

# Study protocol for reducing urinary catheter use: a randomised controlled study



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# Catheter Associated Infections (CAUTIs): The Need for Action

#### **Background**

- CAUTIS have been associated with increased morbidity, mortality and high hospital costs for patients and health systems.
- 26% of patients admitted to an Australian hospital receive an indwelling urinary catheter and 1% of these patients develop CAUTIs.<sup>1</sup>
- An estimated 380,000 bed days are lost each year due to healthcare-associated infections in Australia, a large proportion of which are CAUTIs.
- CAUTIs can increase the length of hospital stay by up to four days.<sup>2</sup>
- CAUTIs are associated with higher risk of antimicrobial resistance (AMR).<sup>3</sup>
- Prolonged and unnecessary catheterisation appear to be the main risk factor for development of CAUTI's. 1, 4

#### Summary

Addressing prolonged catheterisation as the major cause of CAUTIs, this study aims to evaluate the effectiveness of an electronic surveillance device to reduce urinary catheter use: the CATH TAG.

### Key Outcomes

# **Objective 1: Determine efficacy of** the CATH TAG

- 1. Urinary catheter device utilisation ratio
- 2. The number of cases of catheter associated asymptomatic bacteriuria per 100 catheter days
- 3. The number of urinary catheters inserted per 100 patient admissions

# **Objective 2: Impact of the CATH** TAG on nurses' ability to deliver patient care

- Perceived ease of use of the CATH TAG
- 2. Perceived effectiveness of the CATH TAG
- 3. Perceived changes in ownership or interest by patients regarding catheter management
- 4. Perceived barriers to the CATH TAG working successfully in various types of patients

# The Intervention: CATH TAG

device

# **CATH TAG** \* REVIEW NEED FOR CATHETER **CATHETER INSERTION** ALTERNATING RED/GREEN 4 HRS EVERY DAY, FOR 10 DAYS INDICATE LOW BATTERY, REPLACE CATH TAG TEAR OFF & DISCARD IF HAVING MRI - AVOID X-RAY

**Catheter insertion** 

24 hour green flashing

Electronic device, that attaches adhesively to catheter bag

 Indicates reassessment need for catheter through flashing

Figure 1 (left). CATH TAG

Figure 2 (right). CATH TAG

attached to catheter bag

CATH TAG

### Implementation

- 1. A CATH TAG will be attached to every catheter bag (see figure 2) with catheter insertion
- 2. Information and training sessions; distribution of flyers & promotional material in hospital prior to commencement to raise awareness of intervention

**Patient** 4 hour red flashing Reassessment

Figure 3. CATH TAG flashing cycle

# Study Design

- ✓ Max. feasibility
- ✓ Max. statistical power
- ✓ Min. risk for participants

#### Stepped wedge randomised controlled trial over 24 week period → Objective 1

- All wards, included in the trial, will receive the intervention and act as their own control
- Random assignment of wards to intervention, allocation concealed to researchers, no blinding of wards
- Initial control phase for all wards: usual practice regarding catheter removal
- All wards complete the trial at the same time in May 2018



Figure 4. Study Design Overview. White= control; Red = intervention

#### Mixed methods approach →Objective 2

- Anonymous online survey upon completion of trial period
- Qualitative: Focus group two months post trial completion to investigate nurses' perceptions of the CATH TAG

#### Participants trial phase

 All hospitalised patients receiving a urinary catheter >2yrs of age, excluding theatre patients

# Participants survey & focus group

Nurses, who have been working with the CATH TAG

# Data Collection

Participant receives catheter

Medical Notes Review and Microbiology results

Data Collected by hospital staff

Hospital staff review wards

Data de-identified

Data provided to researchers

- 1. Hospital personnel collect data five days a week during both control and intervention periods.
  - 2. Patients who receive a urinary catheter are followed up during the trial period until catheter removal / discharge
    - 3. Collect the following data:
      - Patient demographics
      - Catheter date and time of insertion & removal / discharge
      - Laboratory results (if urinary sample has been taken)
    - De-identified data submitted to Research Team weekly, then monthly

#### Anonymous Online Survey for nurses

Administered via an online survey tool Duration 10 – 15 minutes



Group discussion to receive in-depth feedback on CATH TAG Conducted member of the research team Duration 1 – 1.5 hrs

# Study Progression

- ✓ An Australian Hospital with at least 30,000 admissions and 10 wards will be recruited for the trial
- ✓ ANZCTR registered
- ✓ Ethics approval has been granted (Avondale College) of Higher Education)
- ✓ Prospective trial commencement date: 1<sup>st</sup> Nov 2017
  - Trial period: 24 weeks
  - Prospective finish date: 1st May 2017

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