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

20th November 2024

Brett Mitchell, Katrina Browne, Nicole White, Philip Russo, Allen Cheng, Andrew Stewardson, Georgia Matterson, Peta Tehan, Maham Amin, Maria Northcote, Martin Kiernan, Jennie King, David Brain, Nirmali Sivapragasam

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www.cleenstudy.com

Avondale UNIVERSITY

NSW GOVERNMENT Health Central Coast Local Health District

HMRI Hunter Medical Research Institute

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

ANZCTR
Australian New Zealand Clinical Trials Registry

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?

Does it get cleaned?

What should we clean it with?

“I don’t have time”

“That is not my role”

“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?
Environmental cleaning & observational studies

Journal of Hospital Infection 147 (2024) 25–31

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Review

How long do nosocomial pathogens persist on inanimate surfaces? A scoping review

L. Porter [a,b,†], O. Sultan [a,b,†], B.G. Mitchell [c,d,e], A. Jenney [f], M. Kiernan [g], D.J. Brewster [h,i], P.L. Russo [a,b,c,*]

Infection, Disease & Health 28 (2023) 290–297

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: http://www.journals.elsevier.com/infection-disease-and-health/

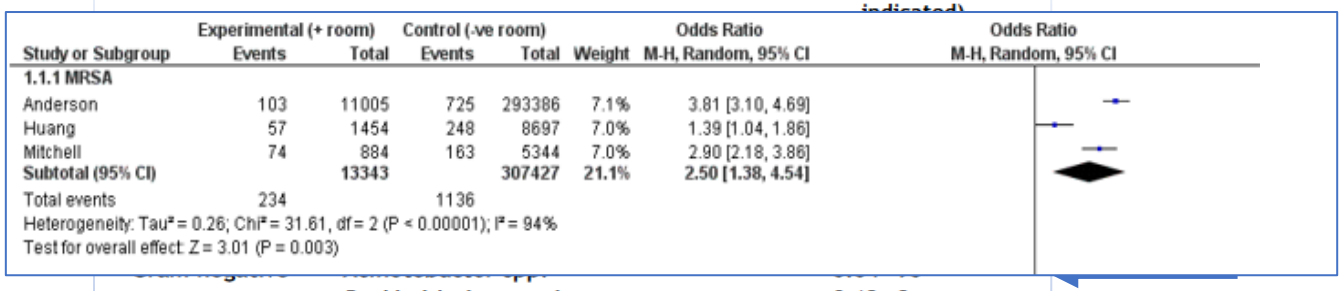
Review

Risk of organism acquisition from prior room occupants: An updated systematic review

Brett G. Mitchell [a,b,c,d,*], Julee McDonagh [e,f], Stephanie J. Dancer [g], Sindi Ford [h,i], Jenny Sim [j,k,l,m], Bismi Thottiyil Sultanmuhammed Abdul Khadar [d,k], Philip L. Russo [b,n,o], Jean-Yves Maillard [p], Helen Rawson [q], Katrina Browne [a,b], Martin Kiernan [b,r]

Table II
Range of survival by pathogen

	Pathogen	Range of survival in days (unless otherwise
	Burkholderia cepacia	0.13–8
	Citrobacter freundii	0.06–0.11
	Escherichia coli	<1 min to 56
	Klebsiella pneumoniae	0.57–600
	Proteus mirabilis	0.16–0.16
	Pseudomonas spp.	0.08–7
	Salmonella spp.	0.29–5
	Serratia spp.	0.29–20
	Stenotrophomonas maltophilia	0.29–1
	Haemophilus influenzae	1–1
Fungi	*Candida auris*	14–14
	Candida spp.	0.13–28
Virus	Animal virus	0.5–7
	Coronavirus	0.04–20
	Cytomegalovirus	<1 min to 0.01
	Human virus	<1 min to 12
	SARS-CoV	1–2



Study or Subgroup	Experimental (+ room) Events	Total	Control (-ve room) Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
1.1.1 MRSA						
Anderson	103	11005	725	293386	7.1%	3.81 [3.10, 4.69]
Huang	57	1454	248	8697	7.0%	1.39 [1.04, 1.86]
Mitchell	74	884	163	5344	7.0%	2.90 [2.18, 3.86]
Subtotal (95% CI)		13343		307427	21.1%	2.50 [1.38, 4.54]
Total events	234		1136			

Heterogeneity: Tau² = 0.26; Chi² = 31.61, df = 2 (P < 0.00001); I² = 94%
Test for overall effect: Z = 3.01 (P = 0.003)

Odds Ratio M-H, Random, 95% CI

What does the evidence tell us?
Randomised control trials

First author	Year	Primary intervention	Primary outcome
Salgado	2013	Antimicrobial surfaces • Copper alloy	• MRSA/VRE colonisation
Boyce	2017	Enhanced cleaning patient rooms • H_2O_2 & QAC	• Colony counts • Colonisation/ infection (MRSA,CDI,VRE)
Ray	2017	Bleach wipe	• CDI incidence
Anderson	2017	Terminal room disinfection • QAC, UV, bleach	• HAI rates
Mitchell	2019	Enhanced cleaning patient rooms	• 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

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 Browne[1], Nicole White[2], Peta Tehan[1,3], Philip L Russo[3,4], Maham Amin[5], Andrew J. Stewardson[3,6], Allen C. Cheng[3,6], Kirsty Graham[5], Gabrielle O'Kane[7], Jennie King[5,8], Martin Kiernan[1,9], David Brain[2] and Brett G. Mitchell[1,3,5,8*]

www.cleenstudy.com

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: 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

Lancet Infect Dis 2024

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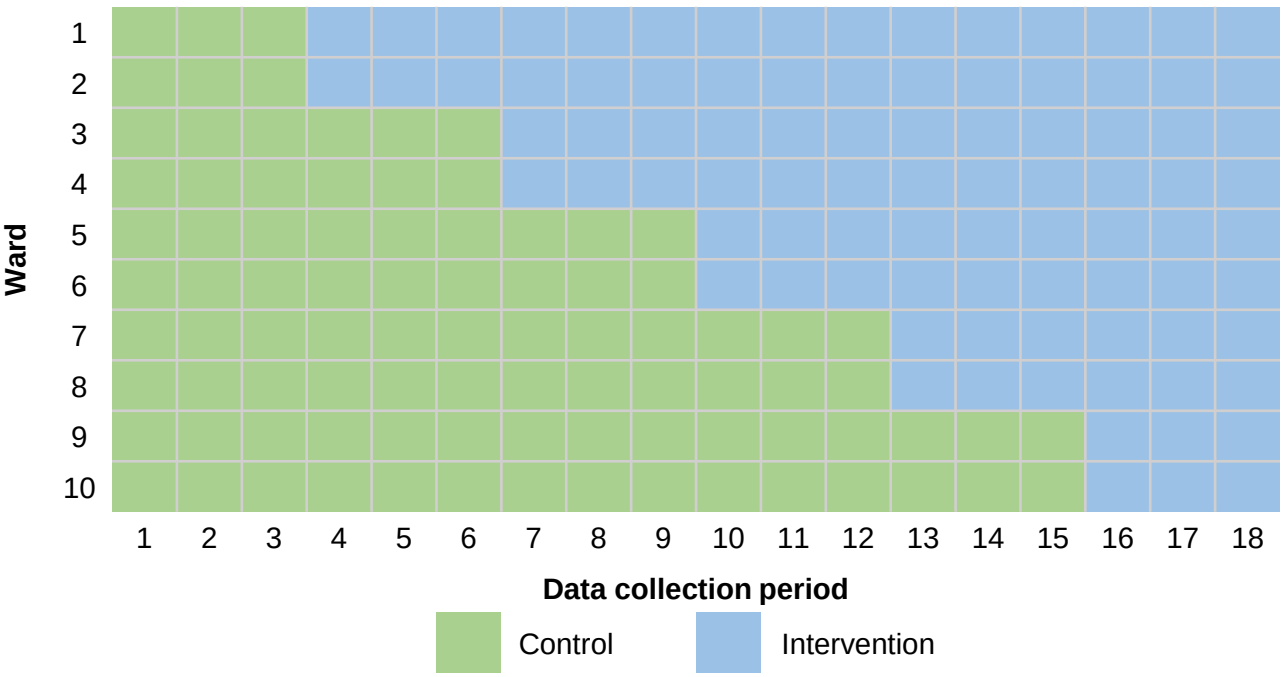
Summary

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.

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

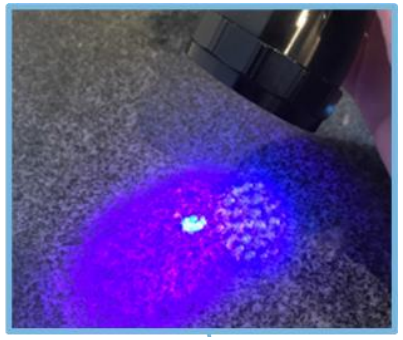
Sub-groups

- 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

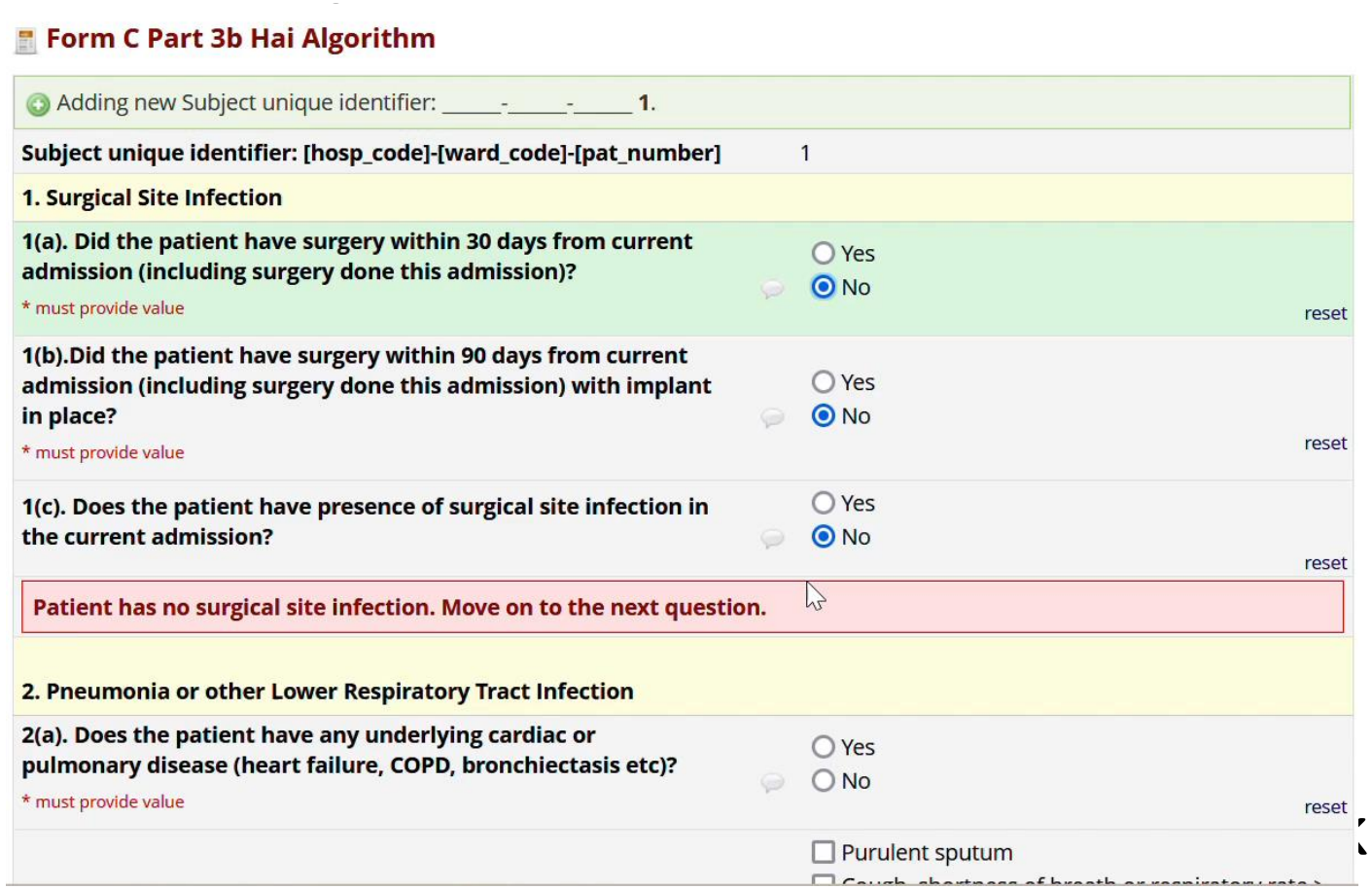
Shared medical equipment

- 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)



prior to intervention

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),
  - Interv .3)

Primary outcome – All HAIs

Control 14.9% (10.4 to 19.4)

Intervention 9.8% (6.1 to 14.1)

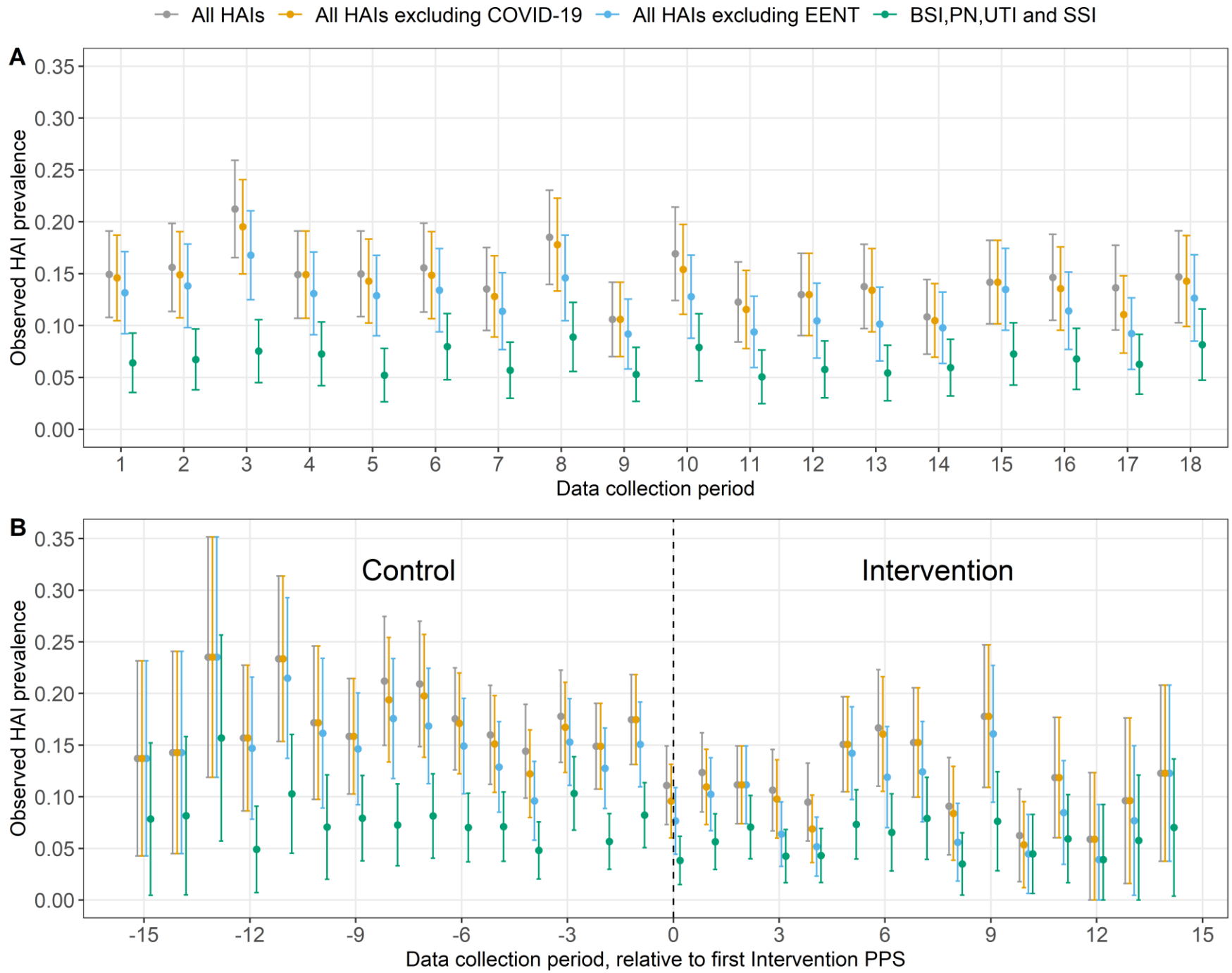
OR 0.62 (0.45 to 0.80), p<0.001

Absolute difference -5.2 (-8.2 to -2.3)

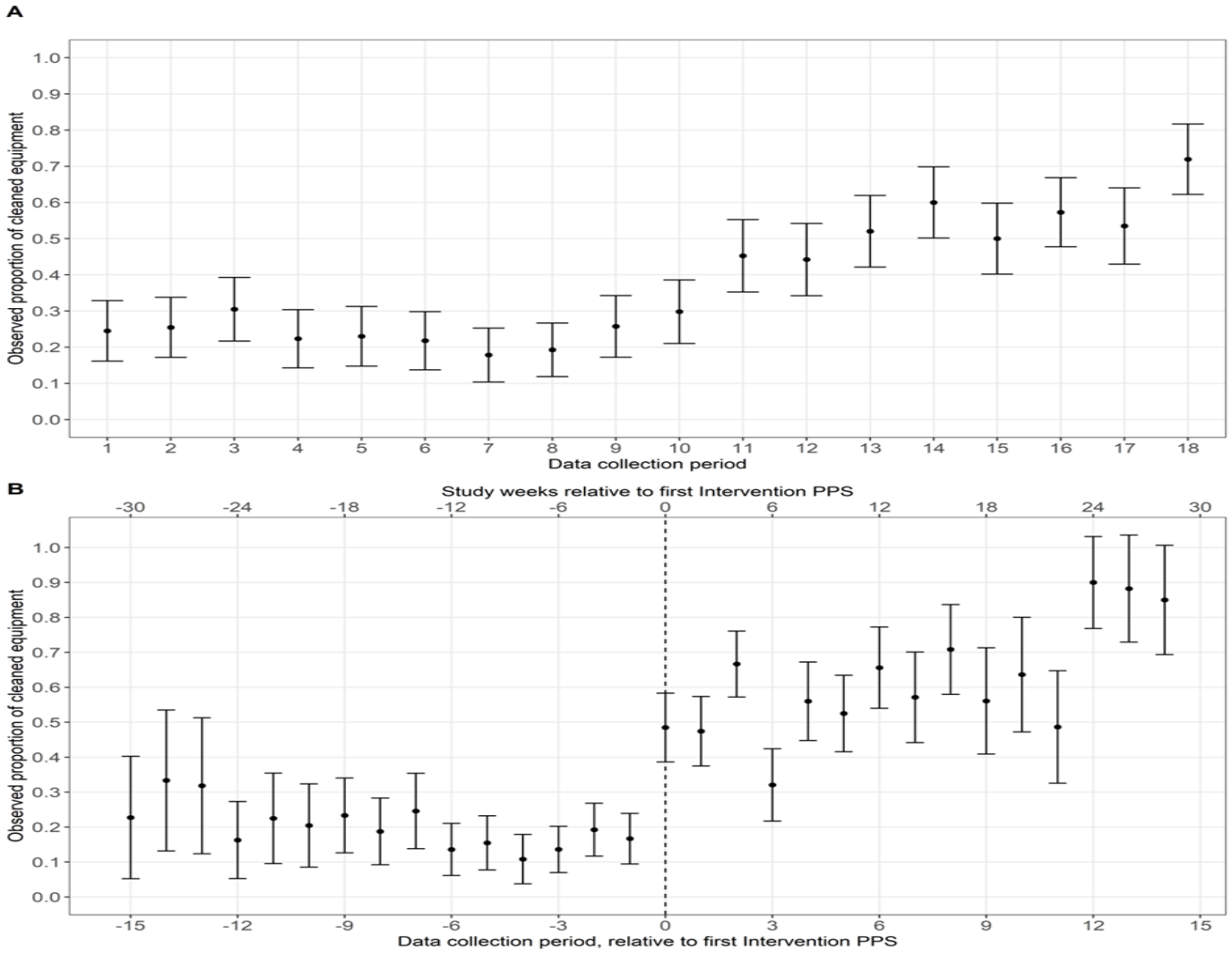
Relative difference -34.5 (-50.3 to -17.5)

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


All HAIs
All HAIs excluding COVID-19
All HAIs excluding EENT
BSI,PN,UTI and SSI
A
Observed HAI prevalence
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18
Data collection period
B
Control
Intervention
Observed HAI prevalence
-15 -12 -9 -6 -3 0 3 6 9 12 15
Data collection period, relative to first Intervention PPS

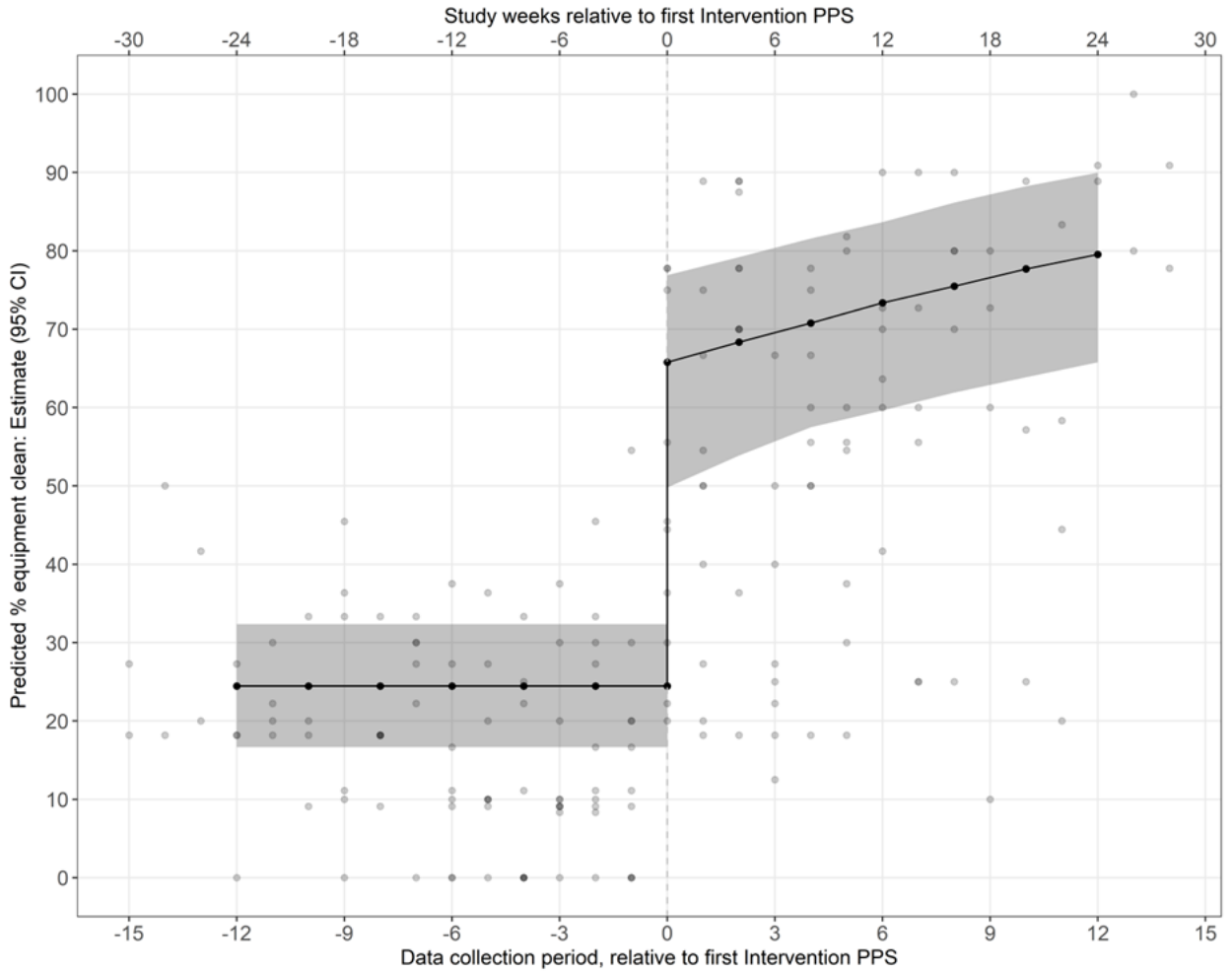
Results: secondary outcome (florescent UV dots)



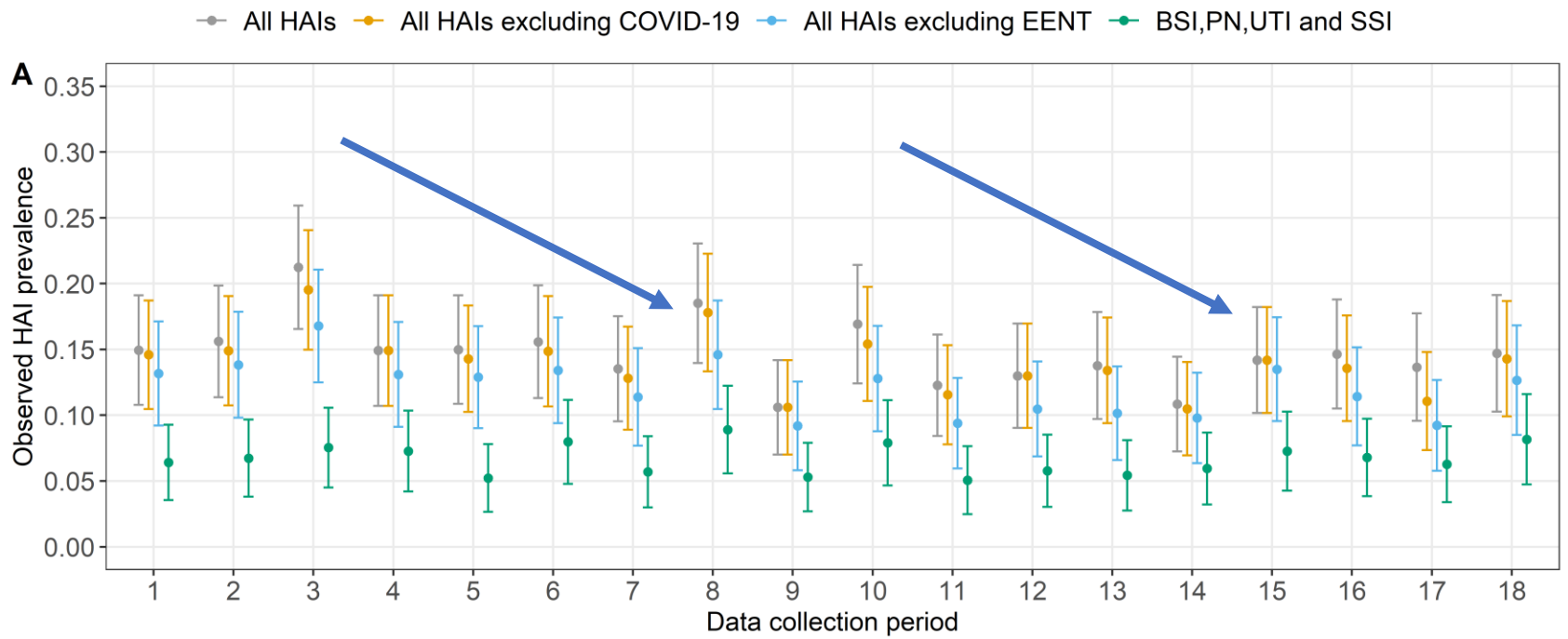
- 1,786 individual pieces of shared medical equipment (925 control, 861 intervention) were audited.

- 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)

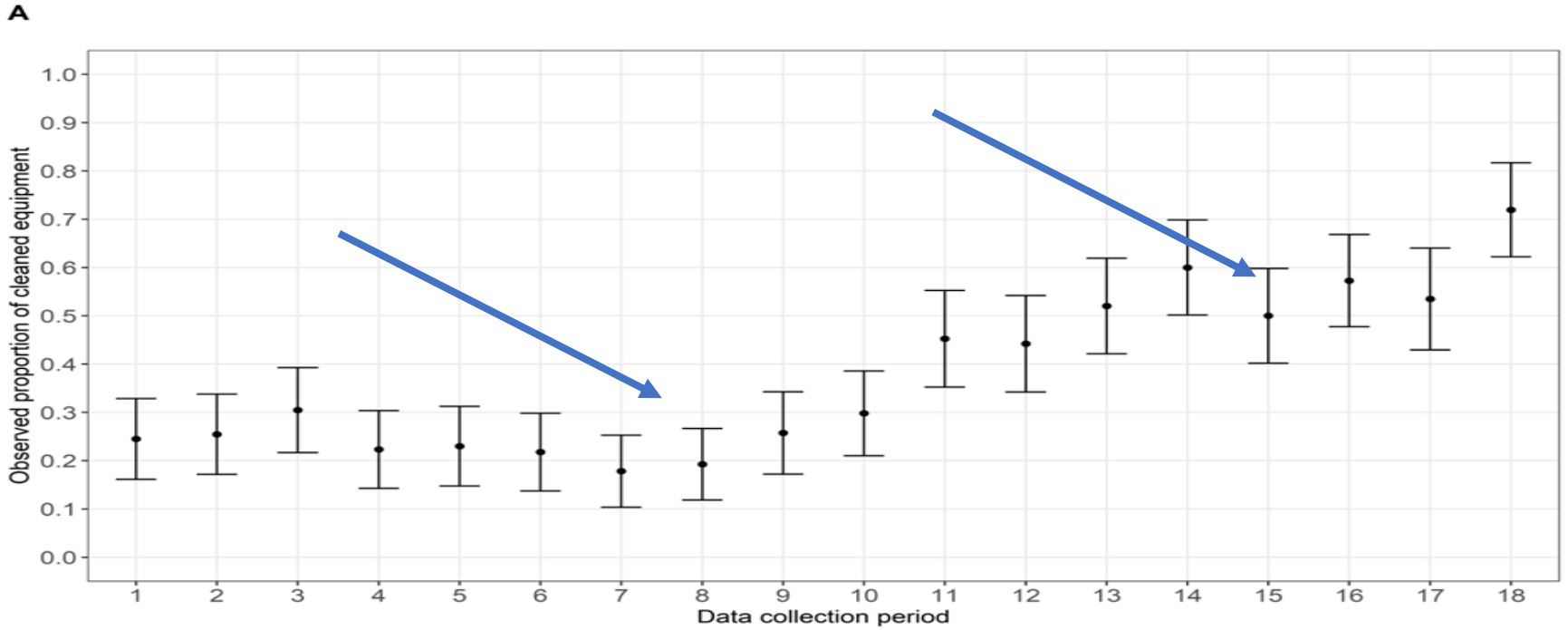
Results: secondary outcome (florescent UV dots)



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

An important request

Please do not share the cost-effectiveness tables or figures on social media or other forums

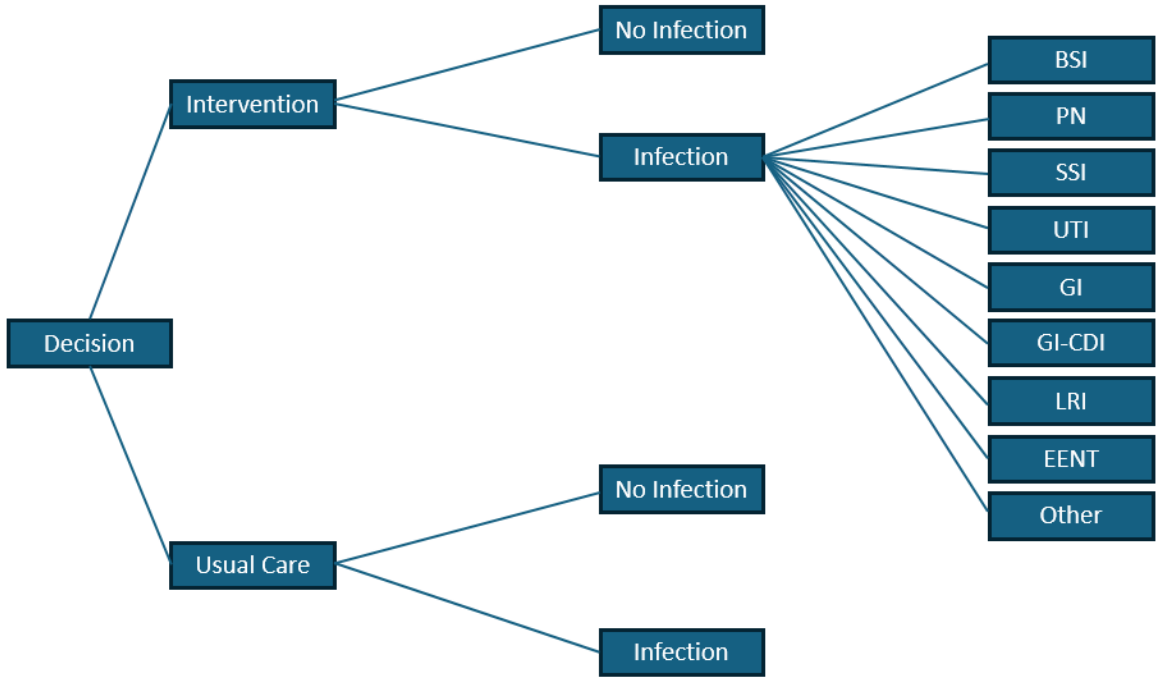
Cost-effectiveness

(early results, not peer-reviewed)

Nirmali Sivapragasam, QUT

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: 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

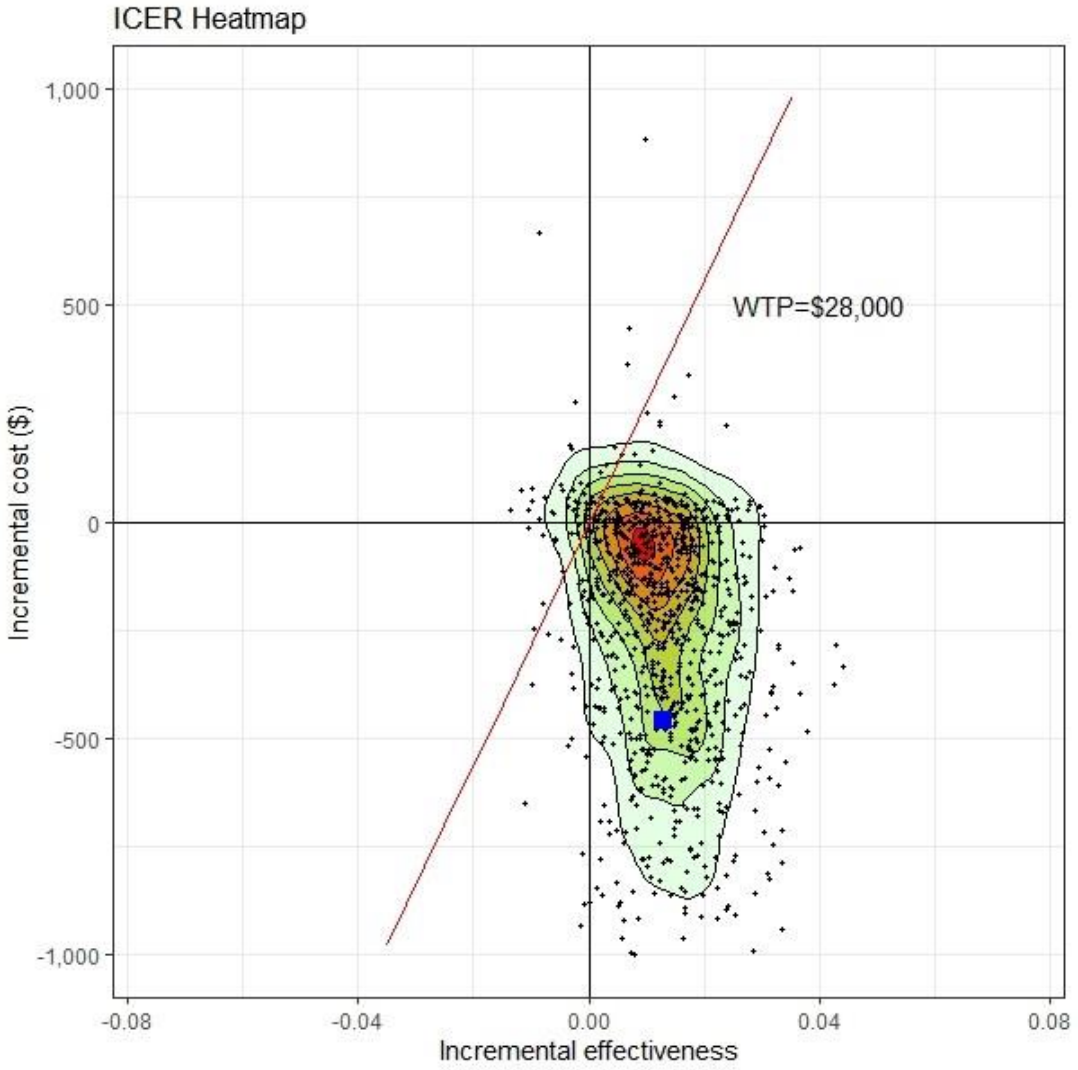
- Length of stay for HAIs
  - Data from literature
  - Only used studies where time-dependent bias was accounted for
- Effect of intervention:
  - Changes in infection rates observed for each infection from CLEEN study

Results

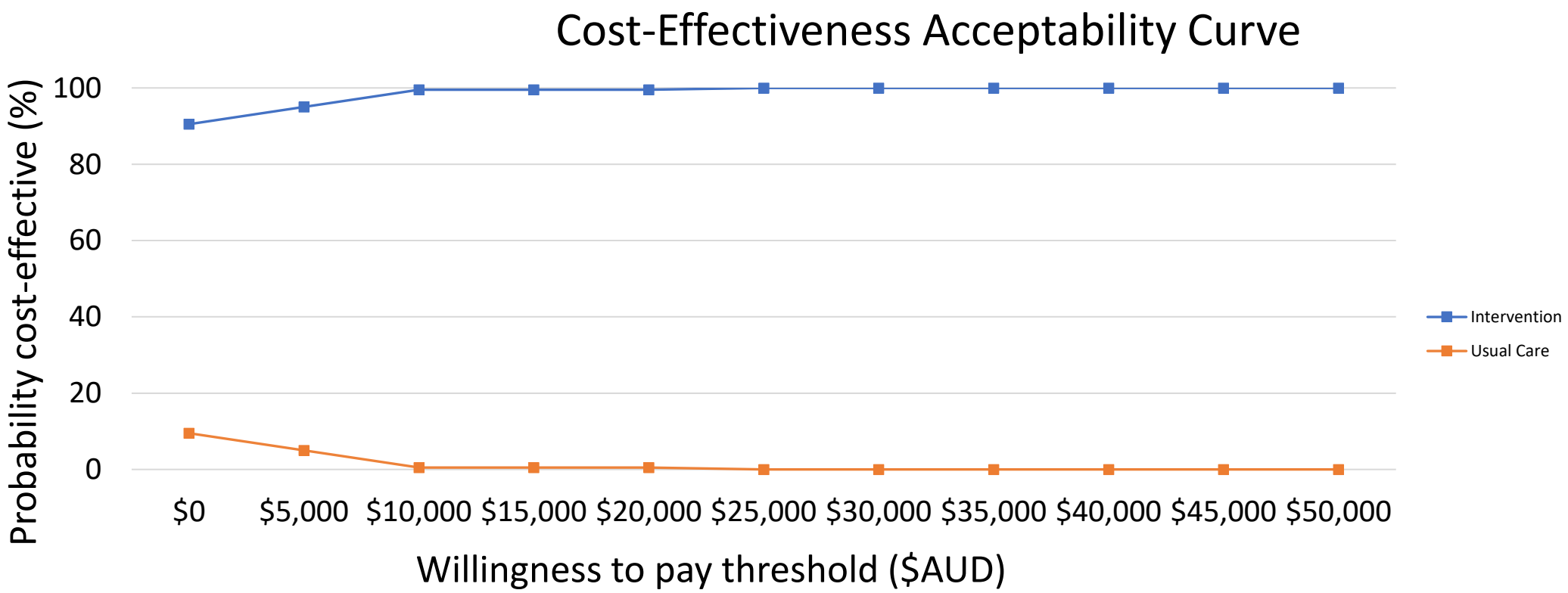
- For a cohort of 1,000 patients, estimated total costs:
  - Intervention: $1,513,000
  - Usual care: $2,155,310

- **For every 1000 patients this trial is implemented for, a hospital could:**
  - **Prevent 30 infections**
  - **Save $642,010**

- On average, each infection prevented saves $21,400



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

CLEEN study – summary

Brett Mitchell

Numbers are people

Future implementation and modelling

Approach	Pros	Cons
Dedicated cleaners like CLEEN	• Ease of implementation • Control / direct line of sight / oversight • Costs easy to quantify • CEA to support	• Difficult to recruit/retain • Boredom / repetitive • Risk of clinical staff cleaning (even) less
Cleaning staff on ward, increase hours/change role	• Ease of implementation • Control / direct line of sight / oversight • Less risk of boredom	• Would they clean shared equipment? Additional time absorbed for 'other tasks' • Risk of clinical staff cleaning (even) less
Centralised cleaning model	• Use of automation for disinfection • Less clutter on wards • Potentially more attractive role	• Space to undertake • Distribution of equipment
Clinical staff to improve clean	• Clean after use benefits	• 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?

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 will be placed on the CLEEN study website, free, open source in due course

Subscribe on the website for updates

www.cleenstudy.com

Subscribe to infection control matters

Final thoughts

If you or a loved one were a patient in hospital

- Would you want this trial implemented in that hospital?

If you are a decision-maker

- Why would you forgo the opportunity to improve patient safety and reduce the opportunity to release bed days for other uses?

If you were funding a hospital

- this intervention helps drive efficiency and productivity without costing you more

As a clinician

- will you follow the evidence?

Team

Avondale University

AlfredHealth

MONASH University

NSW GOVERNMENT Health Central Coast Local Health District

HMRI Hunter Medical Research Institute

QUT Queensland University of Technology







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