

The CLEaning and Enhanced disiNfection (CLEEN) study: A stepped-wedge cluster randomised trial

May 2025

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www.cleenstudy.com



Website disclaimer

This presentation, available on the CLEEN study website was, to the best of our knowledge, correct at the time of posting.

Please refer to the publications for definitive data.

The CLEEN team



Primary roles of the team

- Infectious disease physicians (2)
- Infection control professionals (3)
- Health economists (2)
- Researchers (2)
- Scientist (1)
- Biostatistician (1)
- Educators (1)
- Clinician other (1)

AlfredHealth

Avondale
UNIVERSITY



MONASH
University



Health
Central Coast
Local Health District

Several team members lead IPC hospital team
Severak other team members have led IPC teams

QUT
Queensland
University
of Technology

Declarations

- This project is funded by a nationally competitive government grant, NHMRC Emerging Leadership Investigator grant (Prof Brett Mitchell), (GNT2008392), administered by Avondale University
 - In kind support from Hunter Medical Research Institute and GAMA Healthcare Australia
 - No role in design, data collection, analysis
- Editor-in-Chief, Infection Disease and Health

Study Registration



ACTRN12622001143718

Shared Medical Equipment

Who has challenges with cleaning shared medical equipment in their facility?

Who has solved the problem of cleaning shared medical equipment in their facility?

Cleaning of shared medical equipment a (common) problem?



Who is responsible for cleaning it?

“I don’t have time”

Does it get cleaned?

“That is not my role”

What should we clean it with?

“We don’t have the money”

So, what can we do?

Don't pick a challenge you cannot yet deal with—attack the crux of the situation, build momentum, and then reexamine your position and its possibilities

Does the cleaning of shared equipment make a difference to patient outcomes?

What does the evidence tell us?

Randomised control trials

First author	Year	Primary intervention	Primary outcome
Salgado	2013	Antimicrobial surfaces <ul style="list-style-type: none">• Copper alloy	<ul style="list-style-type: none">• MRSA/VRE colonisation
Boyce	2017	Enhanced cleaning patient rooms <ul style="list-style-type: none">• H₂O₂ & QAC	<ul style="list-style-type: none">• Colony counts• Colonisation/infection (MRSA, CDI, VRE)
Ray	2017	Bleach wipe	<ul style="list-style-type: none">• CDI incidence
Anderson	2017	Terminal room disinfection <ul style="list-style-type: none">• QAC, UV, bleach	<ul style="list-style-type: none">• HAI rates
Mitchell	2019	Enhanced cleaning patient rooms	<ul style="list-style-type: none">• CDI, VRE, SAB

Peters et al, ARIC, 2022

What does the evidence tell us?

Shared medical equipment

- Shared medical equipment has been implicated in transmission and subsequent infection in ICU using WGS (Lee et al, Infect Control Hosp Epidemiol. 2018;39(6):668-75)
- No RCT to examine the impact of improved cleaning of shared medical equipment on HAIs
- Need evidence to inform a common problem in hospitals globally

A microscopic view of various bacteria, including rod-shaped and oval-shaped organisms, set against a dark blue background. The bacteria are illuminated with a blue light, giving them a glowing appearance.

The CLEANING AND ENHANCED DISINFECTION study

First RCT to examine the impact of improved cleaning of
shared medical equipment on HAIs

What does the evidence tell us?

Shared medical equipment

Study Protocol

STUDY PROTOCOL**Open Access**



A randomised controlled trial investigating the effect of improving the cleaning and disinfection of shared medical equipment on healthcare-associated infections: the CLEaning and Enhanced disiNfection (CLEEN) study

Katrina Browne¹, Nicole White², Peta Tehan^{1,3}, Philip L Russo^{3,4}, Maham Amin⁵, Andrew J. Stewardson^{3,6}, Allen C. Cheng^{3,6}, Kirsty Graham⁵, Gabrielle O'Kane⁷, Jennie King^{5,8}, Martin Kiernan^{1,9}, David Brain² and Brett G. Mitchell^{1,3,5,8*} 

www.cleenstudy.com





Extra cleaning of shared equipment



Different parts to the CLEEN study and outcomes

Randomized control trial

- **Effectiveness**
 - Does additional cleaning reduce HAIs?
- **Improvements**
 - Can we improve the thoroughness of cleaning?
- **Cost effectiveness**
 - Is additional cleaning a cost-effective intervention?

Observational, qualitative and modelling

- **Time and motion**
 - How long does it take to clean?
- **Cleaner interviews**
 - Cleaners' experience with feedback
- **Degradation audits**
- **Practical considerations**
- **Scenario modelling**
 - Different approaches to the CLEEN study
- **Dose-response**

CLEEN study: Time and motion

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Time and Motion: Why?

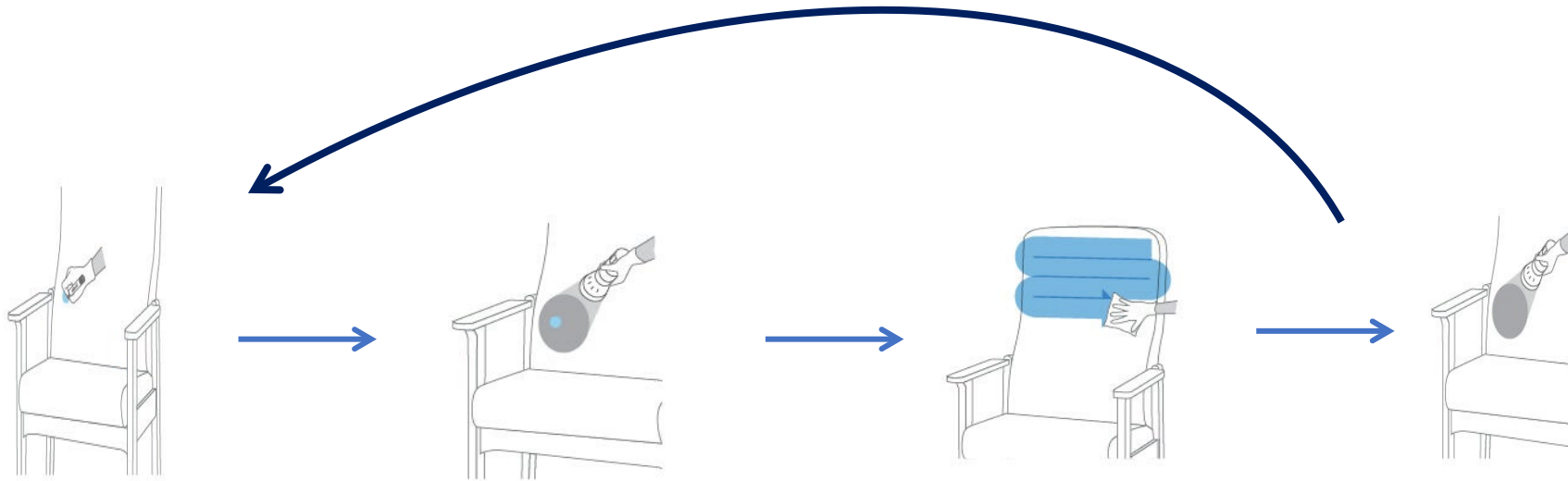
- How can we effectively plan cleaning programs and staff these accordingly?
- Allocating cleaning responsibility means time, especially for clinical staff
- Cost-effectiveness evaluations
- Plan future cleaning models



Time and motion study

Methods

- Observational study, time and motion
- Participants received training on how to clean shared medical equipment
- UV dot placed, item cleaned, recorded how long.



Time and motion study

Results

Type of equipment	Mean time: effectively* clean (min:sec)	Min time (min:sec)	Max time (min:sec)
Blood glucose testing kit	0:50	0:27	1:10
Intravenous stand	1:20	0:40	2:01
Infusion pump	1:21	0:31	2:06
Blood pressure monitor	1:49	1:00	2:13
Patslide	2:17	1:38	3:00
Metal trolley	2:19	1:38	4:20
Wheelchair	2:29	1:21	3:38
Resuscitation trolley	2:29	2:01	3:50
Computer on wheels	2:43	1:46	4:00
Commode	2:58	2:18	4:20
Bladder scanner	3:16	2:09	5:01
Medication trolley	3:53	3:15	4:28

CLEEN study: RCT

Investigating the effect of enhanced cleaning and disinfection of shared medical equipment on health-care-associated infections in Australia (CLEEN): a stepped-wedge, cluster randomised, controlled trial



Katrina Browne, Nicole M White, Philip L Russo, Allen C Cheng, Andrew J Stewardson, Georgia Matterson, Peta E Tehan, Kirsty Graham, Maham Amin, Maria Northcote, Martin Kiernan, Jennie King, David Brain, Brett G Mitchell

Summary

Background There is a paucity of high-quality evidence based on clinical endpoints for routine cleaning of shared medical equipment. We assessed the effect of enhanced cleaning and disinfection of shared medical equipment on health-care-associated infections (HAIs) in hospitalised patients.

Lancet Infect Dis 2024

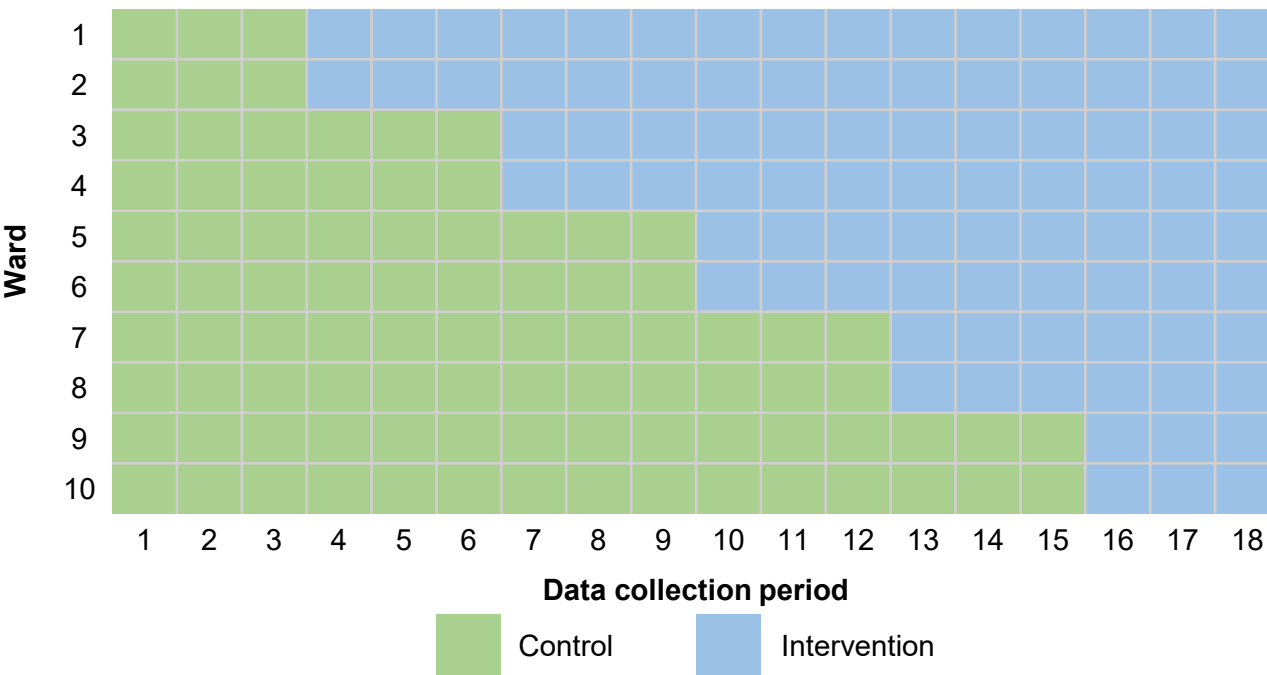
Published Online
August 13, 2024
[https://doi.org/10.1016/S1473-3099\(24\)00399-2](https://doi.org/10.1016/S1473-3099(24)00399-2)

CLEEN study: different parts and outcomes

- Effectiveness of additional cleaning on HAIs
- Improvements in the thoroughness of cleaning
- Cost effectiveness
- Time and motion (sub-study)
- Cleaner's experience (interviews)
- Scenario modelling



Design, population and outcomes



Population

- 1 hospital (500 bed)
- 10 wards, 2 wards per cluster
- 2 week time periods
- 9 months

Primary outcome

- Proportion of adult inpatients with a HAI (any HAI). Examined all HAIs

Sub-groups

- SSI, BSI, UTI & PN (combined)
- All HAIs excluding COVID-19
- All HAIs excluding EENT

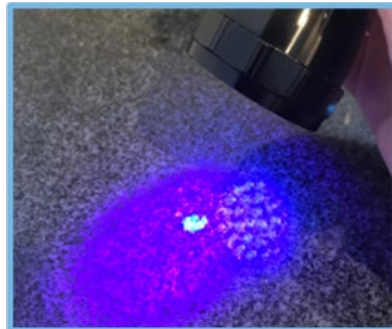
Secondary outcomes

- Thoroughness of cleaning, florescent marker and UV light
- Cost-effectiveness; Cleaning time; Cleaning staff interviews

Intervention



- 3 extra hours per weekday, dedicated for the cleaning of shared medical equipment only (dedicated staff)
- Training
- 2 in 1 detergent and disinfectant wipes
 - Clinell Universal
 - Clinell sporicidal (commodes)
- Fortnightly auditing of the thoroughness of cleaning with feedback to staff



Comparison (standard care)

- No additional cleaning of shared medical equipment
- Cleaning of shared medical equipment remit of clinical staff after use
- No feedback of florescent marker UV dots

Shared medical equipment



Bladder scanner

Blood glucose kits

Blood pressure monitor

Commodes

Computer on wheels

Infusion pumps

IV poles/stands

Medication trolleys

Metal trolleys

Patslides

Rollator frame

Resuscitation trolleys

Walking frames

Wheelchairs

Methods: data collection and quality

Data collection

- Fortnightly PPS on all patients
- Data entry in HAI algorithm
- ECDC PPS protocol for infection definitions
- Single-blinded (data collector)

Form C Part 3b Hai Algorithm

Adding new Subject unique identifier: ____ - ____ - ____ 1.

Subject unique identifier: [hosp_code]-[ward_code]-[pat_number] 1

1. Surgical Site Infection

1(a). Did the patient have surgery within 30 days from current admission (including surgery done this admission)? ☐ Yes ☒ No reset

* must provide value

1(b). Did the patient have surgery within 90 days from current admission (including surgery done this admission) with implant in place? ☐ Yes ☒ No reset

* must provide value

1(c). Does the patient have presence of surgical site infection in the current admission? ☐ Yes ☒ No reset

Patient has no surgical site infection. Move on to the next question.

2. Pneumonia or other Lower Respiratory Tract Infection

2(a). Does the patient have any underlying cardiac or pulmonary disease (heart failure, COPD, bronchiectasis etc)? ☐ Yes ☒ No reset

* must provide value

☐ Purulent sputum

☐ Cough, shortness of breath or respiratory rate

prior to intervention

Methods: data collection and quality

Data collection

- Fortnightly PPS on all patients
 - How many people 'today' have an HAI?
- ECDC PPS protocol for infection definitions
- Single-blinded (data collector)

Statistical considerations

- With 3960 patients, sufficiently powered for a 35% reduction in total HAI infection, baseline prevalence 11%, an inter-cluster correlation of 0.3, coefficient of variation of 0.65—allowing for variation.
- Generalised linear mixed models (GLMM)
- Fortnightly data collection periods were modelled as a categorical fixed effect to adjust for background trends independent of intervention exposure
- Sensitivity analysis assessed
 - Leave-one-out analysis
 - Delays in intervention effectiveness
 - Choice of link function (logit vs log vs identity)

Statistical analysis plan



Results

- 5,005 patients were included in the study
- 2,497 (49.9%) in the control, 2,508 (50.1%) in the intervention
- 49.5% male
- Unadjusted results:
 - Control 433 HAIs from 2,497 patients (17.3%, 95%CI 15.9-18.8),
 - Intervention 301 HAIs from 2,508 patients (12.0%, 95%CI 10.7 to 13.3)

Primary outcome – All HAIs

Control 14.9% (10.4 to 19.4)

Intervention 9.8% (6.1 to 14.1)

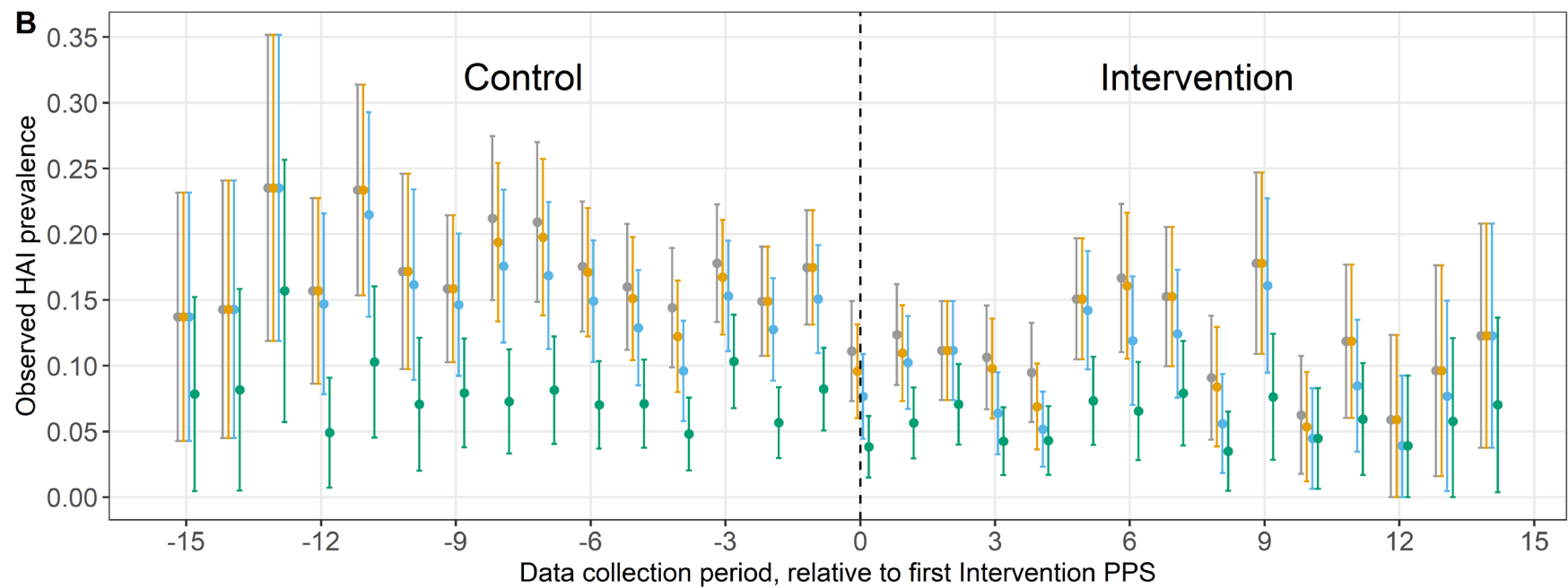
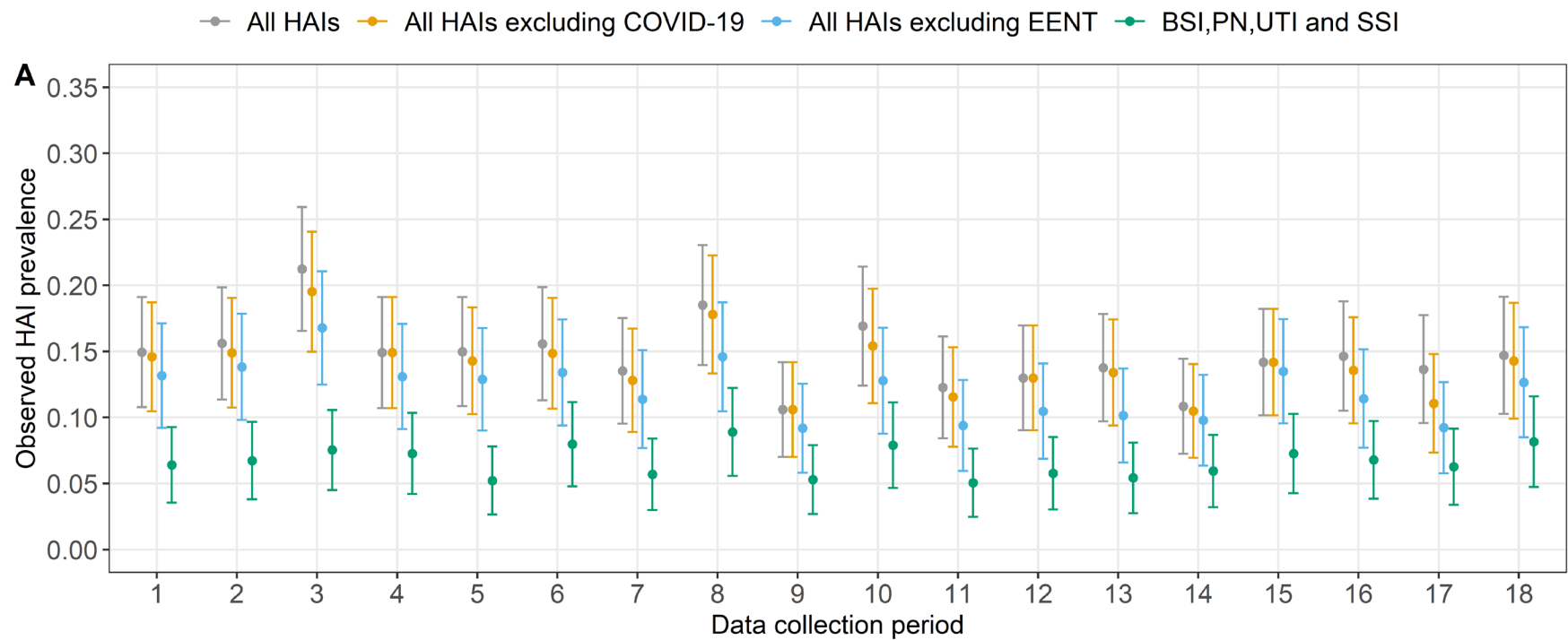
OR 0.62 (0.45 to 0.80), $p < 0.001$

Absolute difference -5.2 (-8.2 to -2.3)

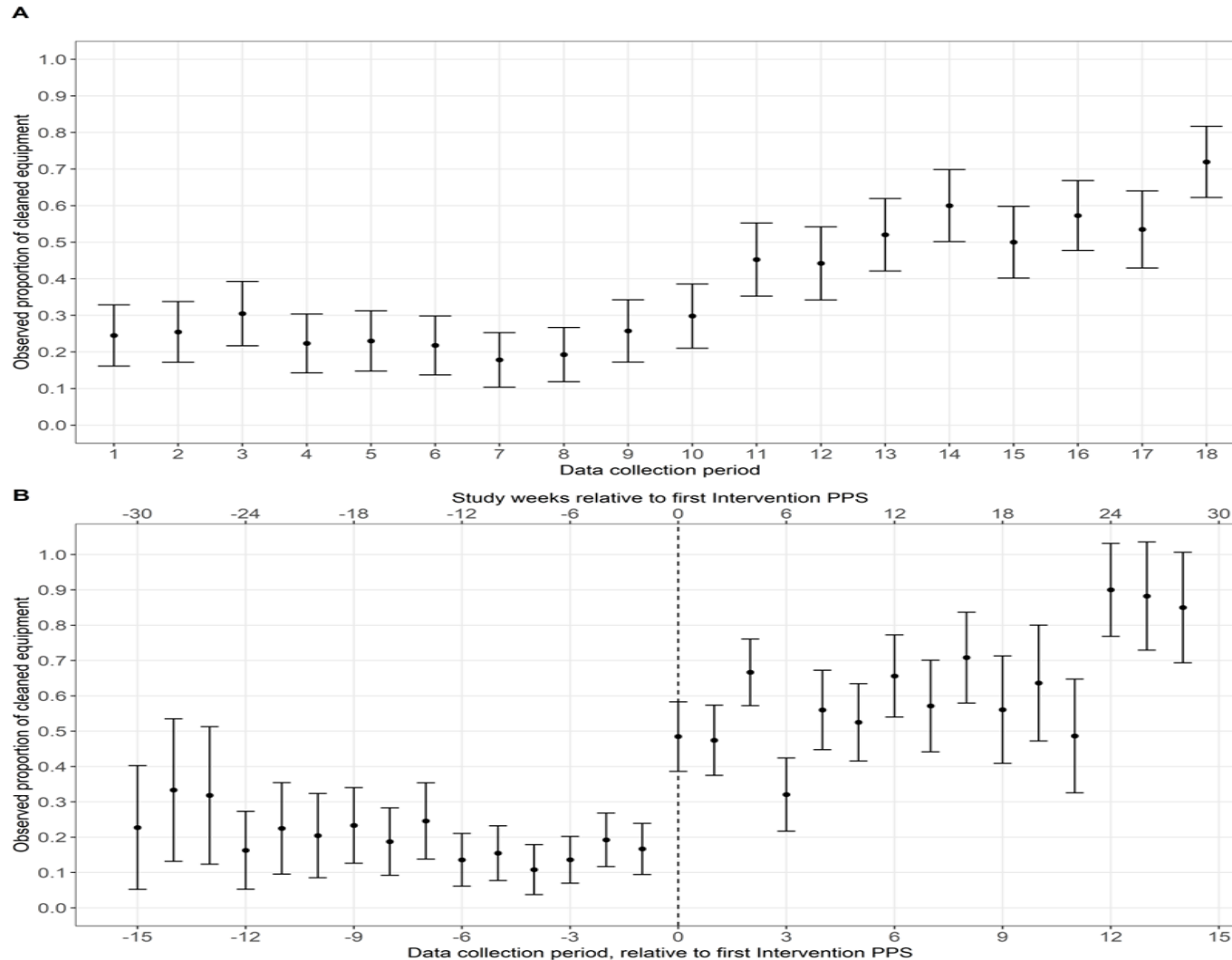
Relative difference -34.5 (-50.3 to -17.5)

Results: sub-analysis

Outcome	Control % (95%CI)	Intervention % (95%CI)	OR (95%CI)	Absolute Difference % (95%CI)	Relative Difference % (95%CI)	p-value
All HAIs	14.9 (10.4 to 19.4)	9.8 (6.1 to 14.1)	0.62 (0.45 to 0.80)	-5.2 (-8.2 to -2.3)	-34.5 (-50.3 to -17.5)	<0.001
BSI, PN, UTI and SSI	6.3 (3.3 to 9.6)	4.0 (1.9 to 6.8)	0.62 (0.42 to 0.86)	-2.3 (-4.3 to -0.7)	-36.2 (-56.1 to -12.8)	<0.013
All HAIs excluding COVID-19	14.4 (10.2 to 19.0)	9.0 (5.7 to 13.4)	0.59 (0.45 to 0.77)	-5.3 (-8.1 to -2.7)	-37.2 (-51.3 to -19.5)	<0.001
All HAIs excluding EENT	13.0 (8.6 to 17.4)	8.3 (4.9 to 12.0)	0.60 (0.45 to 0.81)	-4.8 (-7.6 to -2.1)	-36.7 (-51.7 to -17.4)	<0.001

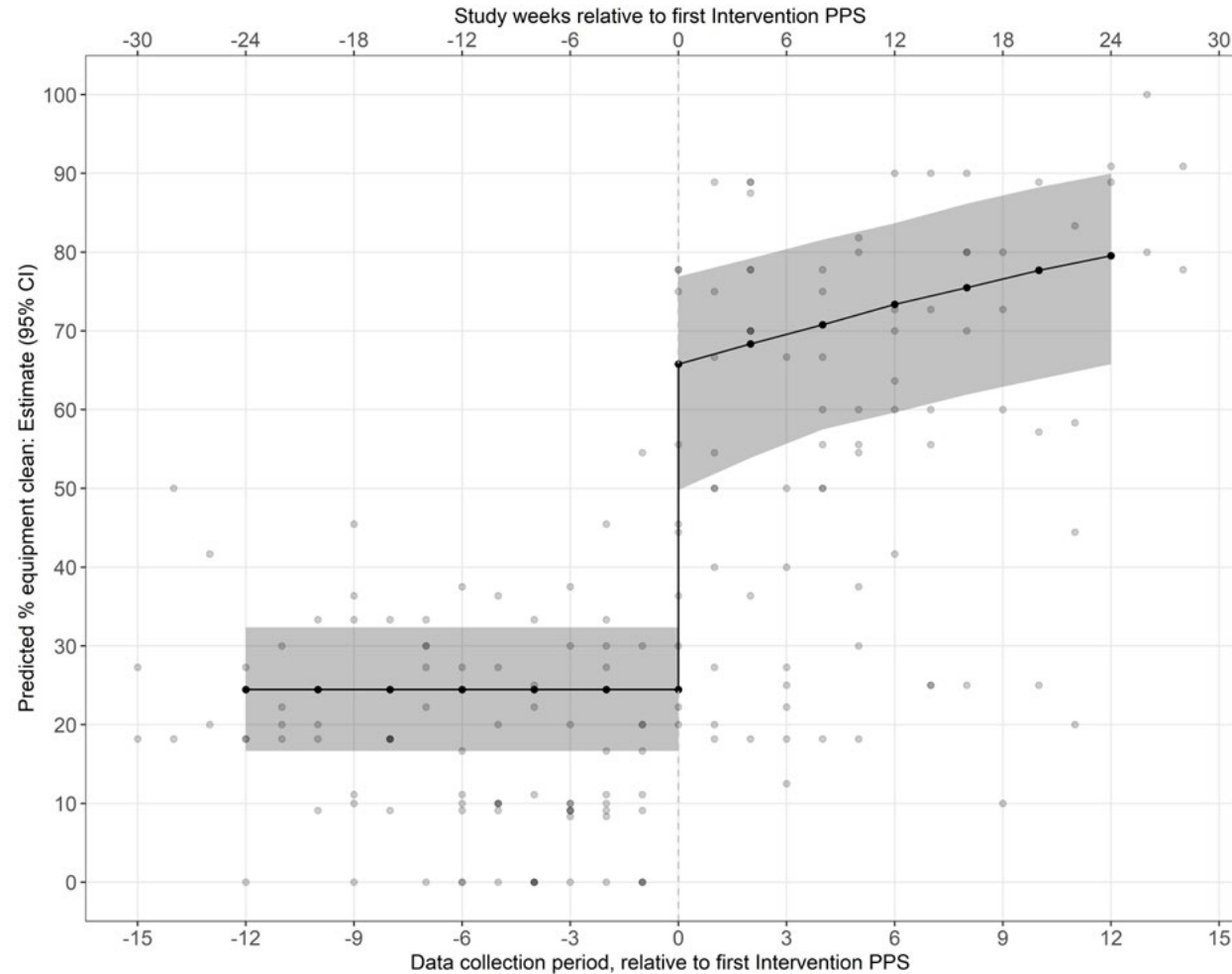


Results: secondary outcome (florescent UV dots)

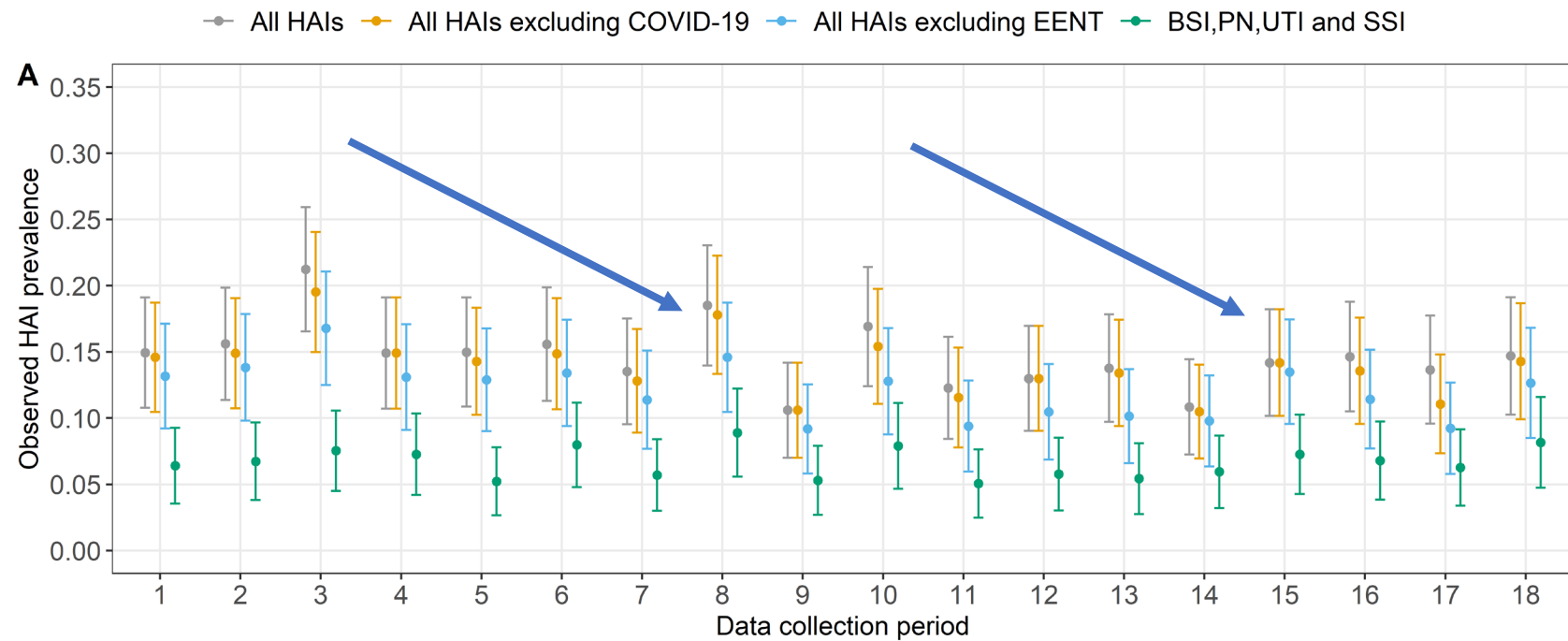


- 1,786 individual pieces of shared medical equipment (925 control, 861 intervention) were audited.
- The proportion of equipment cleaned increased
 - Control: 24.3% (95%CI 15.7 to 33.2)
 - Intervention 65.6 % (95%CI 51.6 to 77.1) 0 weeks after intervention exposure
 - OR 5.94 (4.13 to 8.55, $p < 0.001$)

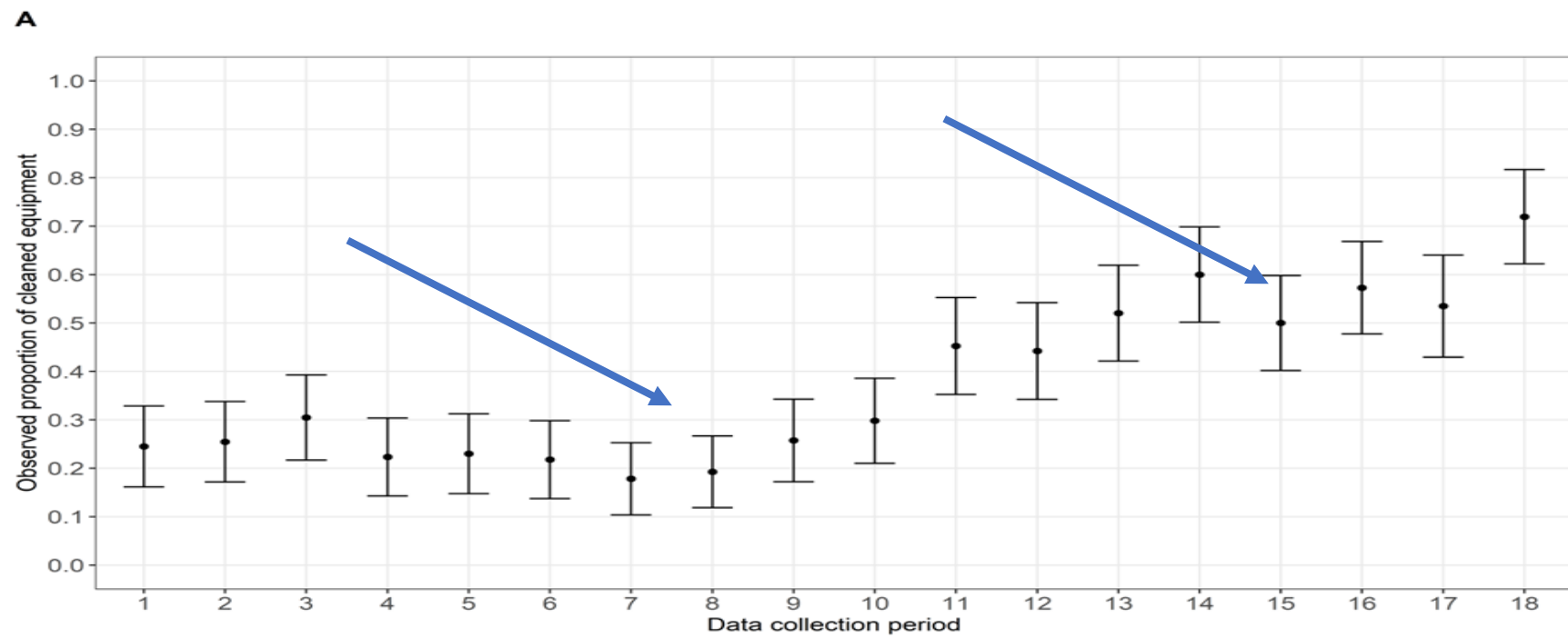
Results: secondary outcome (florescent UV dots)









HAI prevalence



Proportion cleaned equipment



Confounders & other considerations

-  No policy changes, such as screening and isolation
-  No reported outbreaks occurred during the study period
-  Colonisation change in MRO colonisation pressure
-  No long-term secular trends
-  Hand hygiene compliance constant
-  Sensitivity analysis results consistent
 - Leave one out, reduction in all infection types, modelling delays

CLEEN study: discussion

- Reaffirms the importance of a hygienically clean clinical environment for patient safety
- Potential reason for effect size:
 - Control period, low levels of effective cleaning
 - ? 'cleaning in-between'
 - High baseline infection
 - Hand / environment interaction
- Did not assure that multiple-use items were cleaned in between every patient, rather, a minimum standard of once a day
- Limitations: single centre, high baseline infection, no genomics

CLEEN study: Cleaner (PSA) interviews



Remember the point of the study and who is usually responsible for cleaning

CLEEN study: Cleaners experience study

Method and results

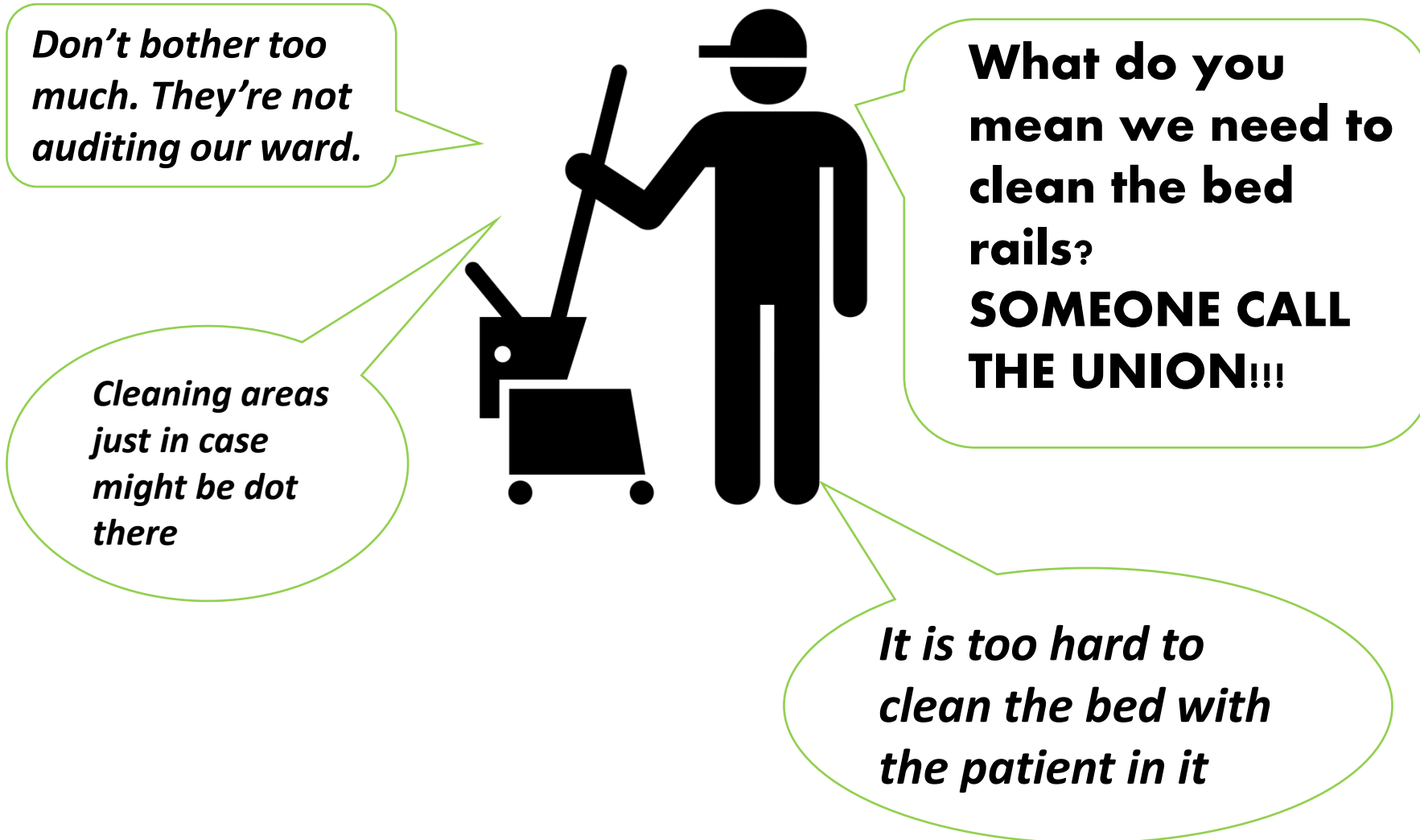
Methods

- Describe their personal experiences of cleaning shared medical equipment and how they prefer to receive feedback about their work
- Semi-structured focus group

Results

- Regarding feedback the cleaners preferred method was verbal or through email (small groups or individually)
- Did not like the public displays of feedback.
- Furthermore, it was noted that cleaners valued demonstrations of cleaning processes as an additional feedback method

Implementation challenges: CLEEN and REACH studies



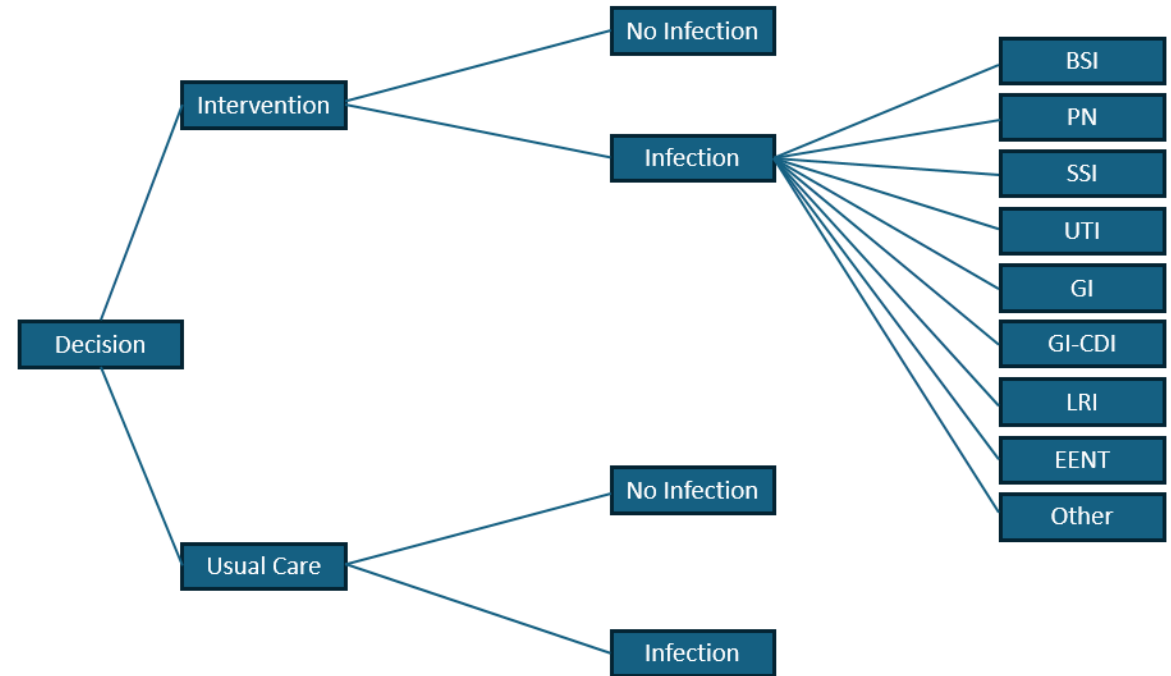
Other thoughts influencing implementation (may or may not control)

- Cleaning is a skilled role, recognise
- Payment and remuneration
- Diversity in workforce and workforce models
- Cleaning services often first to get 'cut' – but they are cost-effective!

Cost-effectiveness

Cost-effectiveness methods

- We undertook a within-trial cost-effectiveness analysis
- We used a decision tree
- We compared the CLEEN intervention with usual care
- Hospital costing perspective



Data sources: transition probabilities (1)

Variable	Parameter (%)	Source
Usual care		
Probability of infection	0.13	Trial data
Probability of BSI	0.09	Trial data
Probability of PN	0.07	Trial data
Probability of SSI	0.17	Trial data
Probability of UTI	0.13	Trial data
Probability of GI	0.14	Trial data
Probability of CDI	0.05	Trial data
Probability of LRI	0.04	Trial data
Probability of EENT	0.15	Trial data
Probability of other infection	0.17	Trial data

Data sources: transition probabilities (2)

Variable	Parameter (%)	Source
Intervention		
Probability of infection	0.10	Trial data
Probability of BSI	0.04	Trial data
Probability of PN	0.11	Trial data
Probability of SSI	0.17	Trial data
Probability of UTI	0.16	Trial data
Probability of GI	0.17	Trial data
Probability of CDI	0.05	Trial data
Probability of LRI	0.01	Trial data
Probability of EENT	0.22	Trial data
Probability of other infection	0.08	Trial data

Data sources: excess LoS

Variable	Parameter (mean, SD)	Source
Excess LoS		
BSI	11.4 (2.8)	Stewart et al
PN	16.3 (4.5)	Stewart et al
SSI	9.8 (2.7)	Stewart et al
UTI	4 (0.5)	Mitchell et al
GI	6 (3.4)	Stewart et al
CDI	0.9 (3.7)	Mitchell et al
LRI	7.3 (2.8)	Stewart et al
EENT	0 (0)	Expert opinion
Other infection	14 (9.1)	Stewart et al

Data sources: costs

Variable	Parameter	Source
Intervention (in-trial) costs		
Audit & Feedback	\$3,537	Trial data
Staff training	\$2,358	Trial data
Trainer time	\$472	Trial data
Staffing	\$106,110	Trial data
Sporicidal wipes	\$1,134	Trial data
Universal wipes	\$9,737	Trial data
Indicator tags	\$1,318	Trial data
UV torch & markers	\$116	Trial data
LOS (daily)	\$2,151	IHACPA

Data sources: costs

- Costs included
 - Audit and feedback
 - Staff training
 - Trainer time
 - Staffing
 - Cost of additional wipes
 - Indicator tags
 - UV torch and markers
- Total in-trial costs ~\$126,000

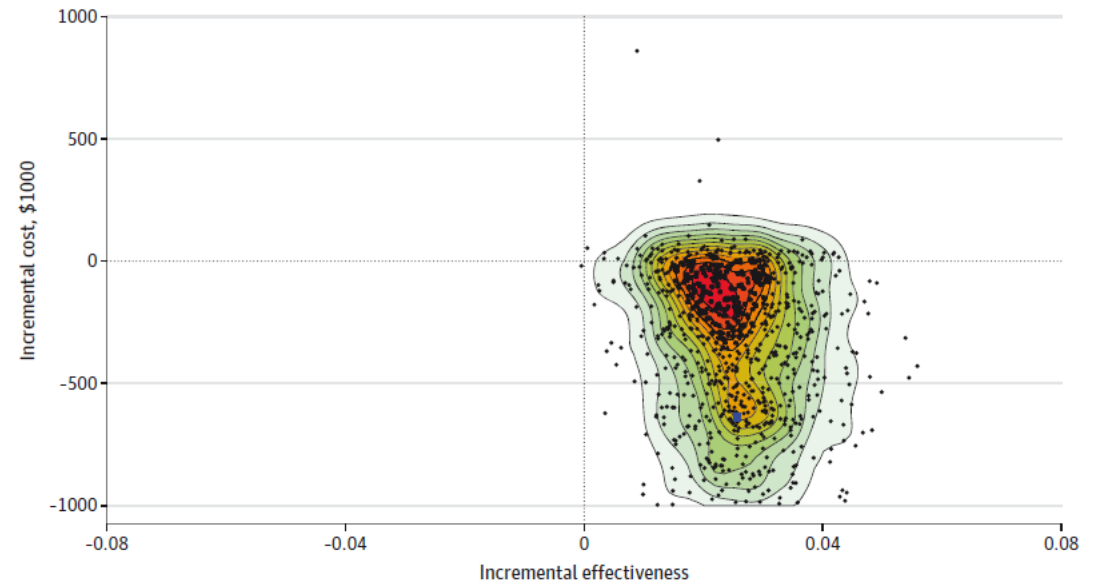
Data sources: other

- Length of stay for HAIs
 - Data from literature
 - Only used studies where time-dependent bias was accounted for
- Effect of intervention:
 - Changes in infection rates observed for each infection from CLEEN study

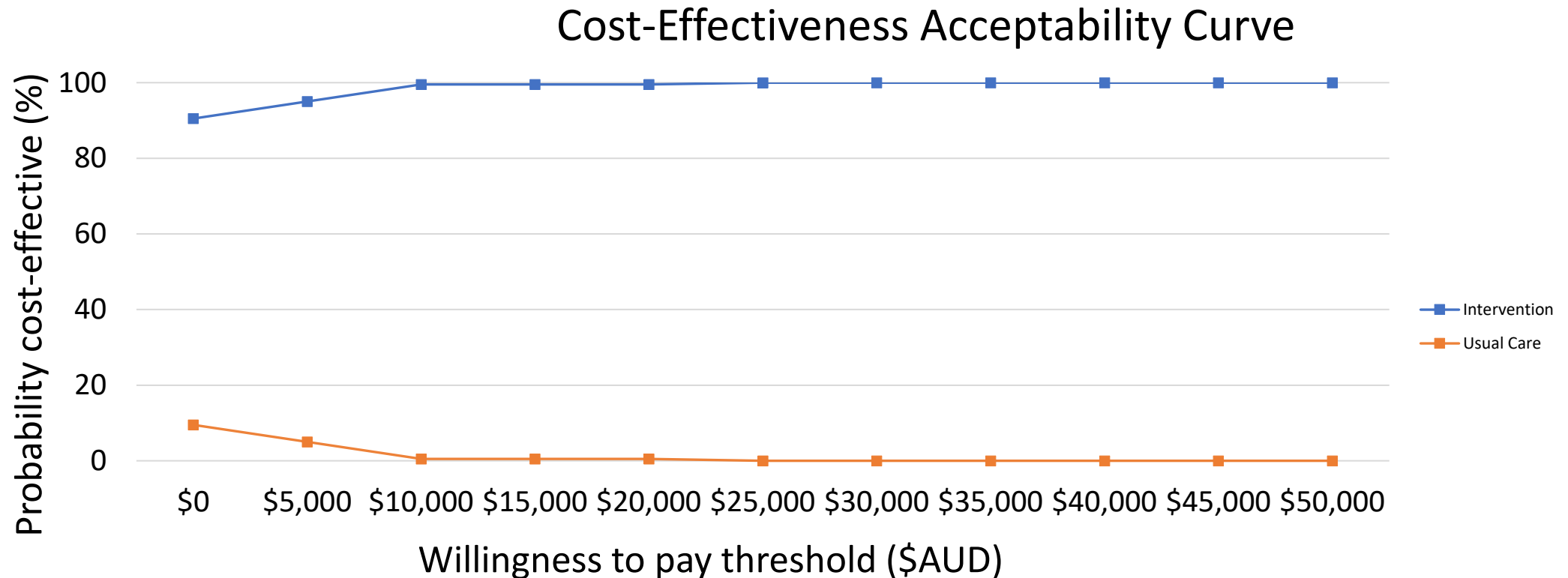
Results

For every 1000 patients this trial is implemented for, a hospital could:

- Prevent 30 infections
- Save \$642,010



Results: CE acceptability curve comparing probability of intervention and usual care being cost-effective



- Even if a decision-maker's willingness to pay for an avoided infection is \$0, the probability that this intervention remains cost-saving is very high (>90%).

But wait, my hospital is different...

- We undertook scenario analyses to explore the impact of uncertainty on results
- Involves changing key parameter values reflecting plausible decision-making scenarios beyond a clinical trial setting
- Two scenarios examined:
 1. A lower effectiveness outcome
 2. Using more expensive biodegradable wipes

Results: scenario analyses

- **Halving the effectiveness per 1000 patients**
 - Prevents 13 HAIs
 - Saves ~ \$460,000
- **A biodegradable wipe (more expensive)**
 - Prevent 25 HAIs
 - Saves ~ \$637,000

CLEEN: Cost-effectiveness conclusions

If a decision-maker is looking to maximise health gain per dollar spent, they should invest in an intervention that focuses on cleaning shared medical equipment.

If they don't, they will forego opportunity to save money, reduce healthcare associated infections and improve patient safety in the hospital setting

Numbers are people



Future implementation and modelling

Approach	Pros	Cons
Dedicated cleaners like CLEEN	<ul style="list-style-type: none">• Ease of implementation• Control / direct line of sight / oversight• Costs easy to quantify• CEA to support	<ul style="list-style-type: none">• Difficult to recruit/retain• Boredom / repetitive• Risk of clinical staff cleaning (even) less
Cleaning staff on ward, increase hours/change role	<ul style="list-style-type: none">• Ease of implementation• Control / direct line of sight / oversight• Less risk of boredom	<ul style="list-style-type: none">• Would they clean shared equipment? Additional time absorbed for 'other tasks'• Risk of clinical staff cleaning (even) less
Centralised cleaning model	<ul style="list-style-type: none">• Use of automation for disinfection• Less clutter on wards• Potentially more attractive role	<ul style="list-style-type: none">• Space to undertake• Distribution of equipment
Clinical staff to improve clean	<ul style="list-style-type: none">• Clean after use benefits	<ul style="list-style-type: none">• Hasn't worked to date• Opportunity cost. Cleaning takes time, what are clinical staff not going to do

CLEEN study: other

- Degradation audit
 - No effect on equipment
- What about detergent wipes?
 - No RCT demonstrating the benefit of detergent cleaning for shared medical equipment on HAIs
- Hospital wards layout
 - Small number of single rooms, mainly two and four-bed
- Hospital was using the same product prior to the trial (just not well)
- Which component of the intervention is most important?

Assumptions and commentary



Same results can be assumed for a detergent or another disinfectant



Secular trends – yes limitation, but (historical) data doesn't support

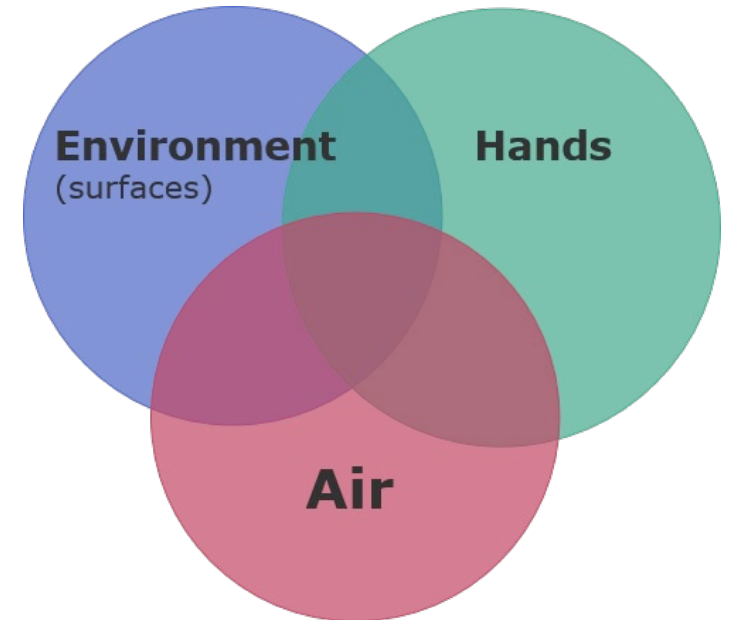


Plausibility for certain infection types



Environment this important?

- Shouldn't look at this in isolation



What's next

- Dose-response paper
- Resources on the CLEEN study website
 - Learning plans
 - Training presentations
 - Feedback examples
 - Publications
 - Podcasts

CLEEN study: conclusions



- Intervention was effective at increasing the thoroughness of cleaning of shared medical equipment and reducing the prevalence of HAIs.
- Baseline, one in seven patients had a HAI, reducing to less than one in 10 patients.
- Enhanced cleaning and disinfection of shared medical equipment can reduce HAIs
- Enhances cleaning and disinfect of shared medical equipment saves hospitals money

Sharing of information

All our resources are being placed on the CLEEN study website, free,
open source

Subscribe on the website for updates



www.cleenstudy.com

Subscribe to infection control matters



Final thoughts

The CLEEN intervention is a cost-saving initiative and a decision-maker who chooses not to invest in it forgoes an opportunity to maximise health gain from a scarce budget.

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