Reviewer's report

Title: Prescriber and patient-oriented behavioural interventions to improve use of malaria rapid diagnostic tests in Tanzania: facility-based cluster randomised trial

Version: 1
Date: 21 January 2015

Reviewer: Stefan Peterson

Reviewer's report:

This is an important study that assesses behavioral interventions with great potential to improve appropriate malaria prescriptions and RDT use/adherence, as demonstrated by the study’s results. Below are comments and suggested revisions:

Major compulsory revisions

- Timeline: It would be helpful to have a clearer timeline (revise Figure 2?) since different interventions were introduced at different times during the study period. This would help clarify the dates for study implementation and particularly in relation to the different rounds of data collection. For example, please make clear in this figure that the workshops were introduced 4-6 weeks after RDT training, and the different lengths of time each intervention was running prior to its evaluation.

- Outcome: More clarity needed in terms of outcomes.
  1. Please provide more precise definitions, including labels in figures/tables (e.g. eligible and ineligible RDT? rAM or AM?)
  2. Lack of clarity also stems from reporting many various indicators, and not just the most critical ones (e.g. Table 4). For example, does this paper need to present “quality of RDT reporting” indicators when it is not central to the discussion or their implications? Does Table 4 need to report all indicators listed or could you refine to only the most important?
  3. I am also not clear if you are consistently reporting the same outcome, e.g. ACT or any anti-malarial treatment (e.g. Table 4 is not clearly labeled and differs from Table 3 in this regard?).
  4. I find Figure 3 hard to follow and it makes me wonder if the primary outcome should simply be inappropriate RDT use and adherence rather than inappropriate malaria treatment for non-malaria non-severe illness, which is a tricky outcome to define and leads to some of this confusion as captured in Figure 3. Does capturing the (small?) issue of AM treatment to non-fevers, UTIs that are not tested (or eligible/ineligible for testing?) muddy the outcome and take away from the central problem of use/adherence to RDTs to improve treatment of non-malaria illness, as defined by a RDT-negative result.

- Tables and Figures need to be streamlined and consolidated, and present only the most important information with clear labels and definitions. For example,
could Table 1 and 2 be consolidated? In Additional Table 1, what is HWC – is that same as HWP? In Tables 3 and 4, how is prevalence defined? what is RDT eligible and ineligible? Are you reporting on recommended anti-malarial or any anti-malarial treatment, and if the latter, why? Need to reduce the number of indicators reported to only the few most important in this table as well as in other figures/tables. I also think Table 4 should show results for each evaluation period, and also stratified by age (under five or older patient), which would be quite informative. Finally there needs to be better harmonization between figures and numbers cited in text. This is now always consistently done (see paragraph starting “Table 3…”). In other instances, it is not clear how numbers cited in text are derived from the figure (e.g. Figure 3 and relevant text). Please clarify.

- Facility selection and randomization: Why did 25 of 90 facilities refuse exclusive use of RDTs? It is also not clear why/how only 36 of 55 eligible facilities were selected and then randomized. Please clarify.

- Malaria transmission: Need to be clear on differences in malaria transmission across study districts and over time during the study period, and to state clearly how this is handled in analysis and then its implications for study results. For example, in the methods section, how is low and moderate transmission specifically defined for the two districts and among facilities? How specifically did transmission differ over time as briefly mentioned in the methods section but not fully discussed elsewhere? It seems you stratified by malaria consultations but you do not state a threshold level for this stratification, nor if malaria consultations were defined by a clinical or confirmed diagnosis. This is important to understand how well the issue or malaria risk is handled in the design/analysis. Finally, did data collection occur during peak or off-peak malaria transmission seasons – or was it a mix for different evaluation periods? How does all of this potentially affect results, particularly the result that the control arm with standard training also showed significant declines?

- Discussion Need to more fully discuss the following important issues:

  (1) The limited nature of the patient intervention (e.g. targeting only patients already presenting at facilities and not community sensitization; implementation challenges – did all patients actually receive the leaflet? Were all patients able to read the leaflet?). Could alternative methods to improve community sensitization to diagnosis and treatment have improved results in the HWP arm?

  (2) Malaria transmission intensity – This is mentioned in the methods section but not in the discussion about its implications for results. Could declining malaria transmission affect these results, and if so, how? Are there contextual factors or other programs operating in these districts that could raise awareness about malaria case management and then also affect results? Reductions in inappropriate treatment in the control arm with standard training require further thought and explanation, possibly due in part to other factors?

  (3) The standard training (control arm) had quite significant reductions without any additional provider or patient oriented interventions, and I think this needs more thought and discussion. Why do you think this occurred? What are program implications of these results? Specifically, when should a program consider doing
only the standard training (which also led to significant declines) and when should a program consider implementing additional interventions for the provider alone or for both provider and patient? What other types of interventions should be further researched, e.g. community sensitization?

- Footnotes: All factual statements need footnotes, which is not consistently done (e.g. first sentence and last sentence in second para of background section; “…despite large number of training interventions…” in background section; footnote evidence for important correlates to primary outcome in methods section; etc etc)

Minor essential revisions

Title:
- Is the outcome to improve RDT use or to reduce inappropriate malaria treatment? Your primary seems to be outcome the latter – so does not necessarily support the title phrasing as it appears now.

Abstract:
- Need for high quality evidence to improve prescribers’ practices is certainly more to do with mixed program success in terms of RDT adherence rather than simply increased RDT investments (if increased investments was met with strong programs there would be no need for this study, correct?)
- Clarify outcomes – is it any anti-malarial or first line treatment? See other comments on outcomes.

Background:
- Second paragraph “…due to persistent preference” – this is too simplistic since RDT non-adherence is result of complex patient-provider interactions and other factors e.g. RDT mistrust. Rephrase.
- Third paragraph first sentence “increasing investments in RDT…” as reason for this study, but isn’t the primary reason actually mixed program results to date – see abstract comment on same point.
- Third paragraph – how was design of intervention based on mixed-methods research – what did this research show and how did it influence the design of this study. Please elaborate. This is also brought up in the discussion section as a unique strength of the trial but it is not well discussed there.

Methods:
- Patient intervention is only among patients already coming to health facilities and not a community intervention to target ‘potential patients’. Is this correct? Need to be clearer in the methods and discussion about the limited nature of the patient intervention, and how this could affect results.
- Figure 2 - Please clarify why there is only data collection in 9 HW-arm facilities during Period 1? Why were there fewer patients in Period 1 and 4 data collection rounds? How does this affect analysis?
- Characteristics of study population – give figures in this first paragraph. Higher proportion of poorest patients found in HWP-arm. How would this affect results?

- HWP-arm – was there any check that these posters and leaflets were consistently displayed or given out to patients at facilities throughout intervention period, if so, how? What about illiterate caregivers that may not read posters or leaflets, and higher proportion of poorest caregivers in HWP arm is problematic for this reason, correct? Where were posters displayed? When and by who gave out leaflets to patients? How was this intervention actually done? Please clarify, and also more fully describe the limited nature of this patient-oriented intervention in the discussion as compared to the provider intervention.

Discussion and Conclusion

- “Formalizing such a process requires….” I think it is more complicated than discussed. Consider revising

- Conclusion says the study demonstrates “that a combination of provider and patient behavioral interventions…” is not necessarily correct since this study did not demonstrate real added benefit of the patient oriented intervention. Moreover, the control arm also showed quite significant declines that has program implications as well and should be raised more fully in the discussion and conclusion.

Discretionary revisions

Abstract:

- Second sentence – ‘both outcomes’ please clarify, not clear what this means

- Conclusion last sentence – refers to ‘acute febrile illness’ but your study examines non-severe non-malarial illness.

Background:

- You state RDT is affordable and accurate, but isn’t a main reason is that RDT in fact allows for diagnosis in remote, rural facilities where it was not previously possible.

- Footnote 19 duplicates previous reference, is this correct?

Methods:

- “Training materials were delivered as planned and well-received” This is not specific and I would think assumed to be the case unless otherwise stated. Consider deleting this sentence.

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