Reviewer’s report

Title: A systematic score-card based approach to site assessment in preparation for Lassa fever vaccine clinical trials in affected countries

Version: 0 Date: 25 Oct 2019

Reviewer: Doris Lanz

Reviewer's report:

The assessment of site capacity is a key factor when moving into a new (geographical or disease) area, and the authors make a good case why it is particularly pertinent in vaccine trials such as those for LF. They also make a good case why such an assessment strategy is particularly timely, given the recent efforts to push the development of vaccines. The author's workings and the main results are only summarily presented, however, which I think is a weakness that could easily be addressed to help it stand out against existing tools and approaches. See comments below for more detailed suggestions.

Comments by section:

Generally, the methods section could be more detailed; for instance, L.131ff. could be clearer as to whether the scoring was predetermined as well (i.e. before receiving site responses).

L.118, reference 7 - perhaps specify that the downloadable "Site readiness checklist for vaccine trial" is meant (presumably).

Compared to this original questionnaire, the questionnaire presented in Table 1 introduces some substantial changes - they appear pertinent (such as inclusion of surrounding infrastructure) but perhaps the subsection "Site assessment" would merit more of a discussion of why certain sets of questions were added or removed.

L.148ff, Results: Compared to other sections (particularly discussion), the results section is somewhat cursory. As a reader I would be interested in learning...

… whether any non-mapped sites responded (e.g. among those targeted through social media)

… in L.163-187, which of the discussed features are particularly lacking in group C, or present in group A. Could more be said on which features would typically tip a site into a lower rated group? Would it not be possible to present a table with summary scores for the three Groups A-C, e.g. grouped by the 4 broad areas derived from TDR competency wheel?

Additionally, the previous conduct of vaccine trials is particularly highly weighted in the scoring. Did any sites who answered "no" end up in group A nevertheless? I wonder if there might be a potential circular argument in that sites previously not conducting vaccine trials (but in countries with high LF prevalence) might be prevented from being selected on such grounds - perhaps much like the CROs that you decry in the discussion section. Of course your data might show the exact opposite - which is why it might be worth showing more detail.
L150: What does "week 9" refer to? Given sites had 3 weeks to respond. If weeks are discussed, it would be useful to give a whole timeline of the research elsewhere.

L196ff, Discussion: While raising many valid points, not all of these appear immediately relevant to the subject, and the whole discussion section could be more focused on the specific study objective. E.g. how does the discussion of regulatory barriers (L290-300) fit into site capacity discussion?

L258-270: How does your approach differ from the ones that CROs take? This could be highlighted more clearly.

The conclusion section only briefly alludes to points that would be very interesting to know more about, such as:

… "most sites are willing to perform vaccine trials in the future, provided certain capacity gaps can be addressed" - does this highlight sites' own responses to what would be needed for capacity building?

… To what extent are the identified gaps within or outside the ability of the individual site to address? E.g. staff training is easier to influence than road surfacing.

… Most importantly, the current use and future plans for this tool are only briefly alluded to in the final sentence of the paper. Please elaborate on follow-on work. Ultimately, this is where the claim "It is feasible to hold Lassa fever vaccine trials in affected countries" (L. 67) can really be validated.

Table 1 comments:

Numbering of questions is inconsistent, please review.

Column "Total" - is this meant as "maximum possible score"?

Please review scoring of the question "How many clinical trials has the site conducted" - there is overlap in the answer categories (2-5 and 5-9).

Please review scoring of the question "How many kilometres away is the ICU (if not on site)" - highest rated answer gives a score of 2, but the maximum score is only given as 1. This would suggest the total score for section 6.2 is 12, not 11.

Question "If not laboratories on site…" in section 6.4 - what is the score here for sites that do have a laboratory on site (i.e. where this question would be not applicable)?

Question "List below the different laboratories available" - the scoring of "highest=6, lowest=1" is not clear to me.

Other minor points

List of abbreviations: Should these not be spelled out?

L. 86-88; unclear wording, please review (What does "These" refer to; "and stockpile and"…?)
L. 107ff. Clarify whether site mapping was restricted to affected countries; potentially specify the countries here.

The paper overall, but particularly the Results section would merit some revision for language, particularly tense (e.g. stick to same tense in results section throughout), punctuation and imprecise wording.

L201-203 - "6677 ongoing clinical trials" - do you mean vaccine trials specifically?

L221 unclear wording, revise.

L230 "can represent a considerable amount" - of what?

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