CLEAN FRONTLINE CAMBODIA
A Stepped Wedge Cluster Trial of an Environmental Hygiene Educational Intervention across Thirteen Cambodian Hospitals

A STUDY PROTOCOL
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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

WaterAid

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Executive Summary

Environmental hygiene is a key component of infection prevention in healthcare, and a driver of healthcare associated infections. Staff who clean in many low resource countries receive no formal training on cleaning, waste disposal and linen handling. This issue has been exacerbated by the COVID-19 pandemic. The only recommended training on environmental hygiene for low resourced facilities, TEACH CLEAN, uses a training of trainers model. A selected cadre of “champions” is trained which in turn train their peers with responsibilities on environmental hygiene at the facility level. Early pilot data to test its effectiveness of this training package are very promising.

The main objective is to evaluate the effectiveness of an environmental cleaning bundle to improve microbiological cleanliness in Cambodian hospitals.

TEACH CLEAN will be implemented across all hospitals (13) of three provinces in Cambodia. A stepped wedge randomised trial will be used to evaluate the effectiveness of TEACH CLEAN to improve microbiological cleanliness in Cambodian hospitals. All facilities will receive the intervention. Hospitals are arranged in groups of three or four based on the randomisation with staggered commencement dates of the intervention at four distinct time points. The design will include ten months of data collection. We expect one month gap between the training of champions and the training of staff at the facility level. The main outcome is microbiological cleanliness (<2.5 cfu/cm2 = clean ; ≥2.5 cfu/cm2 = not clean) measured using a non-specific agar on one side for measuring total Aerobic Colony Counts (ACC/cm2). With 30 sampling sites in each hospital and with a pre-training cleanliness proportion ranging from 30% to 50% will give us over 85% power to detect a 10% absolute post-intervention increase in cleanliness.

Evidence from this trial will contribute to future policy and practice guidelines about hospital environmental hygiene and ultimately reduce healthcare associated infections. This would be the first randomised trial on environmental hygiene in low resource settings.

List of abbreviations

AMR	: Antimicrobial Resistance
DHS	: Department of Hospital Services, Ministry of Health
FGD	: Focus Group Discussion
HAI	: Healthcare Associated Infection
IPC	: Infection Prevention and Control
LMICs	: Low- and Middle-Income Countries
LSHTM	: London School of Hygiene and Tropical Medicine
MoH	: Ministry of Health
NECHR	: National Ethics Committee for Health Research
NIPH	: National Institute of Public Health
ToT	: Training of Trainers

1 Background

Healthcare-associated infections (HAIs) represent a significant burden in low-and middle-income countries (LMICs), with rates are at least twice as high as on the European continent (1). Environmental cleaning is one of the core pillars of infection prevention and control (IPC) across healthcare facilities. The COVID-19 pandemic has thrown renewed attention to the linkages between hand and environmental hygiene, and the need to tackle both to reduce transmission (2,3), so bringing added benefits for preventing HAIs and mitigating antimicrobial resistance (AMR). There are many challenges to rapidly improving hand and environmental hygiene given the weak state of water, sanitation and waste management infrastructure in healthcare institutions, and emergency responses to COVID-19 need to provide both immediate solutions and options bringing sustained and longer-term benefits (4). The COVID-19 pandemic has severely affected Cambodia with a total of over 120,000 cases and substantial disruption to the healthcare system. Strengthening infection prevention is needed to support the healthcare system response to the pandemic.

Training of key workers in environmental hygiene – those whose primary role is cleaning (here called cleaners) – is one of such response mechanisms which brings immediate and lasting gains, and practical guidance on reducing environmental transmission in the face of infrastructural, equipment and supply bottlenecks. These frontline workers are crucial in the face of massive shortages of healthcare professionals, and where overcrowding in healthcare facilities increases risk of transmission from frequent hand-touch fomites. Cleaners in LMICs are often untrained, poorly supervised, and unprotected, and their low levels of literacy present particular challenges for learning modalities (4–6).

Currently in Cambodia, there is no routine formal training of cleaners. The sporadic training sessions that have been organised are insufficient and suboptimal in quality. To bridge this gap in environmental hygiene training, the National Institute for Public Health (NIPH) together with the Cambodian Ministry of Health's Department of Hospital Services (DHS), and WaterAid Cambodia decided to provide training on environmental hygiene to frontline cleaners from 13 public hospitals in Cambodia using an internationally recognised package of training on environmental hygiene: TEACH CLEAN (https://www.lshtm.ac.uk/research/centres/march-centre/soapbox-collaborative/teach-clean) (7). Environmental hygiene training has never been formally evaluated in the low resourced contexts, although pilot evaluation in other contexts show promising results (8). The more recent version is currently being adapted by the WHO for global roll out.

In collaboration with NIPH, DHS, WaterAid, the research team at the London School of Hygiene and Tropical Medicine (LSHTM) aims to thoroughly evaluate this roll out. The study described below represents the first randomised trial in a low-resource setting testing an environmental hygiene education intervention.

2 Objectives

The main objective is to evaluate the effectiveness of an innovative environmental cleaning bundle, TEACH CLEAN, as an intervention to improve microbiological cleanliness in Cambodian hospitals. More specifically, this study aims to:

- Assess whether the quality of microbiological cleanliness (primary outcome) changes as a result of the intervention
- Assess whether in absence/presence of *S. aureus/MRSA* changes as a result of the intervention
- Explore knowledge, self-efficacy and social norms among cleaners and investigate whether they vay by the degree of implementation strength, and possibly by level of microbiological cleanliness

- Explore the association between the degree of implementation strength and microbiological cleanliness

It is expected that an effective and tailor-made environmental cleaning bundle will be taken up and integrated in national training programs and guidelines on environment cleaning and hygiene in healthcare facilities and further scaled up in Cambodia. Ultimately, this will contribute to reducing healthcare associated infections in the country and globally through sharing of such innovative training package.

3 Methods

3.1 Study design

This is a randomised controlled trial using a stepped-wedge random allocation with the following details:

- The environmental hygiene intervention will be rolled out to thirteen hospitals over ten months
- The main intervention – the training of trainers/champions (ToT) will be delivered to selected cleaning champions from three or four hospitals within a certain month (within the same 4 weeks of at a specific month in the schedule), hence there will be a total of 4 steps (4 main periods when training happens)
- **The timing allocation for hospitals matched with the four training periods is random**
- The results across unexposed observation periods are compared with that across the exposed observation period
- The stepped-wedge design, with staggered timings for the start of the intervention and intervention length (2 to 8 months), supports feasibility while maintaining the rigour of the study.
- The design allows the NIPH and its partners to work with a group of hospitals at the time to maximise quality and consistency of the implementation, and avoid having to manage the changes across 13 hospitals simultaneously

This is the suitable design to ensure that all the 13 participating hospitals receive the interventions as proposed by NIPH and its partners whilst keeping the rigor of randomisation based on timing.

3.2 Study sites and population

This study will be conducted in thirteen hospitals in three selected provinces in Cambodia. These hospitals have the following characteristics:

- District and provincial referral hospitals in the selected provinces
- Public hospitals
- 46% of them have an operating theatre
- Range of hospital beds: 30 -220
- Ensuring representation in at least three provinces of the country. The three provinces are selected based on a mix of the prior work conducted by WaterAid in those areas, and aiming to select largest referral hospitals in the country. See Table 1 for key characteristics of these provinces

Table 1. Region characteristics

	% rural (vs urban)	Pop density	Income (GDP per capita, 2015)
Kampong Chhnang	85.5%	95	2,726
Battambang	76%	84	2,881
Kratie	90%	34	2,765

Source of information:
http://hdr.undp.org/sites/default/files/nhdr_cambodia.pdf
https://www.nis.gov.kh/nis/Census2019/Provisional%20Population%20Census%202019_English_FINAL.pdf
https://www.adb.org/sites/default/files/institutional-document/151706/cambodia-country-poverty-analysis-2014.pdf

In Cambodia, there are twenty-five provinces. Battambang is one of the top seven most populous provinces, which consists of 987,400 people in 2019. Besides a large population, Battambang is a prosperous province for being the leading rice-producing province; it is also an economic corridor that connects Cambodia and Thailand. Kampong Chhnang has 525,932 people living in the province, while there are only 372,825 people situated in Kratie in the same year. With a lesser population, Kampong Chhnang and Kratie are listed among the seven poorer provinces in Cambodia, according to Cambodia Poverty Analysis 2014.

3.3 The intervention

TEACH CLEAN is an intervention aimed at improving environmental hygiene in hospitals in low-resource settings. It was created by the Soapbox Collaborative jointly with NHS Grampian (UK) based on international guidelines for environmental hygiene. It was pilot-tested in The Gambia in 2016 and Tanzania 2018, and used in India and Cameroon among others. Key features include participatory methods and pictorial guidelines to facilitate learning for hospital cleaners, who typically have low education and literacy levels (5,9,10). The CLEAN Frontline study will use the most up to the data version of the package which has been updated recently by the WHO for global roll out. TEACH CLEAN comprises the following stages:

3.3.1 Preparatory stage (phase 1)

This stage includes engagement with hospital managers, selection of facility *cleaning champions* in each hospital; assessment of environmental hygiene status and resources; and adaptation of TEACH CLEAN to the local context.

A situation analysis and basic needs assessment will be conducted to collect necessary data and information for preparation and adaptation of the intervention to the local context – contextualization of the intervention through analysis of relevant policy documents and a rapid facility survey. For the latter, trained surveyors will pay a visit to all the 13 hospitals. During the visit, the surveyors will conduct interviews with hospital and ward leaders responsible for IPC and cleaning, using a semi-structured questionnaire (Appendix 1 – available on request). In addition, a hospital walkthrough will be done to observe the cleaning and hygiene facilities and practices using an observation checklist (Appendix 2- available on request). The collected data will be analysed and the findings will be used to

- identify relevant wards and cleaning champions for the intervention,
- map ward specific sites for environmental swabs (with dipslides) and
- adapt the training tools and process to align with existing policies/guidelines, needs and feasibility, including the feasibility of using digital technologies for the training.

A tailored intervention should optimise bundle implementation and compliance, but such tailoring will not compromise the integrity of the individual components and the 'sum of the whole' of the bundle.

3.3.2 Training stage (phase 2)

This stage is primarily a training of facility *cleaning champions* to educate and supervise other existing facility cleaners with environmental hygiene responsibilities – training of trainers (ToT). Cleaning champions are selected on the basis of having a supervisory or senior role within the ward, prior understanding of infection prevention in relation to environmental hygiene, good communication skills and willingness to develop knowledge and take on the role of champion.

The identified facility cleaning champions will be trained as trainers to further train other facility cleaners and staff who are involved in cleaning in the form of training of trainers (ToT). The training content includes as much as possible the seven contextualized modules of TEACH CLEAN training package (CLEAN BOX): i) Introduction to Infection Prevention and Control, ii) Personal hygiene and dress code, iii) Hand hygiene, iv) Personal protective equipment, v) Housekeeping/control of environment, vi) Waste handling, and vii) Linen handling.

The seven TEACH CLEAN training modules cover cleaning agents, frequency of cleaning, cleaning techniques, importance of environmental hygiene for HAI prevention, and, specifically for champions, techniques for supervising staff and methods for attracting sufficient resources. The TEACH CLEAN bundle is currently the only cleaning training for hospitals in resource-limited settings endorsed by several international guidelines including the recent "Best Practices for Environmental Cleaning in Healthcare Facilities: in resourced-limited settings" (7). The CLEAN Frontline study will use the most up to the data version of the package which has been updated recently by the WHO for global roll out.

NIPH in collaboration with DHS will contextualize and deliver the interventions.

The contextualized TEACH CLEAN will be offered primarily to the **three** selected wards identified at the preparatory stage: i) maternity ward, including labour and post-natal rooms, ii) general medicine ward, iv) and paediatric ward.

The timing and duration of the training will be organised with the hospital and ward manager to ensure staff are able to attend whilst maintaining key core personnel in the wards, and to allow for flexibility with staff personal commitments.

3.3.3 Supervision stage (phase 3)

This stage refers to ongoing mentorship by DHS of *cleaning champions* while they educate and supervise existing facility cleaners with environmental hygiene responsibilities. The trained cleaning champions are expected to train other facility cleaners and staff who are involved in cleaning. This requires regular field supervisions and distance support by master trainers to monitor their progress, identify the challenges they face in providing training to other cleaners, and help them address such challenges, including technical support and provision of basic and necessary materials for training and environmental cleaning.

3.4 Evaluation of the intervention and expected outcome

The evaluation aims to ultimately measure the effectiveness of the environmental cleaning bundle (the intervention) in improving the 'microbiological' cleanliness of the study hospitals – the primary outcome of the intervention. This expected outcome will not only depend on the package of intervention but also on how the package will be delivered. Crucially, the trial will provide meaningful results about the effect of the training stage (phase 2) and supervision stage (phase 3). The preparatory stage (phase 1)cannot be evaluated as it will commence virtually simultaneously across the hospitals. Therefore, a process evaluation is needed at the training and supervision stage.

3.4.1 Process evaluation

A process evaluation conducted by the Cambodia WaterAid team together with the LSHTM team will aim to capture information around the following aspects of implementation as recommended by the Medical Research Council (UK) guidelines for process evaluations of complex interventions: implementation fidelity, dose, mechanisms, reach and context:

- **Implementation fidelity** will be measured through semi-structured observations of trainings at the ToT level and facility level – we will aim for at least one set of training to be observed in each facility (N=13-26 trainings observed) and using interviews and focus group discussions (FGDs) with stakeholders by an experienced qualitative researcher (see Appendix 3 and Appendix 4). Phone interviews will be conducted with a sample champions and cleaners at regular intervals across the study to assess both implementation fidelity in terms of supportive supervision and contextual changes described just below (See Appendix 3 and Appendix 4).
- With regards to **context**, we will map the hospital characteristics and context (e.g. staffing, size), infection prevention policies and practices (e.g. antimicrobial stewardship, antibiotic use, screening) and other relevant activities (e.g. cleaning staff changes, policy changes) within the hospital in a qualitative way through stakeholders interviews (see Appendix 3). Ongoing reviews of contextual information throughout the intervention at each site will assist with trial site comparisons, replication and scalability and knowledge translation
- **Dose and reach** of the intervention will also be monitored e.g. number of modules delivered, number of facility staff trained, number of supervision sessions. This information will be collected using training records.
- **Data on mechanisms** (e.g. increase in knowledge) through which the intervention is believed to work will also be collected through a quantitative survey enquiring about knowledge, social norms, network structure and self-efficacy measures. See Appendix 5 for the draft survey. The survey will be administered to all staff who cleans in the selected facilities at the end of the trial will allow us to compared knowledge and attitudes scores between control and intervention clusters. This is particularly important to gauge whether the bundle has impacted not only upon behaviour but also on and knowledge, which are the longer-term drivers of behavioural outcomes.
- All these data collection tools for the process evaluation have been previously used in the former pilot work of TEACH CLEAN (8).

All process evaluation tools (Appendix 3, 4 and 5) are currently in a draft format and will need to be piloted and refined in an iterative way according to the early qualitative results of the study.

3.4.2 Impact evaluation

Randomisation: Hospitals will be randomly allocated to intervention timing 3 months prior to the start of the first training. We will use constrained randomisation to ensure there is a balance in key hospital characteristics in each randomisation step. Specifically, randomisation will be constrained based on region and hospital size using standard methods (11). One of the investigators will be in charge of computer generation of the allocation in terms of time and hospital identifiers. Alternative, we will generate a random allocation using a public method with the key study coordinators (NIPH, WaterAid, DHS and LSHTM) of picking from “a hat” and including all key investigators in this process virtually, but keeping the constrained rules described just above.

During the first month of data collection, i.e. 4 weeks before the start of the first ToT, we will baseline data collection; some intervention aspects of phase 1 of the TEACH CLEAN package will be ongoing

Staff who clean will not be blinded as this is not possible.

		Period/Month									
	March	May	June	July	August	September	October	Novemver	December	January	Feburary
Hospital	0	1	2	3	4	5	6	7	8	9	10
1	Pilot	0	Training group 1	1	1	1	1	1	1	1	1
2	Pilot	0		1	1	1	1	1	1	1	1
3	Pilot	0		1	1	1	1	1	1	1	1
4	Pilot	0	0	0	Training group 2	1	1	1	1	1	1
5	Pilot	0	0	0		1	1	1	1	1	1
6	Pilot	0	0	0		1	1	1	1	1	1
7	Pilot	0	0	0	0	0	Training group 3	1	1	1	1
8	Pilot	0	0	0	0	0		1	1	1	1
9	Pilot	0	0	0	0	0		1	1	1	1
10	Pilot	0	0	0	0	0		1	1	1	1
11	Pilot	0	0	0	0	0	0	0	Training group 4	1	1
12	Pilot	0	0	0	0	0	0	0		1	1
13	Pilot	0	0	0	0	0	0	0		1	1

Figure 1 – Trial structure

Cluster unexposed to the intervention
Cluster in transition period
Cluster exposed to the intervention

Sampling sites: The unit of measurement for microbiological cleanliness is key hand-touch sites – patient beds and other equipment around the patient area (e.g. beds, equipment trolley, bedside locker) in our study. Formative observation identified these surfaces most frequently touched by healthcare workers, closest to the patient, thus providing the greatest risk of pathogen cross-transmission (12,13). Other studies report these hand-touch sites in hospitals.(7,13)

A picture will be drawn for each ward with the selected surfaces sampled to guide data collection.

Dipslides: are a widely used method for measuring surface microbiological cleanliness, in hospitals and elsewhere (14). We will dipslides coated with a non-specific agar on one side for measuring total Aerobic Colony Counts (ACC/cm^2) and a selective agar on the other (Baird-Parker agar, to determine the presence of *S. aureus*; Dimanco, UK). Both sides are applied consecutively to adjacent areas of the sampling site,. Dipslides will be collected from hospitals once a month. They will be transported to local laboratory on the day of collection and incubated in aerobic conditions for 14-36 hours (exact timing will be stablished after piloting because logistics arrangements can impact on bets incubation time) at 37°C. Colonies were enumerated by visual inspection. See Appendix 6 for the laboratory protocol details.

Data collection: An independent team (not involved in the delivery of the training) will collect monthly data from pre-agreed hospital sites. The cluster size i.e. number of sites sampled per cluster will be 30 across all wards. The same patient areas will be used in each monthly measurement. Where possible, the sampling week will not be the same each month for the hospital to minimise bias from study participants. If feasible, we will collect information on water and bleach availability, and patient volume at each monthly visit.

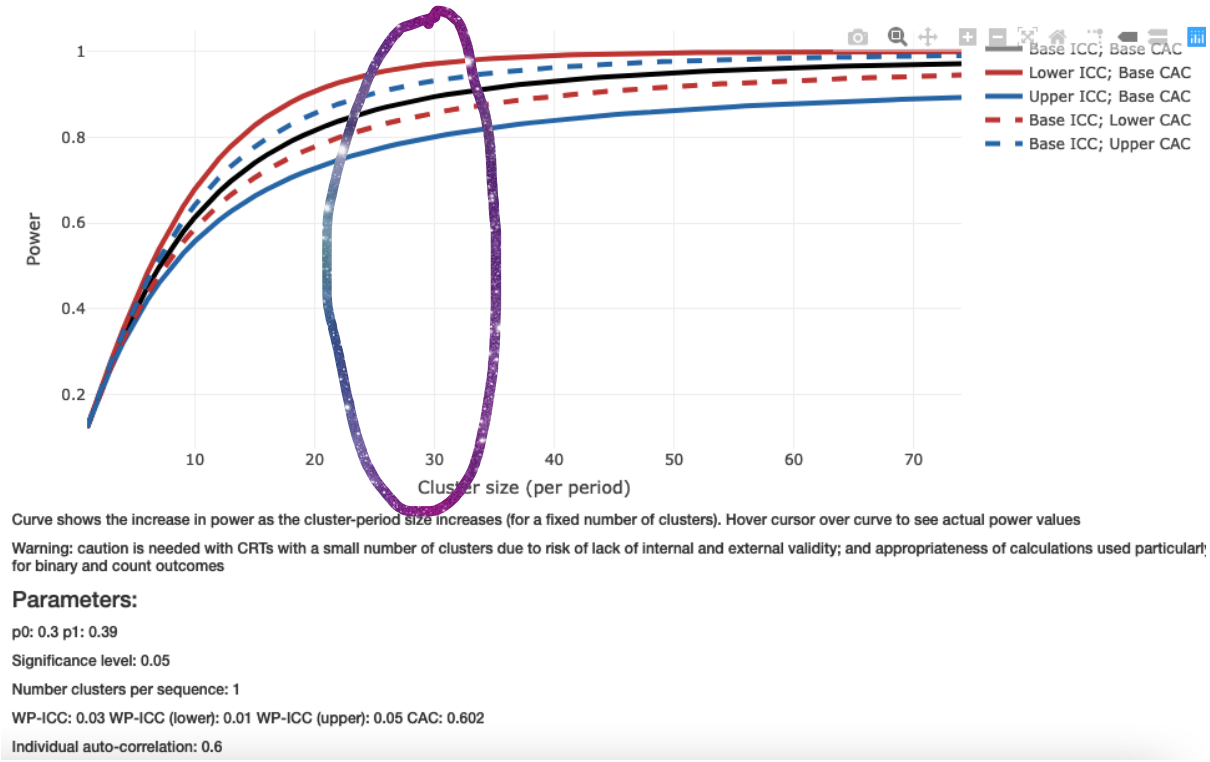
Outcome: Proportion of microbiological cleanliness (<2.5 cfu/cm2 = clean ; ≥2.5 cfu/cm2 = not clean) will be calculated for each cluster as the number of sites with <2.5 cfu/cm2 out of the 30 sites sampled per period/month.

Power calculations for primary outcome: The intervention will be delivered in four steps across thirteen hospitals (3 hospitals per step; except for one step with 4 hospitals – see Figure 1), with 30 sampling sites each and with a pre-training cleanliness proportion ranging from 30% to 50% will give us over 85% power to detect a 30% relative increase in microbiological cleanliness. This is based on a two-sided 5 % significance level, a two-period decay correlation structure with the following conservative estimates of within- period ICC in microbiological cleanliness at 0.03 (previous pilot), auto-correlation of observation at 0.6 and cluster auto-correlation at 0.6, and the intervention timings shown in Figure 1. The pre- intervention cleanliness proportion, and the within-hospital ICC and were estimated using a pilot data from similar level maternity wards in Tanzania as no local data is available on microbiological cleanliness; other available evidence on levels of microbiological cleanliness confirm in settings with no formal training sow similar levels of hospital cleanliness in low resource settings.(8) We assumed one month delay in the treatment effect for the sample size calculation to allow for champions to train staff in their own facility.

We used the website (https://clusterrcts.shinyapps.io/rshinyapp/) and underlying formula operationalised by Hemming et al. (2020).(15) See results in Figure 2.

The power calculations translate **into 4,300 dipslides** (13 hospitals*30 sampling sites*10 months = 3,900 + 10% for contingency purposes)

Figure 2. Sample size calculations



Data analyses: *Aeorobic Colony Counts and S. Aureus outcomes*

- The outcome for unexposed observation periods is compared with that across the exposed observation periods.
- The key independent variable will be the intervention (yes/no). The intervention variable will switch from “no” to “yes” after the first full month of the training
- Characteristics of the individual sites and clusters will be summarised by exposure status so to allow consideration of selection biases and lack of balance.
- These characteristics can be compared by randomisation step. This will include the numbers analysed, the average cluster size, and cluster characteristics
- A few characteristics of the hospital (e.g. size) will be considered as independent variables as these should remain roughly constant throughout the study.
- Each cluster will be analysed according to the actual time when it was “trained” independently on when this was planned for.
- Calendar time is associated with both the exposure to the intervention and also possibly the outcome, and so is a potential confounder and will be adjusted for in the analysis
- Adjusting for the systematically different observation periods and for clustering in the data will be accomplished.
- We will test the residuals of the model to look for autocorrelation over time and will check for influential observations.
- The estimated intra-cluster correlation and time effect from the fitted model will be reported both for use in the design of future trials and to allow appreciation of any underlying confounding effects of calendar time
- We will consider using a small sample correction.

In addition, using the same general model we will create a variable indicating the strength of implementation which we will use as an alternative exposure variable to the simpler *intervention vs control variable*. We will also explore descriptively time trends for each cluster. Finally, we will analyse the knowledge and attitudes descriptively (and by implementation *strength and by microbiological outcomes*) as these measures are only collected at the end of the trial.

Qualitative data from FGDs and observations will be analysed adopting a generalised qualitative approach in which the transcripts were disassembled into low-level descriptive codes and then reassembled into themes that may help explain the observed outcomes

4 Data and reporting

Please refer to our exhaustive data management plan as in Appendix 7. The Consort 2018 extension to stepped wedge randomised trials will be used (16).

5 Ethical approval and consent

Our research team will strictly follow ethical procedures, including the submission of the study protocol and related tools to the National Ethics Committee for Health Research in Cambodia (NECHR) and the ethical review board of LSHTM for review and approval prior to the start. We will also respect the voluntary nature of the participation as well as the confidentiality of the information provided by the participants. Individual informed consent will be sought from the participants prior to data collection. Study information will be posted in all the participating wards (See Appendix 8). The consent forms for each data collection piece are available in the appendices (Appendices 9-11).

6 Quality assurance and risk mitigation

The quality of this study will be ensured by joint efforts of LSHTM and its research partners throughout the whole process of the study, from the study design, preparation of the intervention, implementation and evaluation. All the engagement with hospital staff for the successful completion of the study will follow the principles of Good Clinical Practice. An advisory committee is being established to ensure the study follows the highest standards of research quality.

However, this study may encounter a number of challenges and uncertainties. The COVID-19 pandemic poses extraordinary challenges from the point of view health management and planning. With this mind, we are conscious that, in spite of our best efforts, it might not be feasible to conduct the trial with the timings as intended during national or local lockdowns prohibited. The team behind this study aspires to work together and guided by the Advisory committee adapt to the situation as we go along maintaining where possible the study rigour. Other potential limitations of the study include willingness to participate, participation fatigue, adverse events occurring at the staff, patient or hospital level during the trial, e.g outbreaks of HAIs (COVID-19), seasonal factors, organisational or policy changes. This will be mitigated by frequent monitoring of these in each site. Participating sites will agree to not implement changes that could impact the trial, e.g. cleaning policies or product use, without prior agreement from the study team.

Appendices

- Appendix 1: Questionnaire for interviews with hospital and ward leaders (available on request)
- Appendix 2: Observation checklist for hospital walkthrough (available on request)
- Appendix 3: FGD guide
- Appendix 4: Observation of training
- Appendix 5: Questionnaire
- Appendix 6: Lab SOP
- Appendix 7: Data management plan
- Appendix 8: Study information for wards
- Appendix 9: Consent form – trial
- Appendix 10: Consent form – FGD
- Appendix 11: Consent form – questionnaire

References

1. Allegranzi B, Pittet D. Role of hand hygiene in healthcare-associated infection prevention. Journal of Hospital Infection. 2009 Dec;73(4):305–15.

2. Bedford J, Enria D, Giesecke J, Heymann DL, Ihekweazu C, Kobinger G, et al. COVID-19: towards controlling of a pandemic. The Lancet [Internet]. 2020 Mar 17 [cited 2020 Mar 19];0(0). Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30673-5/abstract

3. Goldman E. Exaggerated risk of transmission of COVID-19 by fomites. The Lancet Infectious Diseases. 2020 Aug 1;20(8):892–3.

4. Ogunsola FT, Mehtar S. Challenges regarding the control of environmental sources of contamination in healthcare settings in low-and middle-income countries - a narrative review. Antimicrobial Resistance & Infection Control. 2020 Jun 9;9(1):81.

5. Cross S, Gon G, Morrison E, Afsana K, Ali SM, Manjang T, et al. An invisible workforce: the neglected role of cleaners in patient safety on maternity units. Glob Health Action [Internet]. 2019 Jan 15 [cited 2019 Dec 14];12(1). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338282/

6. Storr J, Kilpatrick C, Lee K. Time for a renewed focus on the role of cleaners in achieving safe health care in low- and middle-income countries. Antimicrobial Resistance & Infection Control. 2021 Mar 24;10(1):59.

7. CDC. Best Practices for Environmental Cleaning in Healthcare Facilities in Resource-Limited Settings: Version 1. CDC; 2019 p. 91.

8. Gon G, Kabanywanyi AM, Blinkhoff P, Cousens S, Dancer SJ, Graham WJ, et al. The Clean pilot study: evaluation of an environmental hygiene intervention bundle in three Tanzanian hospitals. Antimicrob Resist Infect Control [Internet]. 2021 Jan 7 [cited 2021 Jan 25];10. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7789081/

9. Malone S. Characteristics of adult learners. Training & Development. 2014 Dec;41(6):10.

10. Dramowski A, Whitelaw A, Cotton MF. Assessment of terminal cleaning in pediatric isolation rooms: Options for low-resource settings. Am J Infect Control. 2016 Aug 22;

11. Ivers NM, Halperin IJ, Barnsley J, Grimshaw JM, Shah BR, Tu K, et al. Allocation techniques for balance at baseline in cluster randomized trials: a methodological review. Trials. 2012 Aug 1;13(1):120.

12. Adams CE, Smith J, Watson V, Robertson C, Dancer SJ. Examining the association between surface bioburden and frequently touched sites in intensive care. Journal of Hospital Infection. 2017 Jan 1;95(1):76–80.

13. Smith SJ, Young V, Robertson C, Dancer SJ. Where do hands go? An audit of sequential hand-touch events on a hospital ward. Journal of Hospital Infection. 2012 Mar;80(3):206–11.

14. Rawlinson S, Ciric L, Cloutman-Green E. How to carry out microbiological sampling of healthcare environment surfaces? A review of current evidence. J Hosp Infect. 2019 Dec;103(4):363–74.

15. Hemming K, Kasza J, Hooper R, Forbes A, Taljaard M. A tutorial on sample size calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials using the Shiny CRT Calculator. Int J Epidemiol. 2020 Jun 1;49(3):979–95.

16. Hemming K, Taljaard M, McKenzie JE, Hooper R, Copas A, Thompson JA, et al. Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. BMJ. 2018 Nov 9;363:k1614.

THE CLEAN FRONTLINE STUDY

(London School of Hygiene and Tropical Medicine, National Institute of Public Health)

Study participant information and consent for staff with cleaning duties

Consent from cleaners

To be either read by the respondent, or read aloud by the investigator. The respondent will then either sign the consent form or make a thumb print to indicate that they agree to participate in the study

Introduction

Disinfection of near-patient hospital surfaces is essential to stop Hospital Acquired Infection (HAI) occurring.

Purpose of the study

The CLEAN Frontline study will test whether a training of environmental hygiene can improve environmental hygiene on the wards across thirteen Cambodian hospitals.

Your participation in this study is valuable and will provide key insights for the future use of cleaning fluids in this context and other low-income facilities.

Details of the study:

- The study will occur in your hospital _____. The training will be provided to staff in the new-born, maternal, and c-section wards in each of the participating hospitals (13 across Cambodia).
- The training on environmental hygiene will be provided at some point during the 10 months and the study team will let the hospital now 4 weeks in advance of the training.
- Each of the participating hospitals will receive the training at key four times during the 10 months. The timing on which hospital is trained when is chosen at random.
- An evaluation of to assess the impact of the training on environmental hygiene will occur during the 10 months.
- No human data is collected during this study
- The study will run for ___ months commencing on the ___ of ____

Conditions for participation

You will participate on 1-3 days training on environmental hygiene sometime.

Do I have to take part?
No. It is up to you to decide to take part or now. If you don't want to take part, that's ok. Taking part is voluntary and you are free to stop the discussion process at any time. If you decide not to take part we will respect your decision. We will not ask you why you do not want to participate. There will be no complaint or punishment.

Risk or Discomfort
We do not anticipate any risk to you during this discussion. No information on your personal performance will passed on to any of your colleagues or managers. All information we collect is strictly confidential and anonymous.

What are the possible benefits?
We cannot promise the study will help you but the information we get from the study will help our and the hospital and the NIPH knowledge and understanding to improve microbiological cleanliness in hospital settings.

Cost/Compensation
Taking part in this study will not result in any expense to you and no compensation will be provided.

Contact person for further questions or complaints
If you have a concern about any aspect of this study you can ask the observer any questions and raise any concerns. If they cannot help they will pass the question onto a senior member of the team. You may contact directly:

- National Institute of Public Health Obscured to ensure phone number privacy
- WaterAid Cambodia – Obscured to ensure phone number privacy
- London School of Hygiene and Tropical Medicine - Obscured to ensure phone number privacy

Confidentiality
All information will be kept strictly confidential. Any information about staff will also be anonymous. Your name and any identifying information will not be collected during this discussion.

What will happen to information collected about me?
All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Data will be held by NIPH and will be sent to other study staff in London, at the London School of Hygiene and Tropical Medicine. Transfer of data is necessary to analyse the data and draw conclusions on how to improve environmental hygiene in hospital setting in Cambodia. Aggregate level data will also be shared in the public domain for transparency – no individual identifiable data is collected as per part of this trial. We will not ask you any identifiable information.

Voluntary participation
Taking part is voluntary and you are free to stop your participation at any time. If you decide not to take part we will respect your decision. We will not ask you why you do not want to participate. There will be no complaint or punishment.

Permission to continue
"Do you have any questions for me?"

If informant has any questions, record questions and your response here:

_____
_____
_____

I, _____ (name of the respondent) have read and understood this text, understand what is expected of me and all my questions have been answered. I understand that I can ask for the observation to stop at any time without giving any reason. I freely accept to participate in this study.

_____ _____ **Date**: _____

Respondent's name *Signature*

_____ _____ **Date**: _____

Witness's name *signature*

Witness' signature: A witness' signature and the thumbprint of the participant or nominated person are required only if the staff member is illiterate. If possible, this nominated person should be selected by the staff member and should have no connection to the study team.

I have witnessed the accurate reading of the consent form to the potential participant or nominated person, who has had the opportunity to ask questions. I confirm that the participant or nominated person has given consent freely.

Print name of witness: _____

Thumbprint of illiterate participant

Signature of witness: _____

Date: _____

Investigator's signature:

I have accurately read or witnessed the accurate reading of the consent form to the potential participant or nominated person, who has had the opportunity to ask questions. I confirm that the participant or nominated person has given consent freely.

I confirm that the participant or nominated person has given his/her consent and accepts to participate in the study

Print name of investigator: _____

Signature of investigator: _____

Date: _____

A copy of this informed consent form has been provided to the participant or nominated person. |__|__|__| (Initials of the principal investigator/assistant).