Reviewer's report

Title: Keep Cool: Effectiveness of a web-based education program to improve vaccine storage conditions in primary care: study protocol for a randomized controlled trial

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Reviewer: Liz Baker

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Study protocol
Keep Cool: Effectiveness of a web-based education program to improve vaccine storage conditions in primary care: study protocol for a randomized controlled trial
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Trials (Submitted: 2015-03-04)

Reviewers Report

This protocol describes an RCT principally designed to evaluate the effectiveness of a web-based education program on the storage of vaccines. The target audience is primary care physicians and their assistants who are involved in the administration of vaccines. This study has the potential to contribute to the design of strategies aimed at addressing the deficits in vaccine storage identified in the literature and evident in practice. This issue is particularly relevant given recent increases in the volume and variety of vaccine products that need to be stored due to expanding immunisation programmes worldwide.

Generally, the protocol is clearly written and the RCT appears well planned. Overall I find that this protocol contains all of the required information, and is of a sufficient standard to fully explain the proposed study.

Major Revisions

The methods section is clear and well-structured and the content addressed within the intervention is well described. I have no major revisions to suggest. Comments/ suggestions on minor revisions are outlined below.

Minor Essential Revisions

1. The terms ‘practice assistants’ and ‘practice personnel’ are used along with physicians to describe the target population. It is not clear what professional group these personnel belong to, are they qualified nurses, unqualified health care assistants, clerical staff or all of these? This should be specified as it has implications for the utility of the intervention for training purposes and for the target readership.

2. Page 8, line 33- There is no explanation as to why the refrigerator closest to the reception desk will be selected in those practices that have more than one refrigerator.
3. Page 11, lines 5 and 6- The citations are sequenced wrongly and do not correlate with the reference numbers

4. Editing- The paper would benefit from additional editing before publication as a few grammatical errors are present for example: page 6, line 19: “To set up a comprehensive temperature monitoring” Additional word required: “To set up a comprehensive temperature monitoring system”. Page 4, line 34 “…vaccine storage manager and backup is documented by the study assistant already during recruitment” Re-wording required: “…vaccine storage manager and backup will have already been documented by the study assistant during recruitment”

5. The consistent use of the word ‘breech’ rather than ‘breach’ needs correction (page 2, line 15; page 6, line 13).

Discretionary Revisions/Suggestions

1. Safety issues are not addressed and the actions to be taken by research staff on discovery of breaches in the cold chain that are potentially harmful to patients should be described.

2. Many of the studies discussed in the background section are relatively dated (11, 12, 13, 18 and 19) with publication dates ranging from 1996-2002. Best practice guidelines for vaccine storage cited by the authors post-date these studies. More up-to-date studies should be referenced if available, though a cursory search does reveal a dearth of literature in this area. If this is indeed the case, it could be addressed in the discussion section.

3. The rationale for the sample size could be clarified. As previously noted, studies cited to support the assumption that 60% of refrigerators will be outside the target temperature range are dated (1996-2001), again more up-to-date studies should be referenced if available. The sample size calculation estimates a dropout rate of 20%; a reference could be added to support this choice.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

'I declare that I have no competing interests.'