Protocol paper: Reducing catheter associated urinary tract infections in hospital, a multi-site randomised controlled study

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The impact of catheter associated urinary tract infections (CAUTIs)

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.[1]
- An estimated 380,000 bed days are lost each year due to healthcare-associated UTI's in Australia, a large proportion of which are CAUTIs.
- Hospital associated CAUTIs can increase the length of hospital stay by up to four days. [2]
- CAUTIs are associated with higher risk of antimicrobial resistance (AMR).[3]
- Reducing bacterial colonization around the urethral area has the potential to reduce CAUTI risk.[4]
- Clinical practice needs cost-effective strategies. The cost of chlorohexidine 0.1% solution may be has high as $2.50 per patient versus $0.35 for 0.9% normal saline
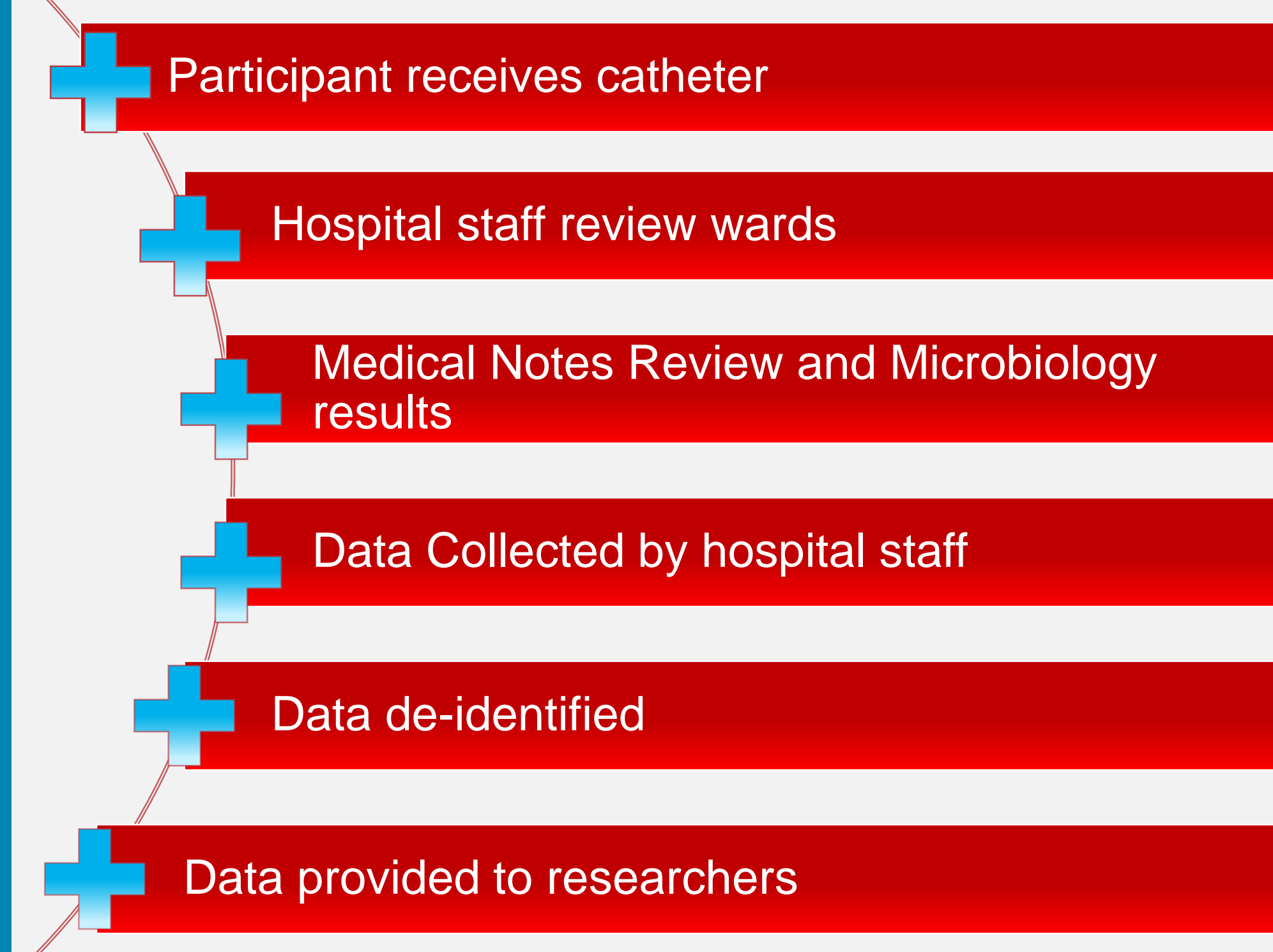
Current Practice

Evidence about the best antiseptic solutions for cleaning is mixed, there is conflicting recommendations in national and international practice, there is variation of practice within Australian hospitals and there is a lack of research in relation to the meatal cleaning solution used prior to catheter insertion.[5]

Summary

Given the importance of meatal colonisation in the pathogenesis of CAUTIs, emerging AMR, the frequency with which catheters are used and the burden of CAUTIs in Australia and in hospital settings worldwide, generation of evidence using a high-quality randomised trial at Canberra Hospital (ACT) (A), Lismore Hospital (NSW) (B) and Sydney Adventist Hospital (NSW) (C) will determine the efficacy and cost-effectiveness of using saline or chlorhexidine in meatal cleaning. The outcomes will inform clinical practice and policy in Australia and internationally.

Study Objectives

1 To evaluate the effectiveness of using chlorhexidine in the meatal cleaning prior to catheter insertion for the prevention of CAUTIs.

2 To estimate the cost-effectiveness of using chlorhexidine in meatal cleaning prior to catheter insertion.

Control Phase Saline (left). Intervention Phase Chlorhexidine (right).

Study Design

Hospital	2 months	4 months	6 months	8 months
A		■	■	■
B			■	■
C				■

White = control; Red = intervention

Stepped Wedge Design

- ✓ A stepped wedge randomised controlled trial in 3 large tertiary hospitals in Australia over a 32 week period.
- ✓ Participants are hospitalised patients receiving a urinary catheter >2yrs of age, excluding theatre patients.
- ✓ Hospitals begin with a control phase using saline for urethral cleaning before catheter insertion.
- ✓ Approximately every eight weeks each hospital switches to the intervention phase, chlorhexidine.
- ✓ The design allows the research team to work with individual hospitals as they change over, maximising consistency of the intervention and aiding implementation.
- ✓ Data collection continues throughout the study, so that each cluster contributes observations under both control and intervention observation periods.

Key Outcome Measures

Objective One: Chlorhexidine Effectiveness

1. A measure of cases of catheter-associated asymptomatic bacteriuria (CA-ASB) per 100 catheter days
2. The number of cases of catheter associated urinary tract infections (CAUTI) per 100 catheter days
3. The number of bloodstream infections (BSI) associated with a UTI

Objective Two: Chlorhexidine Cost-Effectiveness

1. Changes in costs relative to health benefits (incremental cost-effectiveness ratio) from adoption to intervention
2. Changes in costs associated with implementing the intervention relative to the change in quality adjusted life years (QALY's)

Data Collection Process

- Participant receives catheter
- Hospital staff review wards
- Medical Notes Review and Microbiology results
- Data Collected by hospital staff
- Data de-identified
- Data provided to researchers

1. Hospital personnel collect data three days a week at each hospital during both control and intervention periods.
2. Patients who receive a urinary catheter are followed up during the trial period (for a period of 7 days post catheter insertion, discharge or 48 hours post catheter removal – whichever occurs first).
3. Medical notes of patients are reviewed and the following data collected:
   - *Patient demographic data*
   - *Signs and Symptoms of a UTI before and after insertion*
   - *Co-morbidity data*
   - *Catheter insertion details*
   - *Laboratory results of a patient with a suspected UTI*
4. De-identified data submitted to Research Team weekly then monthly

Study Progression

- The three large tertiary hospitals recruited

  - ✓ Canberra Hospital (ACT) (A)
  - ✓ Lismore Hospital (NSW) (B)
  - ✓ The Sydney Adventist Hospital (NSW) (C)

- HREC and Site Specific Approvals sought and granted at all 3 sites as well as Avondale College HREC.
- Randomised allocation of hospitals to A, B or C.
- Study education days carried out at 3 sites with IPC staff.
- Trial commenced 1st August 2017 for 32 weeks (until 12th March 2018).

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Images retrieved:
BACTERIURIA: http://www.onlymyhealth.com/asymptomatic-bacteriuria-1335346277.html
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