



Cleaning over clean: impact of a bundle of cleaning actions on health-care associated infections

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Health-care associated infections (HCAI) are a major threat on patient safety. According to the National and State Healthcare-Associated Infections Progress Report (1), in USA about 1 in 31 hospital patients has at least one HCAI. In 2015, 3% of hospitalized patients had one or more HCAI, and there were an estimated 687,000 HCAs, with about 72,000 deaths due to HCAs during their hospitalizations. Contamination of healthcare facility surfaces is known to play a major role in transmission of pathogens, mainly in intensive care units (ICU) where nosocomial infections continue to have a high incidence and are becoming of an important problem, as it is a major cause of morbidity and mortality in critically ill patients and are associated with increases in the length of stay and excessive hospital costs (2). Although in recent years a positive trend towards a diminution of these numbers can be found (3), there are still several measures to be taken in order to improve HCAI incidence. One of the mainstreams is, in a wide sense, the surface cleaning.

A non-systematic review carried out six years ago concluded that although it is true that a lot of studies support surfaces disinfection as a way to reduce HCAs, there remain a need for carefully conducted studies to determine its impact in real terms (4).

The REACH trial

The Australian group of Mitchell *et al.*, (5) working in this way, developed a stepped-wedge multicenter randomized clinical trial (REACH, Researching Effective Approaches

to Cleaning in Hospitals) in order to assess the effectiveness reducing HCAs of a bundle of cleaning measures. To do this, they designed a trial selecting hospitals with more than 200 beds, having an accredited intensive care unit and having also established HCAI surveillance programs. By means of a stepped-wedge design, hospital was computer randomly allocated to a starting time. Blinding was possible only for patients, because cleaning staff and statisticians were aware of timing of intervention.

The trial intervention was the application of REACH bundle at different times according to a randomization stepping. REACH bundle is a set of recommendations, mainly evidence-based, about optimal types of cleaning agents, as well as techniques, timing, audit strategies and training of cleaning. Hospitals were informed about REACH bundle eight weeks before the control phase, when cleaning procedures started following the training methodology learning. As a kind of quality control of cleaning, dots of a marker (invisible to the eye) were put in specific places in order to check the correctness of cleaning manoeuvres; cleaning staff were unaware of dots placing. 24 h after dots application, the sites were checked with a UV lamp to assess if the dot has been removed by cleaning.

In each hospital at least the 50% of the wards were selected to audit, and specifically the wards with the highest risk of infection.

The primary outcome was incidence rates of HCAI (*Staphylococcus aureus* bacteraemia, *Clostridium difficile* infection, vancomycin-resistant enterococci infections) at each hospital before and 4 weeks after REACH bundle

implementation. Incidence rates were expressed as cases per 10,000 occupied beds per day (OBD). Colonization was not assessed. An economic evaluation (cost-effectiveness analysis) was also done, but was not published in this paper. Secondary outcomes assessed were quality cleaning (measured by means of UV visualization of dots), bio-burden of frequent touch points after cleaning, changes in attitude and knowledge of staff, changes in clinical isolates and patient perception of wards cleanliness.

After application of inclusion and exclusion criteria, between May 2016 and July 2017, 11 hospitals (9 publics, 2 privates) with a median number of overnight beds of 500 were selected to implement cleaning bundle and to assess its effectiveness. Adjusted rate of *Clostridium difficile* (CD) infection per 10,000 OBD increased from 2.34 to 2.52 (relative risk 1.07; 95% CI: 0.88–1.30). Adjusted incidence of *Staphylococcus aureus* (SA) bacteraemia per 10,000 OBD was reduced from 0.97 to 0.80 (relative risk 0.82; 95% CI: 0.60–1.12), and vancomycin-resistant enterococcus clinical isolates rate was reduced from 0.35 to 0.22 (relative risk 0.63; 95% CI: 0.41–0.97), only the last being statistically significant.

With respect to secondary outcomes, the proportion of touch points cleaned increased in both the bathroom (odds ratio 2.07; 95% CI: 1.83–2.34) and the bedroom (odds ratio 1.87; 95% CI: 1.68–2.09). No changes were recorded in hand hygiene compliance, policies in hospitals or in antimicrobial utilization.

Authors concluded that REACH bundle improved cleaning thoroughness and “showed great promise in reducing vancomycin-resistant enterococci infections”.

Critical appraisal

REACH bundle trial is an ambitious effort to improve hospital health-care by means of educational and training cleaning measures, with the final purpose of limit HCAs. However, after more than one year of follow up and almost 5 million OBDs in 11 hospitals assessed, results have been unfortunately quite elusive.

Mitchell *et al.* (5) chosen a stepped-wedge model. This new and at the moment infrequent model is a specific form of cluster trials where randomization decides only when a cluster starts the intervention of the trial. The design includes an initial period in which no clusters are exposed to the intervention, but at regular intervals or steps, clusters are randomised to pass from the control arm to the intervention arm. This process continues until all clusters

have been included on intervention (6). Therefore, this kind of trial has not comparison group in a strict sense, and is in fact a design “after and before”, where every group act as comparator of itself.

A question requiring attention at first glance is the scarce number of hospitals remaining after application of inclusion and exclusion criteria. 30 hospitals were excluded because they have not accredited ICU, and other 13 because they have less than 200 beds. 58 more hospitals were rejected for other varied causes. Finally, only 11 hospitals meet criteria to participate in the trial. This strict selection could made conclusions very narrow and difficult to apply to a wide number of hospitals in a pragmatic way. Considering the inclusion criteria and the final number of hospital chosen, one could think that the REACH bundle works only in “high quality” hospitals. However, what about medium hospitals? Could we assume the same conclusions stated in REACH trial?

In this sense, it should be noted to the importance at the bundle of the education of the staff and the training of participants in the study, as well as the communication and the feedback between the team. This is a strength of study, nevertheless it supposes the need of human resources to be able to carry out in the clinical practice, which is often scarce, mainly in hospitals of the public health system.

Another important question is the baseline rate of CD or SA infections in selected hospitals compared to the non-recruited ones. Authors stated that rates were the same in SA bacteraemia (1.02 per 10,000 OBDs in included hospitals vs. 1.01 per 10,000 OBDs in excluded hospitals), but no data were provided about CD infections. According to a recent systematic review (7), CD infections are a largely variable item, with an incidence density ranging from 0.13 to 50.3 per 10,000 patients-day, being highest in elder patients. Regarding to vancomycin-resistant enterococcus, rates pre-intervention ranging in recruited hospitals from 0.00 to 1.79 per 10,000 OBDs, speaking about a wide variation among hospitals.

Blinding of intervention could be other potential source of bias in REACH trial. Cleaning staff was not blinded to the intervention and statisticians neither. Because this, observations can fall in a kind of “Pygmalion effect” or self-fulfilling prophecy (8), adjusting results to the expectative of the investigational team, as they implicitly recognize in a pilot study carried out with the same methodology but in a more restricted institutional frame (9).

Primary outcomes showed a statically non-significant increase in CD infections, a statically non-significant

decrease in SA bacteraemia and a statistically significant decrease in vancomycin-resistant enterococcus infections (see above for the exact numbers). However, results are presented in an unadjusted form in Table 1 and in an adjusted form in the text and in the abstract, leaving readers to a degree of “statistical” confusion.

Lack of patient colonization examination and of whole genome sequencing were mentioned by authors among the limitations of the study. As an accompanying editorial suggests, it is possible that SA bacteraemia was not affected by cleaning bundle measures because the transmitted cases could be related in a better way with an endogenous source (10).

Authors mentioned as a primary outcome a cost-effectiveness analysis that will be reported separately. This is a very interesting topic but, seeing the results of no change in infection rates after intervention, it lacks relevance. The poor results found cannot justify in our opinion the economic inversion needed to apply cleaning bundle measures. In the pilot study carried out for the same group abovementioned (9), authors spoke about an incremental cost of implementing bundle of AUD\$ 17,109 (USD \$11,759; €10,487) for a 12-month intervention period, being the largest cost these related to staff time. Considering that the only statistically significant result was the decrease of vancomycin-resistant enterococcus infections from 0.35 per 10,000 OBDs to 0.22 per 10,000 OBDs, and applying economic data published (9), prevention of one vancomycin-resistant enterococcus infection per 10,000 OBDs could cost AUD\$ 131,608 (USD \$90,454; €80,669). Really, this is a cost hard to be assumed, that needs a careful assessment considering also the quality of adjusted life years (QALY) gained in order to determine the cost per QALY and to take decisions about effectiveness of cleaning actions according to the threshold accepted.

Conclusions and take-home message

REACH trial, despite of its large sample and good design, failed to demonstrate that a bundle of cleaning actions could reduce HCAs in a significant way, confirming the previous results obtained in another more modest trial of the same group (9). Frequent touch points, however, were better cleaned with intervention, but we do not know how this outcome can improve HCAs.

Nevertheless, this is a very praiseworthy trial, maybe the first on this topic. We need this kind of pragmatic investigations, not only in the epidemiological field but also in drug investigation.

Cleanliness is very important, of course, but reducing HCAs needs other multifactorial interventions.

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