Author’s response to reviews

Title: Task shifting for point-of-care early infant diagnosis: a comparison of the quality of testing between nurses and laboratory personnel in Zimbabwe.

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Author’s response to reviews:

Reviewer #1

Comment 1. In section on Measures: It would be helpful to describe the level of education, number of years of work experience, and number of staff in each facility. These factors can inform the decision to choose someone for task shifting.
Response 1. We have included number of staff in each facility in the subsection. Since this was secondary data analysis, we did not covered by our IRB approval to collect specific demographic data of our testers such as level of education and number of years of work experience.

Comment 2. In laboratory method section you mention the Zimbabwe National Quality Assurance Program (ZINQAP). Please describe briefly about this program to help other teams to replicate this.
Response 2. Done, description given

Comment 3. On last line of discussion you mention task shifting as a good intervention: Describe some negative consequences of task shifting to be considered before implementing the program.
Response 3. From the analysis, we did not have evidence of any negative consequences of task shifting

Comment 4. Also describe limitations related to the study design like accuracy and completeness of data. Done.
Response 4. Included a section on limitations

Reviewer #3

Comment 1 (minor). Title: The present title is not specific as to the study population and study setting. Specifically, non-laboratory trained personnel could refer, for example to "lay personnel" or to any other professional group. I suggest you specify the cadre you involved in your study, as suggested in
the alternative title. If you so wish, the term non-laboratory trained personnel would be appropriate in your discussion section.
Response 1. Proposed change accepted

Comment 2 (minor). Abstract: Authors state that data were uploaded into an Excel-based database for analysis. Would you like to be more specific as to which database this was? For example, your first reported finding of no significant differences in IQC failure rates between the non-laboratory testers and trained lab personnel, p=0.354. In STATA version 15.1, the computation results in a p=0.327 for the stated statistics.
Response 2. Specified it was a project based database

Comment 3 (minor) The introduction/ Background - adequately sets the scene by stating the problem and justifying why the study was conducted. In the last paragraph of the background, please state the objective of this study more clearly than narrating what the data sources were used for (because the latter will be addressed in the methods section).
Response 3. Corrected

Comment 4 (Major)
Under the study design section - "We conducted a quasi-experimental secondary dataset analysis". This should be corrected to - We used a quasi-experiment study design. Then go on to describe the approaches and data sources - retrospective study using …. secondary data sources for the analysis etc. To qualify as a quasi-experiment however, you need to more articulately describe the experimental / intervention group, and the comparison group - so that a reader discerns the quasi-experimental nature. Some questions also need to be answered, for example.
What was the defining feature of the intervention, and how does this differ from the comparison?
How many comparisons were selected per intervention and why?
How were comparisons selected to ensure that there was no contamination of the intervention, or even how was contamination assessed, and/ accounted for in the analysis - especially that this was a secondary data analysis? You might consider including this within your study limitations section.
What was done differently in the intervention, compared to the comparison sites (training, data collections etc). Finally, what exactly was the intervention? - This doesn't come out clearly in the existing write up, even if it is a retrospective analysis, it should be made as clear as possible.
If it is not a quasi-experiment, you had better leave out this nomenclature in your definition of methods, and instead call it ("a cross-sectional retrospective study" using a secondary data analysis). A key definitional feature of an experiment or quasi-experiment is the timeframe through which the intervention should take effect, with our without the randomisation to the intervention, respectively.
Response 4. Suggestion accepted, design changed to a cross-sectional retrospective study" using a secondary data analysis

Comment 5 (minor) "Hub and spoke model" needs a description and reference.
Response 5. Explained that in the “Study sites” section of the METHODS

Comment 6 (minor) "In consultation with the health facility executive, platforms were either placed in the maternal neonatal and child health department (MNCH) or in the laboratory".
What do you mean by platform? Do you mean POC EID testing sites, or health facilities with specific cadres of health care workers, or training facilities? You need to provide more clarity here. Also, how are the hubs and spokes distributed within the platforms?
Response 6. A platform is a very much acceptable word in diagnostics and is synonymous with the word machine. Have indicated that platforms or machines

Comment 7 (Major). You acknowledge that 6 of your sites had nurses, 2 sites had laboratory-trained staff, while the 2 had a combination. Can you present a table that disaggregates how many tests were collected from each of these site categories (nurses only/ lab personnel only/ nurse and lab)?
Response 7a. Done in table 1 and 2
Could you also run a sub-analysis with these sub-categories as it would delineate confounding?, by stratifying your findings within these (naturally occurring) categories.
Response 7b. A sub analysis will not be possible because the proposed categories will be highly correlated with our main variable of interest “type of tester”. So for example the nurses only category will contain only nurses as the type of tester and no lab personnel will be in the analysis.

Comment 8 (Major): Study participants - "We analysed tests conducted by 45 testers (33 non-lab, 12 lab trained)". How were participants distributed between the platforms (hub and spoke testing sites)? I suggest that you take time to describe in detail the sampling process more clearly. If your first stage was sampling at the platform (hub/spoke level), how then did you sample out the next level participants? Perhaps, you should provide the sampling process a sub-heading - to increase the clarity of your methods and to enhance the potential for replicability.
Response 8. As highlighted in the study participants section, we analyzed data from all 46 sites (10 testing sites and 36 spoke sites) in Zimbabwe providing POC EID or near POC EID for routine clinical use. Hence there was no sampling done.

Comment 9 (minor). Measures - "data were downloaded from …… Detect platform" What is the Detect platform? Perhaps you need to describe the information management software run by the POC-EID devices, and reference this too. You also need to describe the nature of data generated by this device - which you downloaded into excel. For example, is it .xls files, .dba files, .mdb files etc.
Response 9. Clarified that data was downloaded as an xls file. Also clarified in comment 6 that a platform is a machine.

Comment 10 (minor) Analysis. "We conducted another binary logistic regression model after controlling for clustering" - at what level was clustering controlled for? If you consider level of experience as a cluster - isn't this spurious as you would expect number of tests to be determined by the workload at the health facility. A more reasonable clustering effect, which would determine the similarity of participants at baseline should be - the timing of EID training/ or, the recruitment into the program/ or the category of health facility (MNCH facilities vs Lab-only personnel, vs combination of MNCH & Lab personnel).
Response 10. We considered the fact that we have multiple test results per tester and due to experience, the assumption of independent observations was violated. Also there was a possibility that only a few individuals where contributing to poor quality of results.
Comment 11 (Major) Analysis. Considering that this is reported as a Quasi-experimental design. There is no mention of how the time element was dealt with. For example, what set of results is considered as baseline, and what set is considered as endline? Or better still, how many general time points (if more than two were considered) for the program implementation does this analysis refer to? Is this a pre-post design with a comparison, or just a comparative analysis? Please note, this comment is related to comment 4.

Response 11. Falling off as I have made revisions to comment 4, considering the study to be a cross-sectional retrospective study design

Comment 12 (Major). "Figure 1 IQC failure rate by type of provider over time". If this were a quasi-experiment, I would expect to see this failure rate in groups (intervention/comparison) shown against each of the time points for which measurements are considered. In its form - this only confirms a comparative retrospective analysis.

Consequently, the discussion and conclusion for a quasi-experiment would base on a regression controlling for baseline findings over the desired endpoints of analysis (e.g model at endpoint time1, time2, time3 etc). This would be more helpful in informing us, given the resource investment of training, supervision etc for EID nurses, how long does it take to obtain EID test results that are comparable to the test results of lab-trained personnel?

Response 12. Falling off as I have made revisions to comment 4, considering the study to be a cross-sectional retrospective study design