Reducing urinary catheter use: a randomised controlled study on the efficacy of an electronic reminder system in hospitalized patients

Research Protocol

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Version 1.1

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SYNOPSIS

TITLE OF STUDY	Reducing catheter use: a randomised on the efficacy of an electronic reminder system
TRIAL REGISTRATION	Registration with the Australia New Zealand Clinical Trial Registry (ANZCTR) pending
PROTOCOL VERSION NUMBER	Version 1.0
SPONSOR/FUNDING BODY	This project is funded by an industry grant.
ROLES & RESPONSIBILITIES	**Chief Investigators:** Professor Brett Mitchell Dr Oyebola Fasugba Professor Allen Cheng Dr Philip Russo A/Professor Maria Northcote **Study team:** Victoria Gregory (Project Manager) Hannah Rosebrock (Project Officer)
PRIMARY OBJECTIVES	1. To determine the efficacy of an electronic reminder system in reducing urinary catheter usage. 2. To determine whether the CATH TAG has an effect on nurses' ability to deliver patient care.
STUDY DESIGN	Stepped wedge cluster randomised controlled trial
STUDY DURATION	24 weeks stepped-wedge control and intervention phases
NUMBER OF PARTICIPANTS	1 hospital
INCLUSION CRITERIA	The hospital must have: 1. An intensive care unit. 2. More than 30,000 patient admissions per year. 3. 10 or more wards/units.
EXCLUSION CRITERIA	Hospitals will be excluded from the study if they do not meet any of the inclusion criteria.
INTERVENTION	The introduction of an electronic reminder system for removal of urinary catheters.
OUTCOME MEASURES	**OBJECTIVE 1** ***Primary outcome*** 1. Urinary catheter device utilization ratio (number of urinary catheter-days divided by the number of patient-days) ***Secondary outcome(s)*** 1. The number of cases of catheter associated asymptomatic bacteriuria (CA-ASB) per 100 catheter days.

	2. The number of urinary catheters inserted per 100 admissions **OBJECTIVE 2** ***Primary outcome*** 1. Perceptions of nurses about ease of use of the CATH TAG **Secondary outcome(s)** 1. Perceptions of nurses about effectiveness of the CATH TAG 2. Perceptions of nurses regarding changes in ownership or interest by patients in catheter management. 3. Barriers to CATH TAG working successfully in varied types of patients
RECRUITMENT & ENROLMENT	The recruitment process will purposively invite eligible hospitals to participate through stakeholder and partner networks.
DATA COLLECTION	Data will be collected prospectively on the number of catheters being used during the control and intervention periods.
STATISTICAL ANALYSES	**Objective 1** Data analysis will be performed using the generalised estimating equations, with the duration of catheterisation as the dependent variable, and intervention as the independent variable. **Objective 2** Through an online survey and focus group the data analysis process will aim to investigate pre-determined themes reflected in the study's objectives as well as to identify emerging themes.
DISSEMINATION	The investigators will implement a dissemination plan that will include communication strategies for all stakeholders, a publication plan (to minimally include a protocol paper and primary outcomes papers) and presentations at national and international conferences.

Contents

Abbreviations

ACIPC	Australasian College of Infection Prevention & Control
ACU	Australian Catholic University
ACSQHC	Australian Commission on Safety and Quality in Health Care
AMR	Antimicrobial resistance
ANU	Australian National University
ANZCTR	Australia New Zealand Clinical Trial Registry
APHA	Australian Private Hospitals Association
ASID	Australasian Society for Infectious Diseases
AVON	Avondale College of Higher Education
CA-ASB	Catheter associated asymptomatic bacteriuria
CAUTI	Catheter associated urinary tract infection
HAI	Healthcare associated infection
HAUTI	Healthcare associated urinary tract infection
HREC	Human Research Ethics Committee
ICU	Intensive care unit
NHMRC	National Health and Medical Research Council
QALY	Quality-adjusted life year
QUT	Queensland University of Technology
UniM	University of Melbourne
UTI	Urinary tract infection

Title

Reducing catheter use: a randomised controlled study on the efficacy of an electronic reminder system

Trial Registration

The trial will be registered with the Australia New Zealand Clinical Trial Registry (ANZCTR), (Registration pending).

Funding, sponsors and partners

This project is led by the Avondale College of Higher Education. Avondale College will be responsible for managing the study design, conducting the intervention, data analysis and interpretation, publication and dissemination of results.
Academic project partners at Monash University and Deakin University will provide in-kind contributions to the study design, conduct, data analysis and interpretation and the publication and dissemination of results.
The project is being funded by an industry grant.

Project partners and governance structure

Table 1 outlines the governance structure for this project and the roles and responsibilities of investigators. Chief Investigator (CI) Mitchell will take overall responsibility for delivering this project.

Table 1. Management role and responsibility

Name	**Organisation**	**Role**	**Responsibility and contributions**
Professor Brett Mitchell	Avondale College	Chief Investigator	Governance Protocol review & development Data analysis Infection control
Professor Allen Cheng	Monash University	Co-investigator	Protocol review Epidemiology & statistics Data analysis Clinical expert

Dr Oyebola Fasugba	Australian Catholic University & Avondale College	Co-investigator	Protocol review Content expert
Dr Phillip Russo	Deakin University	Co-investigator	Epidemiology Health services research Surveillance
A/Professor Maria Northcote	Avondale College	Co-investigator	Protocol review Qualitative input Data analysis – qualitative
Victoria Gregory	Avondale College	Project Manager	Protocol development Project management Ethics & site specific authorisations Budget
Hannah Rosebrock	Avondale College	Project Officer	Protocol development Project management Ethics & site specific authorisations Budget
TBC	Enrolled hospital	Onsite support Advisory role	Data collection

Background

Indwelling urinary catheters are commonly used in healthcare facilities, with foundation work by two investigators indicating that 26% of patients admitted to an Australian hospital receive an indwelling urinary catheter and 1% of these patients develop catheter-associated urinary tract infections (CAUTIs).[1] Healthcare associated urinary tract infections (HAUTIs), including CAUTIs have been associated with increased morbidity, mortality, higher hospital costs for patients and health systems.[2,3] In Australia, an estimated 380,000 bed days are lost each year due to HAUTIs, a large proportion of which are CAUTIs.[3,4] Urinary tract infections (UTIs), specifically CAUTIs are associated with higher risk of antimicrobial resistance (AMR), making the treatment of patients difficult and compounding the effects of AMR when treatment is provided.[5-8] A recent high-level meeting of the United Nations General Assembly addressed the issue of increasing AMR.[9] This further emphasises the need to develop interventions to reduce the incidence of CAUTIs.

Despite advances in infection prevention and control, CAUTIs remain problematic[10], hence further research is needed to identify ways to reduce the burden they create. The greatest risk factor for CAUTIs is prolonged catheterisation, with catheters often placed unnecessarily, lacking documented reasons for insertion, and catheters remaining in place too long and not being promptly removed.[1,11-14] Interventions that prompt removal of unnecessary catheters may therefore enhance patient safety. A reminder intervention is a mechanism used to remind either a physician or nurse that the catheter is still in place and that removal may be warranted if the catheter is no longer required.[12]

The CATH TAG is an electronic device that adhesively attaches to the catheter bag. It has a non-intrusive green light that flashes intermittently for a period of 24 hours upon activation. After 24 hours the green flashing light changes to red, flashing with increased rapidity and visibility. The light will flash red for 4 hours and subsequently change back to green, slower flashing, restarting the cycle. The red flashing light is an indication for the nurse to reassess the need for a urinary catheter and remove it when it is no longer required. This circle will continue for 10 days and then change permanently to the red flashing light to indicate that the battery of the CATH TAG is exhausted.

Emerging AMR and the risks associated with it, the frequency of unnecessary catheter use, the increased costs for hospitals through increased bed days and the increased workload CAUTIs create for nurses in Australia and in hospital settings worldwide, highlight the need for novel methods to reduce urinary catheter use and the burden of CAUTIs.

Research Plan

Research aims

Objective 1: To determine the efficacy of an electronic reminder system in reducing urinary catheter usage.

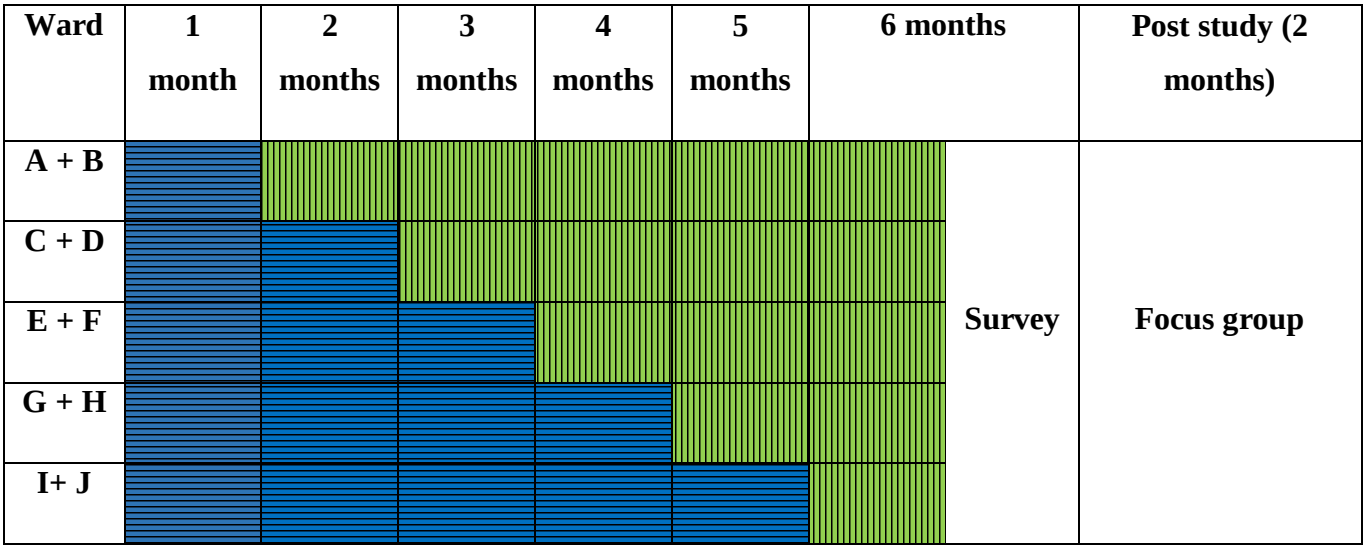
Objective 2: To determine whether the CATH TAG has an effect on nurses' ability to deliver patient care.

Research hypotheses

1. There is no difference in urinary catheter usage when using an electronic reminder system, as opposed to current practice.
2. The CATH TAG has no impact on nurses' ability to deliver patient care.

Study design

A stepped wedge cluster randomised controlled study will be undertaken in one hospital over a 24-week period (Figure 1). A mixed methods approach will be used, as the study includes a qualitative approach. The clusters in the study are pairs of individual hospital wards. The stepped wedge design includes an initial period where no wards are exposed to the intervention.[15] Afterwards, at regular intervals (the "steps") two wards, forming one cluster, are randomised to cross over from the control to the intervention with the process continuing until all enrolled wards have crossed over.[15] There will be a random sequential allocation of the intervention to the wards, i.e. each enrolled ward will be introduced to the intervention two at a time, approximately every 4 weeks until week 20, when all wards would have been exposed to the intervention. The study design enables each ward to act as its own control, which removes the potential for some confounders such as variations in ward size and case mix. Staggered commencement and duration of the intervention, supports feasibility while maintaining the rigour of the study.[16] This design will allow research staff to work with individual wards as they change over, maximising consistency of the intervention and aiding implementation.[16] In addition, data collection continues throughout the study, so that each cluster contributes observations under both control and intervention observation periods. In month 6 of the study, an online survey of nursing staff will be administered. Approximately two months after the stepped wedge study is completed, a focus group will be conducted.



Blue (horizontal lines) = control; Green (vertical lines) = intervention

Figure 1. Study design overview

Setting and eligibility

Population

One Australian hospital will be enrolled in the study.

Eligibility criteria for hospitals

To be eligible to participate and include patients in the trial, the hospital must have:

- An intensive care unit
- More than 30,000 patient admissions per year
- Ten or more wards/units

Exclusion criteria for hospitals

Hospitals will be excluded from the study if they do not meet any of the inclusion criteria. Potential wards and units eligible for inclusion are medical wards, surgical wards and intensive care units. Day-stay units and psychiatric wards will be excluded. Neonates (<2 years old) may be excluded if the CATH TAG is too large for the catheter tubing or interferes with patient care.

Areas of hospital inclusion and exclusion criteria

The study will involve at least ten wards or units within a hospital.

Recruitment of hospitals

The recruitment process will purposively invite eligible hospitals to participate through stakeholder and partner networks. The first confirmed hospital will be accepted. Patient level consent will not be obtained or be required, given the nature of the study and study design. There is no patient intervention or involvement, rather an addition to existing procedures regarding catheter removal.

Other considerations

Hospitals could be excluded from the study if within the study time frame they are:

- undertaking a project that may influence the outcomes measured in this study
- opening, closing or relocating

.

Recruitment of participants (nurses) for survey and focus group

In order to recruit nurses to participate in an online survey, information leaflets will be distributed to each participating ward during month 6 of the study. If possible (e.g. approved by the hospital) the same information will be sent to nurses via email. Other communication methods such as a ward communication diary, reminder at a staff meeting or during handover may also be used. Nurses have been chosen as the participants as they have the primary role in day to day indwelling catheter management and care.

The information leaflet/email will contain details about the survey and a web link (presented as URL and alternatively as QR code) to participate. Upon commencement of the survey, information regarding the study will be provided, in addition to a consent form. To improve response rates, an incentive of ten $50 gift cards will be made available and will be allocated at random to those who complete the survey. To enter the draw for a gift card, participants will need to click on a different web link, provided at the end of the survey. This will ensure that no personal details are linked to the survey.

To recruit participants for a focus group, interest can be registered at the end of completing the online survey. To register interest, participants will need to click on a different web link, provided at the end of the survey. This will ensure that no personal details are linked to the survey. Focus group participants will receive a $100 gift card to compensate them for their time. If more people register for the focus group than are required, purposive sampling will occur to ensure a representative sample of different wards. If it remains such that there are still too many registered than can be enrolled, they will be chosen at random. The focus group will be conducted 2 months after completion of the intervention (month 8 of the study). Prior to or on the day of the focus group, information regarding the study will be provided, in addition to obtaining informed consent.

Discontinuation of study or study site

The study will be discontinued if a regulatory body, funding body, or Human Research Ethics Committee (HREC) judges it necessary for medical, safety, regulatory, or other reasons consistent with applicable laws, regulations and good clinical practice.

Randomisation and blinding

Wards in the hospital will be randomly assigned to cross over to the intervention every four weeks over the trial duration of 24 weeks. All included wards will be provided with sufficient notice of the dates to cross over to the intervention. Computer-generated randomisation of the cross over dates for the wards will be performed independently by one of the investigators, who will not be involved in assessment or delivery of the intervention. Wards will not be blinded because it is not feasible to blind staff to the intervention.

Control phase

During the control phase, usual practice regarding catheter care and removal will occur, according to local policy or process guides. No electronic or alert systems for catheter removal will be used.

Intervention

After four weeks, two wards will cross over to the intervention. The intervention is the use of the CATH TAG. A CATH TAG will be attached to each catheter. When the CATH TAG is attached to a catheter bag it will initially flash green for a set period of 20 hours. After 20 hours the green flashing light will cease and a red light will flash with increased rapidity for four hours, alerting nurses to review the patients indwelling catheter. After 4 hours the red fast flashing light will change back to the more slowly green flashing light, restarting the circle until the catheter is removed. There is no option for nurses to manipulate the flashing light or amend the flashing circle.

For patients who are transferred from a control ward to an intervention ward, a CATH TAG will be attached to their catheter upon transfer. Data collected up to the date of transfer will contribute to the control (ward) dataset. Following transfer, data will be contributed to the intervention (ward) dataset.

For patients who are transferred from an intervention ward to a control ward, the CATH TAG will be removed upon transfer. Data collected up to the date of transfer will contribute to the

intervention (ward) dataset. Following transfer, data will be contributed to the control (ward) dataset.

Implementing the intervention

In the week prior to the intervention commencing, information sessions about the study will be provided to the participating hospital and staff. A variety of methods will be used to further alert staff and raise awareness about the intervention prior to it being rolled out. These methods include placing wall posters in wards and key locations, handing out flyers and information leaflets as well as branded promotional material, such as pens. Nurses will be trained in using the CATH TAG.

Confounders

Potential confounders include the different staff inserting and caring for patients with an indwelling catheter and the indications for urinary catheterisation. The cluster randomised design of this study minimises many of these issues, as wards (clusters) act as their own control. Further, there is no reason to suggest a fundamental change in the control and intervention periods for these variables. Duration of the intervention might have a confounding effect on the outcome variables and will be accounted for in data analysis.

Clinical staff working on a casual basis or across wards have the potential to provide responses to the survey or focus group from a range of perspectives, based on their experiences on different wards. To minimise this, the survey will focus the respondent to experiences in one particular area and obtain details about their exposure to working in different wards/hospital units.

Outcomes measures

There are two objectives for this study, (1) determining the effectiveness of the intervention and (2) the effect of the intervention on nurses' ability to deliver patient care. A summary of the objectives' key outcome measures is shown in Table 2.

Table 2. Key outcome measures

Objective 1 To determine the efficacy of an electronic reminder system in reducing urinary catheter usage.	Primary outcome	1. Urinary catheter device utilization ratio (number of urinary catheter-days divided by the number of patient-days)
	Secondary outcome(s)	1. The number of cases of catheter associated asymptomatic bacteriuria (CA-ASB) per 100 catheter days. 2. The number of urinary catheters inserted per 100 patient admissions
Objective 2 To determine whether the CATH TAG has an effect on nurses' ability to deliver patient care.	Primary outcome	1. Perceptions of nurses about ease of use of the CATH TAG
	Secondary outcomes	2. Perceptions of nurses about effectiveness of the CATH TAG 3. Changes in ownership or interest by patients in catheter management 4. Barriers to the CATH TAG working successfully in varied types of patients

Note: CA-ASB = catheter associated asymptomatic bacteriuria; CAUTI = catheter associated urinary tract infection

Definitions

CA-ASB is defined as the presence of $\geq 10^5$ colony forming unit (cfu)/ml of ≥ 1 bacterial species in a single catheter urine specimen in a patient without symptoms compatible with UTI (Hooton et al., 2010).

Data collection

Objective 1: To determine the efficacy of an electronic reminder system in reducing urinary catheter usage

Data will be collected by a specific staff member at the hospital, supported by the research team. Where data collection results in an increase in workload for the hospital staff (e.g. not part of usual practice), the research team will provide additional resources in the form of funding to account for additional hours for existing staff members or employment of new staff members for the purpose of data collection. The research team will provide the hospital staff member(s) with training about the project, data collection processes and data collection tools, as well as ongoing on-site and telephone support. For the purpose of this protocol, the dedicated hospital staff member(s) will be referred to as hospital personnel.

The figure below (Figure 2) summarises the data collection process with further details provided below.

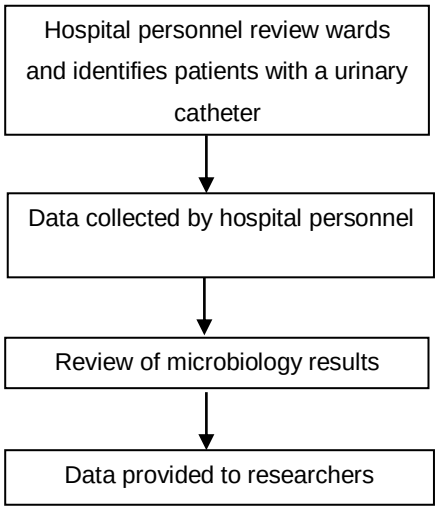


Figure 2. Overview of the data collection process

Hospital personnel will prospectively collect data five days a week on participating hospital wards, during both control and intervention periods. Hospital personnel will visit inpatient areas and patients who receive an indwelling urinary catheter will be identified and followed-up until discharge or catheter removal. Hospital personnel will check that a CATH TAG has been attached to every catheter, on wards that have crossed over to the intervention. The following information will be collected: hospital number, age, sex, date of admission, date and time of catheter insertion, reason for censoring follow-up, date of discharge or catheter removal, designation of person

inserting the catheter, ward and allocation to control or intervention ward. A review of microbiology results will be undertaken by the hospital personnel for each person who receives a catheter and has a urinary sample taken. If a person has a positive urine culture after catheterisation and prior to removal, the following will be collected: data of specimen collection, organism(s) isolated, colony forming units, white cell count.

Table 3 outlines the data to be collected, data sources and timing of data collection. The number of catheter days for each patient included in the study will be estimated from the date of catheter insertion to the date of removal. Hospital personnel will record all captured data locally, on a spreadsheet designed by the research team specifically for the purpose of the trial.

Table 3. Types, sources and timing of data collection

Data collected	**Source**	**Collected by**	**Timing**	**Used for**
Details of patient who received a catheter:				
• Hospital number	Medical notes	Hospital personnel	Control and intervention periods	Link to laboratory data
• Date of birth	Medical notes	Hospital personnel	Control and intervention periods	Data analysis
• Sex	Medical notes	Hospital personnel	Control and intervention periods	Data analysis
• Date of admission	Medical notes	Hospital personnel	Control and intervention periods	Data analysis
• Date and time of catheter insertion	Medical notes	Hospital personnel	Control and intervention periods	Calculating catheter days Data analysis
• Date and time of catheter removal	Medical notes	Hospital personnel	Control and intervention periods	Calculating catheter days Data analysis
• Reason for censoring follow-up (discharged, catheter removal, transfer from control to intervention wards or vice versa)	Medical notes	Hospital personnel	Control and intervention periods	Data analysis
Additional information required:				
• Designation of person inserting	Medical notes	Hospital personnel	Control and intervention	Data analysis

catheter			periods	
• Ward		Hospital personnel		
• Intervention/Control Allocation		Hospital personnel		
Laboratory result of any patient who received a catheter:				
• Has a catheter urine sample been taken (Y/N)	Microbiology laboratory	Hospital personnel	Control and intervention periods	Data analysis
If catheter urine sample has been taken:				
• Date of specimen collection	Microbiology laboratory	Hospital personnel	Control and intervention periods	Data analysis
• Species isolated	Microbiology laboratory	Hospital personnel	Control and intervention periods	Defining the outcome
• Colony count and white cell count where appropriate / provided	Microbiology laboratory	Hospital personnel	Control and intervention periods	Defining the outcome

Sample size:

The at risk population has been defined as patients receiving catheters in hospital. Based on pilot work, an estimated 25% of admissions will receive a catheter.[1] We estimate that, at baseline, the median duration of catheterisation is 4 days (equivalent to a 50% probability that a catheter will be in situ on day 4).[17] We aim to detect a difference of 20% relative risk (10% absolute risk) reduction in catheterisation on day 4, using a stepped wedge study.[15] It is assumed the intra-ward correlation in catheter duration is ρ=0.1). Based on pilot work it is anticipated that there will be 50 patients with a catheter per month on each ward and the study will continue for 6 months.[1]

A power calculation was performed using the stepped wedge module in Stata. This accounts for both the clustering in outcomes by ward, as well as the paired/crossover design of the study.[15,18]

At a significance level of 0.05, 2100 patients (10 wards, with 2 wards implementing the intervention at each month, forming one cluster) will be required to demonstrate a change in the probability of a catheter being in situ on day 4 from 50% to 40% with a power of 81%. Similar power would be expected with 35 patients with catheters per month in 10 wards, with two wards implementing the intervention each month (n=2100, power 81%).

Objective 2: To determine whether the CATH TAG has an effect on nurses' ability to deliver patient care.

Survey:

Data collection will involve the use of a structured anonymous online survey and focus group. The online survey will be administered using SurveyMonkey. Participants will be asked a series of questions that relate to their perceptions about ease of use of the CATH TAG, their views on effectiveness of the CATH TAG, an exploration of their perceptions of change in ownership or interest by patients in catheter management and any barriers to the CATH TAG working successfully nurses might be experiencing, forming the following four dimensions, based on the objectives of the study:

- Ease of use
- Effectiveness
- Perceived changes in ownership regarding patients' health care
- Barriers

Items, exploring those dimensions, will be presented to participants in the form of statements, to be answered on a 5-point Likert scale, as well as in the form of open questions and yes/no questions to investigate possible themes for the focus-group.

Additionally, demographic information about the participants will be collected, including the ward on which they primarily work, age, sex, years of nursing experience (post qualification) and their highest (completed) qualification. No identifiable or re-identifiable information will be collected.

Focus group:
Participants in the focus group will be limited to approximately six to eight people, to ensure the group can be run effectively. If required, a second focus group might be run to ensure representation from more wards. The focus group will be conducted in a location other than the ward on which the participants work. A person with relevant training and experience will lead the group discussion. An exploration of experiences of the CATH TAG will be undertaken, using a series of questions to prompt discussion. The questions will be designed to validate the broad responses and themes received in the online survey and provide the opportunity for in depth feedback not otherwise possible from the online survey.

The timing of this focus group is important. As this study adopted a stepped wedge cluster approach to implement the intervention, scheduling the focus group towards the end of the study will enable the researchers to capture the participants' responses after staggered levels of involvement in use of the CATH TAG.

Using a phenomenological approach, which seeks to understand the participants' lived experience of a phenomena, the focus group questions will aim to capture information about the personal experiences of the hospital personnel, and their construed perceptions of patients' perceptions, regarding the use and effectiveness of the CATH TAG. Clinical staff will be asked to provide responses to questions about the following issues, including both their own perceptions about use of the CATH TAG as well as their construed perceptions of patients' response to its use:

- perceived ease of use of the CATH TAG;
- perceived impact on patient care (effectiveness) of the CATH TAG;
- perceived impact on interactions with patients as a result of using the CATH TAG;
- perceptions of patients' experiences with, interest in and reactions to use of the CATH TAG;
- perceptions of impact on patients' ownership of their own healthcare as a result of using the CATH TAG;

- perceived barriers to using the CATH TAG; and
- additional issues that emerge from an analysis of the participants' survey responses.

The focus group will be voice recorded, with the permission of participants, to enable further analysis of the discussion at a later day. No identifiable or re-identifiable information provided during the focus group will be linked to any participant.

Data analysis

Objective 1: To determine the efficacy of an electronic reminder system in reducing urinary catheter usage.

The primary outcome measure is the duration of catheterisation, and the study aims to evaluate the effect of the intervention. The analysis will be performed using the generalised estimating equations, using the duration of catheterisation as the dependent variable and intervention as the independent variable. Duration of the intervention will be treated as a confounding variable. It is anticipated that duration of catheterisation will be normally distributed, but exploratory analyses (and where necessary transformation) will be performed. Robust standard errors will be used to adjust for correlation at ward level and autocorrelation in time. There is no expected delay in the effect of the intervention on the outcome.

Objective 2: To determine whether the CATH TAG has an effect on nurses' ability to deliver patient care.

Survey:
Data from the anonymous online survey will be analysed using SPSS. It is anticipated that data will be normally distributed but exploratory analyses will be performed, including testing of assumptions of linearity, homoscedasticity, multicollinearity and normality of errors and if necessary transformation of data. Validity and reliability will be examined. Subsequently a general satisfaction score and individual satisfaction scores for the four dimensions of nurses' experiences with the CATH TAG (Ease of use, Effectiveness, Changes in ownership, Barriers) will be calculated. Regression analysis will be conducted to determine if the duration of the intervention or the ward nurses primarily work on had an effect on nurses' experiences with the CATH TAG.

Any problems reported in the open questions will be taken into the focus group to be discussed and subsequently analysed qualitatively (see below).

Focus group:
Data gathered from the focus group/s will be coded and analysed using qualitative analysis software (NVivo). The data analysis process will aim to identify and investigate both, pre-determined and emerging themes, in the data. The pre-determined themes will be drawn from the broad responses to the open questions in the survey, as well as from the study's objectives and will be reflected in the focus group questions. As themes are identified in the data, constant comparison analysis will be utilised. This process reduces redundancy in the analysis results by collapsing similar themes, identifies any relationships between the themes and ensures saturation is achieved. In this way, the essence of the hospital personnel's perceptions will be determined.

Ethics

Ethics approval from the HREC at Avondale College of Higher Education will be obtained prior to study commencement. Where a participating hospital requires local HREC and/or site specific authorisation, this will be obtained prior to study commencement. The project manager will submit and, where necessary, obtain approval from each HREC for all subsequent protocol amendments, once approved by the study investigators. The project manager will also notify the HREC of deviations from the protocol or serious adverse events occurring at the hospital in accordance with local procedures. The investigators and project manager will be responsible for adhering to ethics committee requirements throughout the study.

Online survey and focus group

Informed consent will be obtained from the participants in both the online survey and focus group. For the survey, study information and consent will be at the beginning of the survey. It will not be possible to progress to the questions in the survey, without having provided consent. No identifiable or re-identifiable data will be collected. For the focus group, consent will be obtained at the beginning of the session. Only participants who sign the handed out consent form will proceed to participate in the focus group.

Catheter data

For this study, individual patient consent will not be obtained. There is no patient intervention, simply a collection of existing data, provided to researchers in a de-identified format. Researchers have at no stage any patient contact or access to patient information. The timing of consent can be problematic in stepped wedged designs, as evidenced by a study, in which the Research Ethics Committee considered it was reasonable not to obtain informed consent at the start of the study (when care as usual was delivered).[19]

A request for waiver of informed consent will be sought from the HREC, using the criteria for waivering of consent as stated in the National Statement on Ethical Conduct in Human Research (NHMRC). The following points will be made to support this waiver:

- Involvement in the research carries no more than low risk for participants. The insertion of a urinary catheter will occur in patients, regardless of whether they are involved in this research or not. This is the decision of the treating clinician. Placement of the CATH TAG on catheters does not involve a change in existing procedures but rather involves an addition to existing procedures. The CATH TAG serves to prompt responsible nurses to revise catheters still in place after 20 hours. The CATH TAG will not affect the decision if the catheter has to be removed or will stay in place. This remains the decision of responsible nurses and clinicians. No harm or discomfort is anticipated with the implementation of the CATH TAG. However, should patients show signs of discomfort by the CATH TAG, the CATH TAG will be removed immediately.
- As there is no anticipated harm or risk for use of the CATH TAG, during consent we would be required to counsel patients on a risk that is negligible and potentially distract them from the wider medical issues resulting in the need for catheterisation in the first instance. Such counselling would result in a significant administrative burden, for no perceived value given the low risk involved. There is a prospect of causing undue harm if the need to uphold the autonomy of each individual were to be exercised to the fullest extent. This harm (maleficence) is considered to be higher than the harm arising from potential misuse of patients' personal information. For example, consent would require holding additional identifiable information about the patient e.g. name and date of birth.
- It is impracticable to obtain consent for a number of reasons:
    - Urinary catheters are inserted in a variety of settings within a hospital. It would not be possible for researchers to determine or access patients (participants) who are about to receive a catheter. Similarly, urinary catheters are inserted by clinicians (nurses and

medical doctors) at any time of the day, it is not possible for all staff involved in catheterisation to be reached.

- Obtaining consent would require researchers to have access to a higher level of patient history and personal data.
- The clinician obtains consent for the insertion of a catheter, as part of usual medical treatment/processes, following local hospital policy.
- Urinary catheters are often inserted at a time where the patient (participant) requires urgent medical or surgical attention. Obtaining consent related to this study may delay the insertion of a catheter, compromising patient (participant) harm and increasing the risk of harm to patients.
- Retrospective consent, i.e. an approach that would result in the researchers retrospectively contacting participants to seek permission to access their medical records would raise the following ethical issues:
    - There would be considerable loss of participants included in the study as there is no system in place to identify which patients had a catheter inserted while in hospital. As such, the research could not be conducted. If a system were established, it would be administrative in nature. Further it would require the researchers to have access data of potential participants so they could be contacted. These details would include data such as names and postal addresses – information the researchers are not required to have as part of the proposed study design.
    - There would be the risk of contacting patients who underwent significant harm whilst in hospitals, suffered a traumatic event or may have passed away. The process of acquiring informed consent retrospectively would potentially result in increased harm for those participants.

- There is no known or likely reason for thinking that participants would not have consented if they had been asked as there is no risk involved and no patient intervention.
- The clinician will be following local hospital policy regarding the insertion of a catheter.
- There is no variation of care, rather an addition to existing policies, unless contra-indicated.
- De-identified patient data is being collected by the researchers, no identifiable or re-identifiable information is being collected.

In addition to the NHMRC National Statement on Ethical Conduct in Human Research, there is the Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials. This statement makes the following recommendation with respect to waiver of consent:

"Recommendation 6: A REC may approve a waiver or alteration of consent requirements when (1) the research is not feasible without a waiver or alteration of consent, and (2) the study interventions and data collection procedures pose no more than minimal risk." [20,21]

- As described in the preceding sections, consent is not feasible and the intervention is no more than minimal risk.

Data management

The project manager, chief investigator and study staff are responsible for maintaining a comprehensive and centralised filing system of all study-related (essential) documentation, suitable for inspection at any time by the approving HREC or applicable regulatory authorities.

Documentation will be stored on a network storage service, which has an automated back-up system. Data will be shared via a password protected file storage server at Avondale College. Data will be stored in de-identifiable format.

Timelines

The table below summarises the proposed timelines for this project.

Table 4. Project timeline

Activity	**2017**						**2018**												**2019**					
	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
Appointment and commencement of project manager	X	X																						
Finalise protocol, recruitment of sites and ethics approval at administering organisation	X	X																						
Clinical trial registration and submission of protocol	X	X																						
Site specific approvals/authorisation and local ethics approvals		X	X																					
Study commencement and data collection						X	X	X	X	X	X													
Survey											X													
Data analysis Manuscript writing											X	X	X	X	X	X								
Focus group													X											
Peer review journal publication(s) submission Dissemination and translation into practice activities														X	X	X	X	X	X	X	X			

Resourcing and Budget

The project is funded from an industry grant. In-kind support is provided by Avondale College and higher education institutions with which the Chief Investigators are affiliated. CI Mitchell will take responsibility for the budget and allocation of resources, with support from the Project Manager and Project Officer.

Monitoring

The investigators and research team, led by the project officer, will monitor data collection processes for each ward or unit at least weekly. Data will be reviewed on a weekly basis to ensure correct collection of the control and intervention data sets. Support (site visits, video conference, telephone and email contact) will be provided by the project manager as required during the initial parts of the control and intervention phases to check core trial processes and maintain data quality.

Adverse event reporting

The project manager is responsible for ensuring that all adverse events observed by the investigator/s, research team or reported by wards or units are collected and recorded in the source documents. The project manager will notify the approving ethics committee of serious adverse events occurring at any of the sites. Adverse events could require reporting as per hospital specific policy.

Incident monitoring and reporting

The project manager is responsible for ensuring that all incidents observed by the investigator/s, research team or reported by wards or units are collected, reviewed and recorded in the source documents. Incidents could require reporting as per hospital specific policy and/or notification to the approving ethics committee.

Intellectual property

All Intellectual Property generated through the project will be managed in accordance with Avondale College's Intellectual Property Policy.

Intellectual property that pertains to the electronic reminder system resides with CATH TAG.

Safety

The following will be used to evaluate the safety of staff involved in the study:

- adverse events report

- incident monitoring.

Dissemination

The investigators will implement a dissemination plan that will include:

- communication strategy for all stakeholders
- a publication plan (to minimally include a protocol paper and primary outcomes papers)
- presentations at national and international conferences

In addition to the above, dissemination activities will include some or all of the following:

Research Phase:

- The hospital involved in the study
- ACIPC and Australasian Society for Infectious Disease (ASID)
- The Australian Centre For Health Services Innovation (AusHSI)

Completion Phase:

- Australian College of Nursing (Peak professional nursing organisation)
- NHMRC, enhanced by three investigators' committee membership
- The Australian Centre For Health Services Innovation (AusHSI)
- Australian Commission on Safety and Quality in Health Care, enhanced by two investigators' committee membership
- NSW, Clinical Excellence Commission

An online presence will also be used during both the research and completion phases. This will include an online webinar and social media, particularly blogs and Twitter feeds of investigators and/or their departments.

Authorship of publications

Authorship requirements and publication standards that align with the following will be used to guide publications:

- NHMRC Australian Code for the Responsible Conduct of Research (http://www.nhmrc.gov.au/guidelines-publications/r39)
- International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

Avondale College will enter into a research collaborative agreement with the company supplying the device, to ensure Avondale has full right to publish research results.

References

1. Gardner A, Mitchell B, Beckingham W, Fasugba O. A point prevalence cross-sectional study of healthcare-associated urinary tract infections in six Australian hospitals. *BMJ Open* 2014;4.

2. Saint S. Clinical and economic consequences of nosocomial catheter-related bacteriuria. *Am. J. Infect. Control* 2000;28:68-75.

3. Mitchell BG, Ferguson JK, Anderson M, Sear J, Barnett A. Length of stay and mortality associated with healthcare-associated urinary tract infections: a multi-state model. *J. Hosp. Infect.* 2016;93:92-99.

4. Magill SS, Edwards JR, Bamberg W, et al. Multistate Point-Prevalence Survey of Health Care–Associated Infections. *N. Engl. J. Med.* 2014;370:1198-1208.

5. Nicolle LE. Catheter associated urinary tract infections. *Antimicrobial resistance and infection control* 2014;3:23.

6. World Health Organisation. Antimicrobial resistance: global report on surveillance. Geneva World Health Organisation,; 2014.

7. Fasugba O, Koerner J, Mitchell B, Gardner A. Systematic review and meta-analysis of the effectiveness of antiseptic agents for meatal cleaning in the prevention of catheter-associated urinary tract infections. *J. Hosp. Infect.* 2016.

8. Fasugba O, Mitchell BG, Mnatzaganian G, Das A, Collignon P, Gardner A. Five-Year Antimicrobial Resistance Patterns of Urinary Escherichia coli at an Australian Tertiary Hospital: Time Series Analyses of Prevalence Data. *PLoS One* 2016;11:e0164306.

9. World Health Organisation. United Nations high-level meeting on antimicrobial resistance. 2016. http://www.who.int/antimicrobial-resistance/events/UNGA-meeting-amr-sept2016/en/. Accessed 27th January, 2017.

10. Saint S, Greene MT, Krein SL, et al. A program to prevent catheter-associated urinary tract infection in acute care. *N. Engl. J. Med.* 2016;374:2111-2119.

11. Jain P, Parada JP, David A, Smith LG. Overuse of the indwelling urinary tract catheter in hospitalized medical patients. *Arch. Intern. Med.* 1995;155:1425-1429.

12. Meddings J, Rogers MA, Macy M, Saint S. Systematic review and meta-analysis: reminder systems to reduce catheter-associated urinary tract infections and urinary catheter use in hospitalized patients. *Clin. Infect. Dis.* 2010;51:550-560.

13. Maki DG, Tambyah PA. Engineering out the risk for infection with urinary catheters. *Emerg. Infect. Dis.* 2001;7:342-347.

14. Fakih MG, Dueweke C, Meisner S, et al. Effect of nurse-led multidisciplinary rounds on reducing the unnecessary use of urinary catheterization in hospitalized patients. *Infect. Control Hosp. Epidemiol.* 2008;29:815-819.

15. Hemming K, Haines T, Chilton P, Girling A, Lilford R. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015;350:h391.

16. Hall L, Farrington A, Mitchell BG, et al. Researching effective approaches to cleaning in hospitals: protocol of the REACH study, a multi-site stepped-wedge randomised trial. *Implementation Science* 2016;11:44.

17. Wald HL, Ma A, Bratzler DW, Kramer AM. Indwelling urinary catheter use in the postoperative period: Analysis of the national surgical infection prevention project data. *Arch. Surg.* 2008;143:551-557.

18. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp. Clin. Trials* 2007;28:182-191.

19. Zhan Z, van den Heuvel ER, Doornbos PM, et al. Strengths and weaknesses of a stepped wedge cluster randomized design: its application in a colorectal cancer follow-up study. *J. Clin. Epidemiol.* 2014;67:454-461.

20. Taljaard M, Weijer C, Grimshaw JM, Eccles MP. The Ottawa Statement on the ethical design and conduct of cluster randomised trials: précis for researchers and research ethics committees. *BMJ : British Medical Journal* 2013;346.

21. Weijer C, Grimshaw JM, Eccles MP, et al. The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials. *PLoS Med.* 2012;9:e1001346.