Reviewer's report

Title: The effect of implementing an aseptic practice bundle for anaesthetists to reduce postoperative infections. Protocol for a stepped wedge, cluster randomised, multi-site trial. The Anaesthetists Be Cleaner (ABC) Study.

Version: 0 Date: 05 Dec 2018

Reviewer: Karla Hemming

Reviewer's report:

Can you please justify why you think it is not necessary to take informed consent from patients (their data will be used in an anonymous form, the intervention is low risk and having to take individual level consent would render the study infeasible, perhaps).

It is really admirable that you are taking consent from the health care practitioners. Can you expand a little of the level and type of this consent. What will happen if someone declines to participate? You might be interested in looking at the Ottawa statement on the ethics of cluster trials - they have recommendations for from whom you should take consent in cluster trials and you are following their advice, which is commendable.

Line 219 to 220: "Quite substantial differences in practices and case mix may exist between departments, but intra-cluster correlation is likely to be quite high.". I think you mean "so" rather than "but" here.

Line 221 can you clarify if this is 4*5 clusters or just 4 clusters (wording unclear)

Could you justify your design more please? I understand and it is clear why you use cluster randomisation. But, please can you clarify the justification for using a SW design. You mention it is to do with the ICC, is this because you expect the SW design will be more statistically efficient due to the high ICC?
Inclusion and exclusion criteria - can you please clarify these at the individual level? What are these criteria for the clusters and for the health care participants?

Under withdrawal - are anaesthetists also free to withdrawer?

In table 3 you provide the schematic for the study. But, it looks like the order of the transitions has already been revealed - as the clusters are named on each of the rows. Can you clarify when the clusters were told when they would transition. And, can you clarify how this order was determined under a section subheading of randomisation.

Do you need to include a transition period during which the intervention will be embedded into practice? During this period observations could not be treated as either fully exposed or unexposed to the intervention, and so they would be excluded from the analysis. (I see you say this later, but please mention it earlier under the design).

Within cluster contamination: your outcome is 90 day survival essentially. How will you treat patients who are still on the ward when the hospital transitions to the intervention condition?

You intend to use a non-parametric approach. Jennifer Thompson has developed and published a permutation test for SW trials which you might be interested in. Using your approach can you clarify how you will present the treatment effect and its associated uncertainty? Simply reporting a P-value is unlikely to be informative.

You sample size justification needs a lot more detail. What method have you used, how did you implement it? Does it correspond to your proposed analysis? What is your event rate and your treatment difference? (It might be useful to consult the CONSORT for SW where there is a table of items to report in a sample size calculation). It might be OK to remove the power calculation for the secondary outcome.

Your section on "structure" needs to come much earlier. This is essential information that is needed before you justify your sample size.
You have a section on data collection on analysis, but you have already seemingly outlined the analysis earlier.

Can you expand on the interim analysis. How will you analyse the outcomes, and what outcomes will you look at? Will you make any multiplicity adjustments?

What will happen if one of the sites doesn't adhere to your allocation?

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