REACH: RESEARCHING EFFECTIVE APPROACHES TO CLEANING IN HOSPITALS

TRIAL SITE INFORMATION

Participating in the REACH study

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REACH
AN NHMRC PARTNERSHIP PROJECT

QUT ihbi Institute of Health and Biomedical Innovation

WESLEY MEDICAL RESEARCH

RATIONALE

Why is the REACH study being done?

Healthcare associated infections (HAI) are a major cause of avoidable costs, morbidity and deaths among hospital patients[1]. In Australia 200,000 cases of HAI arise each year and 1.9 million hospital bed days are diverted to treat them[1]. Reducing important HAI requires multiple evidence-based approaches.

Why the study focus on environmental cleaning?

Contamination of the patient environment in healt care settings is linked to the risk of HAIs[2].

The hospital environment acts as a reservoir for transmission of infections. Infected patients and staff colonised with micro-organisms contaminate surfaces and equipment. The multiple interactions between staff, patients and surfaces mean these micro-organisms can then be transferred to new patients where they cause infections[3].

Health service organisations are required to ensure effective environmental cleaning to minimise the risk of infection to patients and the workforce[4] however there remains great inconsistency in cleaning practices across Australian hospitals. This is a result of uncertainty around optimal environmental cleaning methods as well as confusion regarding product use, frequency of cleaning and auditing practices[5,6].

What evidence gap will the study address?

Data on the role of environmental cleaning are scare and environmental cleaning is currently under-researched. Previous cleaning research has focused on single interventions, such as a new cleaning product or auditing strategy. There is little evidence on cleaning practices relating to intervention cost, cost-effectiveness, feasibility, and end-user concerns.

In addition, implementing cleaning in a hospital setting is a multifaceted and complex process. Evidence about how to translate positive research findings into improvements in cleaning practice and how to sustain these changes in behaviour is also required.

> *"Hospital cleaning is usually taken for granted but it is invaluable in preventing hospital acquired infections"*
>
> *Prof. Christian Gericke, Chief-Investigator*

How will the REACH study outcomes be used?

To address this gap, the REACH study will investigate the effectiveness of an evidence-based cleaning bundle intervention in eleven major Australian hospitals. The findings from this research study will show clinicians and decision makers in both public and private healthcare sectors whether investing in the implementation of an environmental cleaning bundle in acute hospitals will improve cleaning performance, improve cost-effectiveness and reduce the risks of HAI. This is particularly important given the current economic climate and pressure on public spending.

PARTICIPATING

Who can participate?

Eleven major public and private Australian hospitals that:

- have an intensive care unit (ICU) accredited for advanced clinician training by the College of Intensive Care Medicine (Australia & New Zealand), and
- are classified by the National Health Performance Authority (NHPA) as a 'major hospital' (public hospitals) or have over 200 in-patient beds (private hospitals), and
- have an established HAI surveillance program in place that collects data on *Staphylococcus aureus* Bacteremia (SAB) infections, *Clostridium difficule* infections (CDI) and Vancomycin resistant *enterococci* (VRE) infections.

These criteria support the inclusion of major public and private hospitals that have a complex patient case mix. The recruitment process will purposively select eligible hospitals to optimise the feasibility and practicality of completing the trial. Stratification will occur to allow a representative sample of private and public hospitals and to provide representation across at least four states and territories.

What are the benefits of participating?

The REACH study will provide each trial hospital an opportunity to contribute to the generation of new evidence about effective hospital cleaning through a well-supported, rigorous and innovative trial. Participation will demonstrate an organisational commitment to quality improvement and research activities with potential benefits for patients, families and the wider hospital community. For environmental services staff, hospital participation in the trial will provide an opportunity to access training and performance activities that promote development, recognition and empowerment of the cleaning workforce.

Is participation confidential?

A list of participating sites will be available on the REACH project website. All data and outcomes will be reported by the REACH team as de-identified data.

STUDY DESIGN

What sort of trial is the REACH study?

This is a randomised controlled trial using a stepped-wedge randomised trial design. There will be sequential roll-out of the environmental cleaning bundle to 11 public and private hospitals over 58 weeks. All hospitals receive the intervention and will act as their own control, with analysis undertaken of the change within each hospital before and after the intervention.

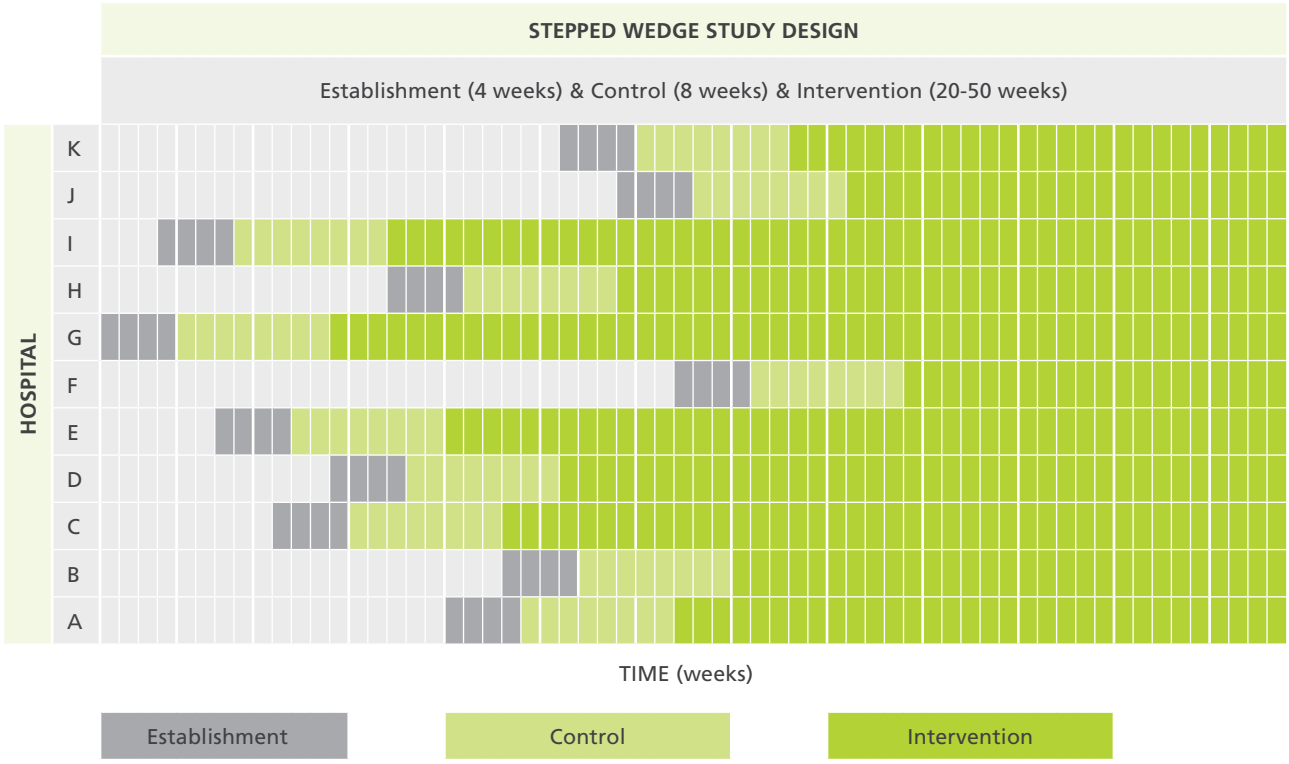
Why use a stepped-wedge trial?

Staggered intervention times improve the feasibility of the study, allowing research staff to work with individual hospitals as they change-over, rather than simultaneously managing change at 11 sites. This design will also aid recruitment by avoiding having control hospitals that get no intervention. Each hospital acts as its own control, which removes the potential of confounders such as hospital size, case-mix and differences between public and private hospitals.

What length of participation is required?

All hospitals have a four week establishment period, followed by an eight week control period for baseline data collection. The shortest duration for the intervention arm is 20 weeks, and the longest duration for the intervention arm is 50 weeks.

What does the stepped-wedge trial look like?



ENROLMENT

What does enrolment involve?

Fourteen hospitals will be recruited. Each hospital will be supported to complete the necessary ethical/site specific approvals and to establish a trial site agreement with QUT. The first eleven sites to complete these requirements will be enrolled in the study and then randomly allocated to the stepped intervention timings.

What does the trial site agreement include?

The trial site agreement includes requirements for the trial site to:

- provide in-kind support of at least three key staff to form the site team (including one each from environmental services and infection control)
- nominate one staff member from the site team to be available as the point of contact at all times
- maintain timely collection and provision of data to the study team, in accordance with the study protocol
- unless otherwise agreed to in writing, not use, disclose, copy or distribute study materials or outcomes.

What approvals and consent will we need?

The study team will work with each site to secure the required ethics approvals.

Informed consent will be required where a trial site staff member participates in study related activities where individual staff data is collected, such as discussion groups, interviews or surveys. Prior to any such study related activity, the study team will ensure that each participant is fully informed about the nature and objectives of the project and possible risks associated with participation, including answering any questions the participant may have.

When will the trial start?

Recruitment of trial sites commenced in May 2015. It is expected that site agreements and ethics processes will take two-three months and that the trial intervention will commence by early 2016.

DATA COLLECTION

What data will be collected?

At each trial site data will be collected on:

- HAI infection rates
- the effectiveness of cleaning of frequent touch points (using an ultraviolet gel dot system and, in three trial sites, adenosine tri-phosphate luminometry)
- environmental services and cleaning staff attitudes, educational needs and knowledge related to environmental cleaning at the site
- resources and costs associated with the bundle intervention, including training costs, audit time, staffing
- particular information about the trial site, including hospital characteristics, size, environmental services workforce and staffing.

Some of these data will routinely be collected by the trial site already.

Who is responsible for data collection?

The study team will work with each site to establish timings for providing data, to clarify data requirements and to support some of the data collection activities, including the use of patient satisfaction data where it is already collected by the hospital.

The investigators and study team, led by the project manager, will monitor data collection and trial processes for each site at least monthly. Data will be reviewed to ensure correct collection of the baseline and intervention data sets and implementation of the bundle intervention.

What happens when the trial is complete?

Project support for implementation of the intervention and the related data collection will continue until the end of the intervention period. Trial sites will have the opportunity to engage in review, de-briefing and knowledge translation activities as part of the post intervention data collection process and may choose to continue any aspects of the cleaning bundle intervention.

THE REACH STUDY

What are the objectives?

The primary objectives of this trial are to evaluate the effectiveness and the cost-effectiveness of improving environmental cleaning, using an evidence-based bundle, to reduce HAI.

What are the outcome measures of the trial?

Key outcome measures include:

- whole of hospital HAI rates in each trial site
- the thoroughness of routine hospital cleaning in each trial site (using the DAZO® Fluorescent Marking Gel and UV light system)
- bio-burden of frequent touch surfaces post cleaning (using adenosine tri-phosphate (ATP) luminosity measurement)
- changes in staff knowledge and attitudes around environmental cleaning
- change to costs relative to health benefits (incremental cost-effectiveness ratio).

Has this trial been done before?

Michelle Allen completed a pilot study at Logan Hospital, Queensland in 2014 as part of her QUT PhD work in the Centre for Research Excellence in Reducing Healthcare Associated Infections (CRE-RHAI). The pilot study ensures the REACH trial and intervention is acceptable to hospital staff, has outcomes that can be reliably measured, and is feasible to implement.

Does the trial have ethics approval?

The REACH trial has ethics approval from UnitingCare Health Human Research Ethics Committee and QUT Human Research Ethics Committee, and is registered with the Australia New Zealand Clinical Trial Registry (ANZCTR).

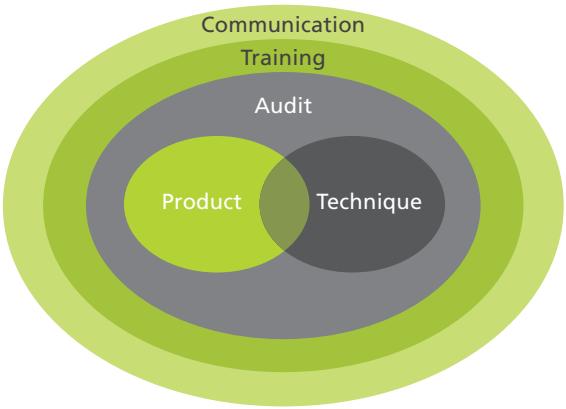
What is the cleaning bundle intervention?

The REACH cleaning bundle consists of five interdependent and ongoing evidence-based components, delivered as a hospital wide intervention. These components were agreed, based on evidence and feasibility, by an expert panel at a meeting in Brisbane 11 July 2013, convened by the pilot project lead. Feedback from the pilot site surveys and data confirm these bundle components remain valid for the REACH trial.

The use of an evidence based bundle is a practical method for improving practice, and provides a simple, straightforward set of processes that when performed collectively and reliably have a proven ability to improve patient outcomes[7].

Can the intervention be tailored to suit our hospital?

These five bundle components will be implemented at each trial site. However, we will optimise implementation of the cleaning bundle by targeting education and resources based on behavioural change and learning practices, the current evidence-practice gap at each hospital, and the hospital's operational context. This will be supported by use of a contemporary knowledge translation framework, Promoting Action on Research in Health Sciences (PARIHS), which suggests that successful implementation is a function of evidence (e.g. characteristics of the interventions, local data), context (e.g. leadership, culture, receptivity to change) and facilitation (tailored to each site, based on evidence and context)[8].



> *"These components are core principles that are evidence based. By ensuring that they are all done together, the outcome is greater than the sum of the parts"*
>
> *Dr Lisa Hall, Chief-Investigator*

RESOURCES & SUPPORT

What resources will be required?

The REACH study industry partners provide all resources for the cleaning audits, including the gel dot and luminometry technology and materials, and auditing software for the length of the baseline and intervention phases of the trial. The study team will provide an Ipad mini and all resources required for on-site training and support throughout the trial.

What does the trial site need to provide?

The trial site will provide, through an in-kind contribution, three staff members, one of whom will be an associate investigator, as direct contacts throughout the trial and to lead data collection, education and audit activities.

What support will there be from the study team?

During the **establishment phase** the study team will meet with the trial site team to establish roles and responsibilities, collect hospital specific information and to provide training in the audit software.

During the **control phase**, the study team will visit to assist with baseline data collection, and to conduct surveys, interviews and discussion groups with environmental services and infection control staff. Once the trial site moves to the **intervention phase**, the study team will commence the education and training component of the bundle intervention and provide ongoing support and resources as required.

Tailored support (site visits, telephone and email contact) will be provided by the study staff as required throughout the intervention phase to support core trial processes, maintain data quality and to review trial progress.

At the end of the intervention period the study team will again conduct surveys, interviews and discussion groups with environmental services and infection control staff.

Who is in the study team?

The QUT + WMR study team includes:

- a project manager
- a training facilitator, and
- Two senior research assistants.

In addition, there are ten chief investigators and three associate investigators, all directing and providing input to the study in relation to their area of expertise.

REFERENCES:

1. Graves N, Halton KA, Robertus L. Chapter 17 Costs of health care associated infection. In: Cruickshank M, Ferguson J, eds. *Reducing harm to patients from healthcare associated infection: the role of surveillance*. Sydney: Commonwealth of Australia; 2008.
2. NHMRC. Australian Guidelines for the Prevention & Control of Infection in Healthcare. Canberra: Commonwealth of Australia; 2010.
3. Donskey CJ. Does improving surface cleaning and disinfection reduce health care-associated infections? *American Journal of Infection Control*. 2013;41(5, Supplement):S12-S19.
4. Australian Commission on Saftey and Quality in Health Care (ACSQHC). National Safety and Quality Health Standards. Sydney ACSQHC; 2011.
5. Mitchell B, Wilson F, McGregor A, Dancer S. Methods to evaluate environmental cleanliness in healthcare facilities. *Healthcare Infection*. 2013;18(1)(1):23-30.
6. Tasmanian Infection Prevention and Control Unit (TIPCU). *Evaluating environmental cleanliness in hospitals and other healthcare settings What are the most effective and efficient methods to use? Available at www.dhhs.tas.gov.au/tipcu.* Hobart 2012.
7. Resar R, Pronovost P, Haraden C, Simmonds T, Rainey T, Nolan T. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. *Joint Commission journal on quality and patient safety / Joint Commission Resources*. 2005;31(5):243-248.
8. Kitson A, Harvey G, McCormack B. Enabling the implementation of evidence based practice: a conceptual framework. *Quality in Health Care*. 1998;7(3):149-158.

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