an acute confusional state, affects up to 29% of acute inpatients 65 years and over. 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 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 65 years and over, admitted to surgical, medical and intensive care wards in four intervention hospitals and one control hospital. The primary clinical outcome will be the incidence of delirium. Secondary outcomes include: length of stay, severity and duration of delirium, in-hospital mortality rates, re-admission rates, and use of psychotropic drugs. 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 two hospitals, 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. Results seminars will provide a quality feedback mechanism for staff and health policy bodies.

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 delirium rates in acute care.
- 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 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

more likely to die during the admission.[10] Patients diagnosed with delirium have a higher risk of developing dementia (adjusted relative risk of 5.7, CI 1.3 to 24.0), and the presence of dementia increases the risk of developing delirium two to five times.[10 11]

The Australian Commission for Safety and Quality in Health Care (ACSQHC, the national agency for initiatives in this domain) published the National Delirium Clinical Care Standard (the Standard) in 2016,[12] which includes a multi-component intervention for reducing delirium in acute care.[13] These strategies for preventing and treating delirium were developed in the United States as part of the Hospital Elder Life Program (HELP),[14] and were influential in informing the Delirium Care Pathway developed by the Australian Government in 2011.[15] 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 Heath 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 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 hospital management.

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

Month	Intervention Hospital	Control Hospital
1	• 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*	• *Implementation model development* • *Pre-implementation activities completed*	*Note: Standard not implemented in control hospital*
4*	• *Standard implementation*	
5-6	• Interviews with nursing and quality control staff • *Interviews with implementation teams and hospital management** • Interviews with patients and their carers and relatives	
7-8	• Second medical review period (2 to 4 weeks) • Second assessment of hospital compliance against Standard	
9-11	• Clinical and cost-effectiveness analyses completed	
12	• 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 publications[12]

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

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 by the senior nursing staff on the study wards and approached to take part in the study. Additional management, quality, and finance staff at each hospital will be identified for consent to be interviewed for the costing analysis.

Sample size calculations

Our main outcome of interest will be the incidence of delirium. We hypothesize that delirium may be under diagnosed at baseline,[27] and that implementing the Standard protocols will result in an increased incidence rate. A Cochrane review estimated prevalence rates on admission of 10%-31%, and hospital acquired incidence of 3%-29%.[8] We estimate a weekly admission rate of 0.84 patients aged 65 years and over per bed,[7] and an average of 18 beds 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 Indicators[24]

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

To evaluate the implementation process we will use the five dimensions of the RE-AIM framework (reach, efficacy, adoption, implementation, and maintenance).[26] The RE-AIM checklist will provide a structured approach to analyzing the implementation through discussions with the implementation team.[26] This will include a pre- and post 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 responsive systems; 2) ensure a skilled and informed workforce; and 3) enable partnerships between clinicians, patients, carers and families.[12]

Interviews with Staff

Registered nurses working on the study wards during implementation will be interviewed (n=10 per hospital), in the post-implementation period (months five and six in Table 1). These interviews will assess the initial and medium-term impact of the Standard on their working practices, their views on the implementation process, and whether implementing the Standard has impacted the diagnosis, treatment, and prognosis of inpatients with delirium. Questions relating to the Standard will be removed from the interview questionnaire at the control hospital, and replaced with questions relating to current practice about the identification and management of delirium. The interview format and questions are included

in **Supplementary File 2.** Interviews relating to costs will be conducted using an open-ended question format. Question topics will relate to the resources, activities, and indicators identified in the implementation model.

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 2).** 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.[30]

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. Under the terms of the Standard, each hospital will determine the most appropriate tests to screen and diagnose delirium. We will collect the scores for these tests and construct severity scores for those tests that have been validated to assess severity.

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 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 both the resources required to design the individual components of the Standard, and the overall effectiveness of the Standard implementation, using the RE-AIM framework and checklist.[26] A summative evaluation report will be compiled to combine these results and be presented to stakeholders.[33] 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 both

quantitative measures, e.g medical record review data, and qualititative outcomes, e.g 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.[29 34]

IMPLICATIONS OF THIS RESEARCH

Delirium has been shown to have a significant impact on patient outcomes but most importantly up to 30%-40% of cases are deemed preventable using evidence based guidelines for implementing changes to inpatient care.[10 35 36] 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, including identifying criteria within the Standard that have been more challenging to implement, 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 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.

Funding: Funding for this research was provided by the NSW Ministry of Health under the NSW Health Early-Mid Career Fellowships Scheme.

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

Q9 Reason for admission

Q10 Length of stay (days)

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

- Code 1 _____
- Code 2 _____
- Code 3 _____
- Code 4 _____
- Code 5 _____

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

- Yes
- No

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

- Known cognitive impairment or dementia (1)
- Severe illness/risk of dying (2)
- Hip fracture (3)
- Cognitive concerns raised by others (4)

Q14 Was cognitive impairment noted within 24 hrs of admission?

- Yes
- No or not specified

Q15 Was cognitive function tested within 24 hrs of admission?

- Yes
- No or not specified

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

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

- ACER _____
- AMTS _____
- CAM _____
- CAM-ICU _____
- MOCA _____
- RUDAS _____
- SMMSE _____
- 4AT _____
- Other (please specify) _____

Q17 Who conducted the test?

- Allied Health
- Geriatrican (Consultant or Senior Registrar
- Nursing staff
- Other medical staff
- Psychiatrist or Psychogeriatrician

Q18 Was an additional cognitive function test performed during the admission?

- Yes
- No

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

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

- Test used _____
- Score _____
- Days since admission_____

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

- Test used _____
- Score _____
- 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

- Test used _____
- Score _____
- Days since admission_____

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

- Depression
- Diminished activities of daily living
- Hearing impairment
- High alcohol use
- Immobility
- Previous history of delirium
- Previous history of cognitive impairment
- Visual impairment

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

- Polypharmacy (five or more prescription drugs)
- Benzodiazepine use
- Opioid analgesic use

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)

- Sodium _____
- Potassium _____
- Glucose _____
- Albumin _____

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

- Anti-convulsants _____
- Anti-cholinergics _____
- Anti-dementia drugs _____
- Anti-parkinsonian drugs _____
- Anti-psychotics _____
- Benzodiazepines _____
- Lithium _____
- Melatonin _____
- SNRIs _____
- SSRIs_____
- Stimulants _____
- TCAs _____
- Others _____

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

- Yes
- No

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

Q27 Was a delirium screening/diagnostic test performed?

- Yes
- No

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

- CAM _____
- DSM V _____
- ICD10 _____
- 4AT _____
- Other (please specify) (5) _____

Q29 Were any of the following precipitating factors present?

- Central line
- Evidence of dehydration
- Evidence of malnutrition
- Evidence of multiple bed moves (>2 wards)
- General anaesthetic given
- Indwelling urinary catheter
- Three or more medications added to medications on admission
- Use of physical restraints

Q30 How many days did the delirium episode last for?

- Number of days _____
- Not specified
- Not resolved prior to discharge or transfer

Q31 Was the patient prescribed any psychotropic drugs in hospital prior to the delirium episode? Please use generic names in lower case

- Anti-convulsants _____
- Anti-cholinergics _____
- Anti-dementia drugs _____
- Anti-parkinsonian drugs _____
- Anti-psychotics _____
- Benzodiazepines _____
- Lithium _____
- Melatonin _____
- SNRIs _____
- SSRIs_____
- Stimulants _____
- TCAs _____
- Others _____

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

- Yes
- No

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

- Anti-convulsants _____
- Anti-cholinergics _____
- Anti-dementia drugs _____
- Anti-parkinsonian drugs _____
- Anti-psychotics _____
- Benzodiazepines _____
- Lithium _____
- Melatonin _____
- SNRIs _____
- SSRIs_____
- Stimulants _____
- TCAs _____
- Others _____

Q34 Did the patient have a fall in hospital?

- Pre-delirium episode
- During or post delirium episode
- Not specified

Q35 Did the patient develop a hospital acquired pressure injury?

- Pre-delirium episode
- During or post delirium episod
- Not specified (3)

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

- Patient was identified as high risk for developing delirium
- Patient was identified as high risk and appropriate screening was carried out
- A comprehensive assessment was made to investigate the cause of delirium
- The patient was assessed for risk of falls
- The patient was assessed for risk of pressure injuries
- The patient was given an individualised care plan
- The patient was re-admitted with delirium within 28 days
- The patient was re-admitted for any other reason within 28 days

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:

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 control 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