Reviewer's report

Title: Improving data quality and supervision of antiretroviral therapy treatment sites in Malawi: an application of Lot Quality Assurance Sampling

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Reviewer: Stephanie Topp

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Review:
Improving data quality and supervision of antiretroviral therapy treatment sites in Malawi: an application of Lot Quality Assurance Sampling

This paper quantifies current levels of data quality in Malawi’s national HIV program which relies on comprehensive review of all patient records and associated registers, and compares with a proposed Lot Quality Assurance Sampling method. The rationale for this study is to assess whether the LQAS approach reduces overall workload (while maintaining appropriate quality assurance) to improve efficiency and sustainability of data management for Malawi’s national HIV program.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

1. Abstract: The authors state in the abstract that the study will ‘evaluate the feasibility’ of LQAS as a tool to lower the costs. This differs from the stated goal (pg 4, para 3) to: ‘evaluate the performance of a LQAS algorithm to prioritize ART sites with poor data quality’. Feasibility implies testing under operational conditions, with LQAS subject to the challenges and limitations of implementation. Recommend re-phrasing abstract to more closely reflect the actual study and goals as stated in body of the text.

a. Similarly applies to page 6, para 2: should be rephrased to “evaluate the performance of LQAS algorithm…” The feasibility cannot be established from this study since the research was done in clinics whose staff anticipated a full (100% of records) review. The findings presented here do not establish how staff / supervisory teams perform under the LQAS system, and so cannot genuinely establish feasibility.

b. Page 11, para 2: the claim that ‘this system addresses the disappointment of clerks and heath workers...’ is unsubstantiated and needs to be removed.

2. Background (pg3, para 2): Additional background as to the make up of the quarterly supervision teams (for example are they ever accompanied by or led by NGO or other partner organization staff?), where funding comes from and how it is administered, and the reporting responsibilities and other mentoring duties of the teams, is important to understand how a shift to LQAS might impact QA in
this setting.

a. Page 9, para 1: ‘one unique benefit of LQAS system is that the assessment is integrated into routine supervision and immediately linked to actions that improve data quality” # this link is not well described and further detail is necessary to understand this benefit.

3. Background/Findings/Discussion (pg4, para 1): Page 4, para 1, last five lines discuss how Malawi struggles to maintain data quality; this seems inconsistent with later claims (Discussion, pg 9, para 2) regarding the overall high level of data quality, and the claims that clinic staff mostly update and correct their own registers. More nuance is needed in describing the baseline situation, and the impact of QA in this setting to make sense of the quantitative findings being presented. For example – the findings from this study report generally high levels of concordance between patient cards / registers, BUT also reports fairly low quality and inconsistent recording levels for side effects, pill counts. What accounts for these differences across different indicators – and how would they impact assessments of clinics’ data management performance?

4. Did the clinics’ know in advance that the supervisory team would be accompanied by researchers?

5. Limitations should acknowledge possible Hawthorn effect on both clinics (if relevant) and supervisory team.

6. Limitations should acknowledge that the extrapolation regarding number of team hours taken to clean data each quarter (pg7, para 1) assumes the same average quality of data across all clinics in Malawi. Since these findings are based on a non-random sample, this may not be the case.

7. Page 9, para 1: Of 16 sites, only 41%-97% of sampled treatment cares were from patients alive on treatment? – what was the break down of dead, LTFU…etc

8. Findings need to explicitly state how many cards were not available (resulting in the ‘skipping’ protocol).

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Abstract: final sentence of ‘methods’ needs revision to make sense.

2. Abstract: in findings, suggest revision to ‘28.5 hours in total’ to clarify it is not this much time per clinic

3. Background (pg3, para 1): Need to define ‘experienced sites’ -- +1 year, + 2years?

4. Background (pg3, para 2): List of primary outcomes and secondary outcomes should be punctuated to read more clearly. EG: Primary outcomes include: i) alive on ART; ii) died; iii) stopped ART….etc

5. Background (pg3, para 2): what is the difference between ‘stopped ART’ and ‘lost to follow-up’?

6. Page 6, para 1: n=76 is redundant and could be removed.
7. Page 6, para 3: Stata V.11 and R v.2.0.1 (insert period after both ‘v’)

8. Page 10; recommendation 1: seems counter-intuitive that smaller (versus larger, busier) sites are making more errors? Background/site selection discussion could provide more detail on this.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

1. Background (pg3, para 1, line 4): ‘The success of Malawi ART program…’ suggest revision to ‘The successful scale-up of Malawi ART program’ since ‘success’ can be defined in many different ways.

2. One site had demonstrably poorer data management that the others. It would be interesting to understand why this was the case

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests