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Citation: Gould, D. & Drey, N. (2024). Success of the CLEEN study. *The Lancet Infectious Diseases*, doi: 10.1016/s1473-3099(24)00454-7

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Success of the CLEEN study

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Words in text = 734

Healthcare-associated infections (HCAs) are the most frequently occurring adverse events in healthcare. They pose a major threat to patient safety and for many years were regarded as an inevitable risk of healthcare. Contemporary opinion is that fifty percent of HCAs are avoidable, however (1). Designing and executing rigorous trials to evaluate interventions to prevent and control HCAI demands methodological ingenuity. Consequently, the evidence base underpinning infection prevention and control (IPC) is fragile, and most IPC guidelines are based on expert opinion (2). Happily, the trial reported by Mitchell and colleagues (3) shows that robust IPC research is achievable.

Potential pathogens survive well on inanimate surfaces. Traditionally cleaning was undertaken to reduce the numbers present to avoid the risk of transmission but there was no evidence that cleaning could actually reduce HCAI (4). Over the last fifteen years however, observational studies have demonstrated that methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant Enterococcus spp. (VRE), *Clostridium difficile*, *Acinetobacter spp.*, and norovirus can be transferred from the environment to patients (5). Risks are compounded because it is unclear which staff are responsible for cleaning medical equipment that is shared between patients and is often overlooked (6). Mitchell and colleagues reviewed this literature (7) and identified an absence of well-conducted trials to demonstrate that better decontamination could reduce HCAI. The strengths of the trial that this team went on to undertake (3) lie in its rigorous design, implementation and the practicality of the intervention.

Although they are often large, ambitious studies, stepped-wedge cluster randomised controlled trials (RCTs) are manageable because the intervention is rolled out in waves to each new cluster, and it is possible to investigate and address any disadvantages of the intervention in the earlier clusters as the study progresses (8). A drawback is that the clusters receive the intervention sequentially over a period of time (8) and may be prone to confounding due to temporal trends, in this case seasonal variations in infections. The authors of the CLEEN Study (3) were alive to these risks and reassure us that the trial, which took place over nine months and covered the winter season when infections peak, was free of confounding. No major policy or other secular changes were documented while it was in progress.

The appeal of stepped-wedge cluster RCTs to health providers is that a potentially beneficial intervention will become available to everybody taking part. In the trial by Mitchell and colleagues (3), the enhanced cleaning and disinfection was additional to usual practice, directed at the regular cleaning team and did not involve the purchase and introduction of costly new technology. Cleaning staff received a one-hour training session conveniently delivered in-house and undertook a reasonable three hours of extra work each weekday. Process evaluation (interviews) revealed their preferred mode of receiving performance feedback.

IPC interventions are most persuasive if their 'success' is demonstrated through lower HCAI rates. All too often, authors report only proxy measures of infection: the 'effectiveness' of hand hygiene campaigns frequently rests on compliance to a hand hygiene intervention with no attempt to report HCAI (9). Michell et al (3) evaluated the impact of their intervention through two weekly point prevalence surveys of HCAI. Thoroughness of enhanced cleaning and disinfection was taken as secondary outcome measures. The economic impact of the trial is an important, substantial element of the work. The authors have sensibly decided to publish these findings in a separate paper.

Michell and colleagues (3) undertook their trial in a single organisation. This is a potential weakness as it is unclear whether the hospital is representative of others more generally, so external validity is unknown. However, as the authors point out, the issues related to cleaning and disinfecting shared medical equipment have been reported in many different countries and the equipment decontaminated was typical of equipment used in all clinical settings.

In summary this is a well-planned, well-executed study written in a clear and accessible style. The findings will be of major interest to health providers, IPC experts and policy makers internationally. The effect of reading it is like coming to the end of a good novel: the reader is left wondering what will happen next. Will this successful intervention be sustained in the participating hospital? How soon will the important economic findings become available? How will the IPC community respond to the findings of this important and well-conducted trial? Reports of replication in other health provider organisations are awaited with interest.

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