PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A stepped wedge, cluster controlled trial of an intervention to improve safety and quality on medical wards: the HEADS-UP study protocol
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VERSION 1 - REVIEW

REVIEWER	Yogen Amin UCLH, UK
REVIEW RETURNED	09-Mar-2015

GENERAL COMMENTS	I very much like the simple intervention approach. I have some questions. The design of the study is confusing, is this prospective, with the results collected from 2013-2015 or retrospective? Wht was the the primary outcome of measurement of excess of length od stay compared to peer instituions, and not look at its own data (with own control)? The authors have not described any problems with implementation of the tool, which is usual with an intervention of this nature as described well with other said types of intervention. Is there any control/standardisation of the briefing, or qualitative measure taken? On an ethics and duty of candour point of view, I would like a more robust follow up on some of the questions that may potentially caused harm to the patient, especially if themes are comimng from a particular area? I think having a more qualitative approach to the briefings and findings would eb useful, and yield more learning for the teams. The questions on the Heads up brief are confusing, in as they are mixed, some are directed at the team, some at the ward, some for the individual patient. The statistics needs more expert opinion.

VERSION 1 – AUTHOR RESPONSE

1. As previously discussed, the study should be registered, even if it is now retrospectively. The registration details should be given at the end of the abstract. It is worth also explaining to the office who advised against registration that cluster RCTs should still be registered.

The study is now registered with the ISRCTN registry (www.isrctn.com), identifier ISRCTN34806867. We have been transparent in the full manuscript that this registration took place prior to completion of data collection (page 19).

"The authors were initially advised by the Office for Regulatory Compliance at the Imperial College Academic Health Science Centre that registration with a clinical trial database would not be required, given the nature of the intervention. This decision was reviewed again, and the study registered – prior to completion of data collection – at ISRCTN (http://www.isrctn.com), identifier ISRCTN34806867."

2. The design of the study is confusing, is this prospective, with the results collected from 2013-2015 or retrospective?

As stated in the first line of the Methods section, this is a prospective study (page 8).

3. Why was the primary outcome excess length of stay compared to peer institutions, rather than looking at its own data (with own control)?

Wide baseline variation in length of stay – primarily due to differences between short stay patients on the acute admissions unit and longer-staying patients on downstream wards – limits study power. Using excess length of stay increases study power, without requiring an impractical time period for data collection or an unreasonable number of wards. We have now made this clear in the 'outcome rationale' table (Table 1).

"Length of stay varies substantially within institutions, with wide differences between the acute admissions unit and downstream wards. Using excess length of stay as an outcome increases study power, facilitating statistical detection of a meaningful change in outcome without requiring an excessive number of wards or data collection period."

4. The authors have not described any problems with implementation of the tool, which is usual with an intervention of this nature as described well with other said types of intervention.

We agree this is an important point. We have clarified that the narrative diary will focus on the factors perceived to facilitate or hinder the effective implementation of HEADS-UP, in the 'Fidelity of implementation and confounding factors' subsection of the Methods and Design section (page 14).

"The narrative account will also describe the observation of a number of HEADS-UP briefings, and the extent to which they held true to the perceived ideal in terms of participants, timeliness, focus and intent. The individual, team and organisational barriers and facilitators to the effective implementation of HEADS-UP will be assessed. Together with the objective outcomes listed in Table 1, and the staff survey (SAQ) data, this will complete a mixed methods analysis of the HEADS-UP programme."

5. Is there any control/standardisation of the briefing, or qualitative measure taken?

The reviewer is right that briefing standardisation would be preferable for high fidelity implementation. However, service pressures during the study period meant that no protected time was available for formal HEADS-UP training. Instead, the proposed format of the briefing was publicised in grand rounds, team meetings and opportunistic discussion with participants. We have made this limitation clear in the 'HEADS-UP implementation at ward level and clinical engagement' subsection of the Methods and Design section (page 13). How HEADS-UP was conducted in practice in each area, and the extent to which this adhered to the preconceived ideal briefing, will be described in the narrative assessment (see point 3, above). As we stated in the original manuscript, the conduct of the briefings will also be assessed in terms of the number and type of concerns documented, and the team decisions taken as a result – information which is available from the completed daily HEADS-UP pro-forma.

"No protected time will be available for HEADS-UP training, but the ideal format for each briefing will be discussed in departmental rounds, team meetings and with participating clinicians."

6. On an ethics and duty of candour point of view, I would like a more robust follow up on some of the questions that may have potentially caused harm to the patient, especially if themes are coming from a particular area?

Again, we agree with the reviewer that follow-up of specific safety concerns raised during the study period should be described in the protocol. We have clarified our study practice in the 'HEADS-UP implementation at ward level and clinical engagement' subsection of the Methods and Design section (page 14).

"…specific safety concerns and significant adverse events raised through HEADS-UP briefings will be emphasised to the responsible clinical team or governance body in order that they take appropriate action."

7. I think having a more qualitative approach to the briefings and findings would be useful, and yield more learning for the teams.

Please see points 3 and 4 above. The importance of the qualitative account of the study, which we recognise, was not emphasised in the original manuscript. We have now addressed this, as described above.

8. The questions on the HEADS-UP brief are confusing, in as they are mixed, some are directed at the team, some at the ward, some for the individual patient.

With respect, we see the range of information captured by HEADS-UP as a strength, rather than a point of confusion. As stated in our Introduction, frontline staff are privy to a host of insights about organisational and departmental performance, and individual patient care, which are rarely captured effectively. Both the literature review on which we based HEADS-UP prompts (e.g. Lubberding et al, 2011 – reference 1 in manuscript) and ongoing clinician input have highlighted individual, technical and structural components to unintended events.

The structure of the briefing moves deliberately through background service constraints, team problems, and onto issues with individual patients. This reflects the feedback we received from frontline physicians and nurses during the early pilot period, about what they deemed important. We have specified this was the case (page 17). As the reviewer says, this covers a range of issues. We felt that HEADS-UP briefings were an opportune moment to capture these diverse problems.

"Subsequent iterations of the HEADS-UP tool incorporated further feedback from clinical staff and clinical governance teams on the content and use of the HEADS-UP briefing."