Author's response to reviews

Title: Assessment of Directly Observed Therapy following Tuberculosis regimen change in Addis Ababa, Ethiopia: a qualitative study

Authors:

Daniel F Fiseha MD, MPH (danielfsh3@gmail.com)
Meaza D Demissie MD, MPH, PhD (meazademissie@gmail.com)

Version: 6 Date: 15 May 2015

Author's response to reviews: see over
Reviewer's report (Reviewer 1)

Title: Directly Observed Therapy following Tuberculosis treatment regimen change in Addis Ababa, Ethiopia: a qualitative study

Version: 5 Date: 4 February 2015
Reviewer: Desalegn Woldeyohannes

Reviewer's report:
Minor Revision: Editorial errors all through the document and it need to be edited.
Thank you for the comment, the whole document was thoroughly reviewed and all editorial errors were corrected.

Major Essential Revisions: The title needs modification………………was not exhaustively stated…..title must at least explain the abstract and some of the objectives. Please improve it accordingly
Accordingly the title modified as below
Assessment of Directly Observed therapy (DOT) following Tuberculosis regimen change in Addis Ababa, Ethiopia: a qualitative study (See L 1)

Abstract: should be rephrased……the same sentence in the text appeared as they are here…..not recommended.
Comment accepted and the abstract section was revised accordingly (See L 2 – L 54)

Background: The second and third sentences are not necessary. Rather you could mention some points on the statements of the problem.
The 2nd and 3rd sentences were omitted, some points on the statement of the problem included (See L 31)

Avoid the word ‘tried’ and replace with ‘aimed’ Methods:
“Tried” replaced by “aimed” (See L 33)

Mention software used to analyze the study Include:
Software used included which is Open code V 3.5 (See L 39)

Study area: AA (selected clinics and hospitals)
Study area included (See L 38)

Results: do not report all the thematic areas identified such:
No DOTS for continuation phase
Family support is very essential.

Comment accepted and Result section modified accordingly (See L 42 – L47)

Conclusion: Conclusions should direct your major findings relative to your objectives for example HF workers concern was not mentioned.
Modified accordingly (See L 48 – 54)

Good to mention challenges identified.
Delete the second sentence…..fit ill the recommendations must only be emanated from the gaps observed in the result……some of them aren’t and some are left unmentioned.
Comment accepted modified accordingly (See L 51 – 53)

Main text

Background: should focus on the local situation and the area of interest, Assessment of DOTs after regimen change and be able to justify their study objectives.

Second sentence seems Ethiopia accounts for 80% of the world’s TB cases.

Sentence modified (See L 59)

Need to rephrase! Write words and/or phrases in full first to abbreviate ........and once abbreviated you don’t need to write in full again..... so many of these in the whole text.

Checked the whole document and corrected accordingly

You should include gaps observed from other studies carried out elsewhere on DOTs after regimen change......major limitation of background. It lacks also coherence and somehow appeared choppily. DOTS Vs DOT throughout the text....don’t use interchangeably as they have different meanings. The background is too long.........try to shorten it....maximum 1 and half A4 size.

Comment accepted and modifications made accordingly

Methods: The journal requirement is not fulfilled Please go and read the authors instructions

Hint: it is good to classify into subsections include:

Study design
Study setting
Study participants
Data collection and procedure
Data quality assurance Data analysis
Ethical considerations

Comment accepted modified according to the outline recommended above (L 100 – L152)

Avoid redundancy of sentences to keep the quality of the study.

Comment accepted and correction made in accordance

Results: Well presented but still need rigorous cleaning for grammatical and topographical errors.

Comment accepted and correction made

Discussion: The discussion section needs much improvement. One can show the important findings of a study in short at the beginning the discussion, Suggestion on how to organize the discussion

1. First main findings of the study in relation to the objective (very short)

2. Interpretation of the result by authors

3. comparison with other studies/ with similar themes/ ....major weakness of this study................. as the BMC Infectious Diseases is an international journal with international readership, it will appeal more to readers if authors could compare their findings with other studies in other settings of Africa and Asia as well as middle-income countries with results and also suggest/discuss reasons for these differences/similarities in the outcomes.

4. Limitations of the study
Comment accepted and limitation of the study was included (See L 375 to L 378).
In addition; Paragraph 4 need reference/s Lacks coherence for example paragraph 6 should come before paragraph 5.
Comment accepted and paragraph 6 was taken up before paragraph 5 (See L 346 to L 358).
Conclusion: Conclusion made is weak…..this could possibly be arise from disjunction occurred between objectives and results In general, conclusion should focused on major gaps/findings/results relative to objectives……………………suggestion you can focus on the five themes identified.
Recommendations should be emanated from the gaps identified……again consider conclusion and hence the 5 points….common mistake! Given the above information……..I strongly recommend to rewrite it……….the current one is choppy.
Conclusion and recommendation modified accordingly
Abbreviations: are not exhaustively written out example HEW, HC, HCP etc and even those listed have topographical errors.
Additional list of abbreviation included
References: Don’t follow the BMC series Journals style of citations. Go and refer please!
1 Journals should be italicized
2 Full stops at the end
3 Write full name of authors at first not first letter as in 5 for example
4 Try to list all authors …avoid etal as in 11, 14.
5 First letter of author’s middle and sure names are necessary for example in 13.
6 Journals should appear in bold. In general needs major revisions. Its strength is most of the references cited are in the last 5 years!!
References journal style of citations modified in accordance

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

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

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:** I declare that I have no competing interest
Reviewer's report (Reviewer 2)

Title: Directly Observed Therapy following Tuberculosis treatment regimen change in Addis Ababa, Ethiopia: a qualitative study

Version: 5  
Date: 8 February 2015  
Reviewer: Akaninyene – Out

Abstract

Background
Line 40–41. It is pertinent to state how much of the previous regimen (prior to 2010) was directly observed. Consider recasting the statement line 41-43:  
Thank you comment accepted and the previous regimen DOT was mentioned (See L 28 to L 30)

Therefore this study tried to investigate the experiences of implementing directly observed therapy (DOT) as a means of TB patients’ treatment supervision from both TB patients and some health care providers’ perspective in three public health facilities in Addis Ababa.  
Comment accepted and modified in accordance (See L 30 to L 31)

Results
Line 34: 34 participants (18 TB patients and 16 Health care providers) were involved  
Correction made (See L 34)
Line 53: had implications for (See L 40)
Line 53: TB patients had to (See L 41)
Line 54: on a daily basis (See L 42)
Line 55: Health care providers shared their deep concern regarding the risk of acquiring (See L 44)
Line 56: multi drug resistant TB (MDR-TB) while working in (See L 45)

Conclusion
Line 60: associated with a facility based DOT as a method of TB treatment  
Line 62: indicative of the situation in other health facilities found here in Addis Ababa or  
Line 66/67: and has to introduce and strengthen a more patient-centered approach and further decentralize DOT to ensure adherence of TB patients to their TB  
Line 80: and control the TB epidemic.  
Comment accepted and modification made in accordance (See L 47 to L 52)

Line 88: Consider breaking this sentence: This recommendation was based on the trial of the International Union against Tuberculosis and Lung Disease (The Union) demonstrating increased
efficacy of 2HRZE/4HR over 2HRZE/6HE and the pressure for adoption of the 6-month regimen increased once it was shown to be clinically superior to the 8-month regimen [8] also the 8-month regimen (2HRZE/6HE) is associated with more relapses and deaths than the 6-month rifampicin regimen (2HRZE/4HR)

Comment accepted and sentence modified (See L 70 to L 75)

Line 106: Consider breaking this sentence: Since September 2010, the federal Ministry of Health, decided to implement the regimen change across the country in a phased manner, and it was piloted in selected facilities of three urban regions namely Addis Ababa, Dire Dawa and Harari, and followed by full expansion and scale-up into all the public facilities of the country, With strong consideration for implementation of patients supervision and support throughout the whole course of their treatment by a facility health worker, a health extension worker, a family member, a community leader or a religious leader, also called TB treatment supporter (TTS).

Comment accepted and sentence modified (See L 81 to L 85)

Line 115: Treatment (DOT) that is, watching the patient swallow every scheduled (See L 85)

Line 119: avoids the emergence of drug resistance (See L 87)

Line 125: Therefore this study explores (See L 93)

Line 126: observed treatment (DOT) for the whole course of treatment (See L 94 and 95)

Line 127: using qualitative methods for both health care (See L 94 and 95)

Line 135: Consider deleting as this has been stated earlier: the capital city of the Federal democratic Republic of Ethiopia. ???

Line 138: A qualitative study method was utilized. Data was collected using (See L 101 and 102)

Line 146: assistant data collector and was involved in the facilitation of the data collection process (See L 111)

Line 147: collection processes. At the beginning of each of the data collection days, (See L 112)

Line 147: This sentence is too long and needs to be re-phrased.

At the beginning of each of the data collection day there was a discussion which was followed by end date debriefing meeting where we had an opportunity to discuss any issues related to interviews this activity had repeated till the end of the data collection
Comment accepted and modified in accordance (See L 112 to L 114)

Line 150: Individual’s patient and DOT provider interviews took place in private area inside the facilities or TB clinics. Prior facility visits were made to explain a (See L 115 to L 117)

Line 153: objectives and get permission from the heads of the respective facilities to (See L 116)

Line 154: conduct the research and to making arrangements for data collection. (See L 116 to L 117)

Line 155: Each Interview was done using a semi structured questionnaire with developed in English and translated into Amharic, all the interviews were (See L 118 and L 119)

Line 157: developed in English and translated into Amharic. All the interviews were

Line 161: Consider deleting: “and is suitable for the group discussions”.

Comment accepted and sentence was deleted

Line 162: All arrangements were made in

Line 165: This needs to be re-phrased: A FGDs Interviews questions were used to initiate discussions and to gear the whole session of the discussions towards the topic and a FGD guide was also used throughout the whole processes

Comment accepted and modified in accordance (See L 121 to L 124)

Line 168: All sessions of the in-depth (See L 123)

Line 172: Data analysis was started together with the data collection process. All the (See L 126)

Line 175: Each of the audio record was repeatedly listened to and transcribed verbatim and translated into English by the principal investigator (DF). All the field notes, transcripts and translations were read repeatedly till the investigator becomes familiar with them. (See L 127 to L 130)

Line 180: This was followed by identifying the most frequently observed category and the development of themes. (See L 131 and L 132)

Line 187: and risks of participating was provided. (See L 137)

Line 188: participant’s anonymity and privacy during interviews in private areas were used and following the data collection from each study participants’ audio records were kept confidential. Each study subject was identified only by code (See L 139 to L 140)

Line 192: Also the collected data were kept secure (See L 140)

Line 194: A total of thirty-four participants (18 TB patients and 16 health care providers) were involved in both in-depth interviews and four focus groups (Table1 and 2). (See L 144)
DOTS in continuation phase (See L 149) of the patients often come on foot to the clinic every day due to lack of money for transportation. A female patient described her daily visits to one the health centre as follows: (See L 153 to L 158)

Line 215-222: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 160 to L 166)

Line 228: They also describe, in their daily encounters that most patients (See L 170 and L 172)
Line 231-236: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 172 to L 174)

Line 241: patient said she feels she will die if she does not take her drug for one day (See L 185 and 186)

Line 242: Most patients also reported that the advice they got from (See L 186)
Line 245: Most patients also reported that DOT providers
Line 251-258: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 193 to L 197)

Line 261: frequent change of the health care providers at the TB clinic during the course of their treatment. (See L 99)

Line 265: health care providers (See L 199)

Line 267-273: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 204 to L 208)

Line 275-282: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 210 to L 216)

Line 284-290: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 218 to L 225)

Line 292: TB patients felt close family support was vital (See L 227)
Line 294: The majority of TB patients stated they told close family members (See 229)
Line 296: But few of respondents did however say they often felt stigmatized by (See 231)

Line 298: Below a female patient described

Line 302-319: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 235 to L 243)

Line 321-326: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 245 to L 249)

Line 328-334: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 258 to L 263)

Line 338: No DOT in continuation phase (See L 265)

Line 345: this was very difficult to implement (See L 274)

Line 342-349: Consider rephrasing and introducing periods (full stops).
Comment accepted and modified in accordance (See L 271 to L 279)

Line 350: DOT provider and a (See L 277)
Line 352: supervised treatment for six months. (See L 278 and L 279)
Line 354-375: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 290 to L 298)
Line 381: centers in study are MDR-TB treatment follow-up center (TFC) and St. Peter Hospital which is an MDR-TB treatment initiating center (TIC). They stated they felt concerned that this might put them at increased risk of acquiring (See L 303 to 304)

Line 386: health center describes her and another colleague’s concern about work at a TB clinic (See L 308 to 309)
Line 387-392: requires major editing and insertions of periods (full stops).
Comment accepted and modified in accordance (See L 311 to L 316)
Line 400: We also found most health care providers (See L 316 – L 318)
Line 406: it shortens the total (See L 330)
Line 408: disadvantage of this regimen (See L 331)
poor adherence and MDR-TB could increase if strict DOT is not followed for (See L 332)
Line 415: the challenges and difficulties imposed on the TB patients (See L 335)
Line 419-427: Consider rephrasing and fragmenting
Comment accepted and modified in accordance (See L 339 to L 345)
Line 432-437: education, and consultation by the DOTS provider for patients could help to increase the knowledge and understanding of the TB patients about their disease condition could motivate them to adhere to their treatment. The support from the family and community is also very important for patients to comply with their treatment. These supports could be financial or psychological.
Comment accepted and modified in accordance (See L 349 to L 351)
Line 440: understanding, determination and motivation to complete treatment. Also health care providers, families and the community could play a vital role in (See L 352 to 354)
Line 445: Health care providers shared deep (See L 371)
Line 462-470: Consider fragmenting
Line 475-482: Consider fragmenting
Comment accepted and modified in accordance (See L 358 to L 370)
Line 497: identified in this study may be indicative of similar situations
Line 502-508: Consider editing fragmenting
Comment accepted and modified in accordance (See L 394 to L 408)
Reviewer's report (Reviewer 3)

Title: Directly Observed Therapy following Tuberculosis treatment regimen change in Addis Ababa, Ethiopia: a qualitative study
Version: 5 Date: 11 February 2015
Reviewer: Sibhatu Biadgilign

Reviewer's report: Directly Observed Therapy following Tuberculosis treatment regimen change in Addis Ababa, Ethiopia: a qualitative study

The authors raised an important topic of interest that address the challenge and progress of TB program implementation in Ethiopia after the regimen change. Despite this, the paper needs to address the following comments.

• The authors should shorten the introduction section to the level that the reader can understand the topic that they want to disseminate.

Thank you for all the valuable comments and suggestions - the introduction section was shortened (See L 57 – 95)

• Why the authors need to focus on the months of March and April 2014? Or is that a data collection period or actual patient enrollment?

Yes, the months March and April are the data collection period (See L 101 and L 102)

• How the authors come up with using interview guide and semi-structured questionnaire.

The Interview guide and semi-structured questionnaire were developed by consulting different literatures and national documents in addition both were pretested before the actual data collection and modification was done accordingly (See L 119 to 120)

• Please explicitly mention in the method section about the number, size, their characteristics of FGD and in-depth interview done with of the respective participants in detail.

Detailed information about the number, size and characteristic of the participants included (See L 105 to L 108) and also table 1 and table 2

• Better to characterize the study settings in detail. The methods paragraph should include some background socio-demographic information on the study setting (e.g. size and population, poverty rate, key economic activities, HIV prevalence etc). It should also provide further detail on how participants were selected?

Detailed information added (See L 98 to L 103)

• Please re-write on the usage of wording appropriately like in … in FGD guide on line 167 (See L 127)

• Avoid some redundancy statement and sentence pattern to maintain the flow of idea

Thank you for the comment, the whole document was thoroughly reviewed for redundancy corrected

• Avoid the word “regional” in line 184 (word avoided See L 142)

• How do the authors ensure the quality of their data?
Thank you for the comment, information regarding data quality assurance included (See 132 to L 137)

- The authors should write first the word rather than listing the acronym like HCPs in line 202 (Comment accepted checked for consistency of acronyms throughout)
- Missing a lot of punctuation in different place e.g. line 222 (Corrected)
- Re-writes some of the quotes statement as some words, feelings are not well elaborated in detail….

Thanks you , All of the quotes were re-wrote

- Please write the right word as it is missing in different place….like moths on line 312 (Corrected)
  - Better not to mention the quotes from line 314-319 (Quote was re wrote)
  - The authors should support some of the thought with scientific evidence rather than speculation and perceptions that can augment the finding of their study especially the discussion section.

Thank you for the comment, the whole document especially the discussion section was thoroughly reviewed tried to correct it.

- Revise the reference lay out and writes it in detail way as per the recommendation of BMC public health journal style.

Reference list corrected per the recommended style

- The authors need to carefully check the paper for English grammar or transcription errors. There are a problem of language edition and spelling error. Kindest regards,

Thank you for the comment, the whole document was thoroughly reviewed for grammatical and editorial errors and corrected

**A Level of interest:** An article whose findings are important to those with closely related research interests

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

**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.
Reviewer's report (Reviewer 4)

Title: Directly Observed Therapy following Tuberculosis treatment regimen change in Addis Ababa, Ethiopia: a qualitative study

Version: 5 Date: 16 February 2015
Reviewer: Pedro Palha

Reviewer's report:

General impressions – analysis of the article "Directly Observed Therapy following tuberculosis treatment regimen change in Addis Ababa, Ethiopia: a qualitative study"

The manuscript presents errors both in your typing and translation;

Thank you for the comment, the whole document was thoroughly reviewed, we tried to correct all grammatical, editorial errors and typology errors throughout the document

Two of the three keywords presented are not indexed by the Medical Subject Headings (MeSH);

Key words were changed (See L 20)

In the introduction, contextualizes the problem of tuberculosis in the country, the historical aspects of the evolution of the treatment of TB. However, cites the name of services in which the study was conducted, this compromises the ethical aspects related to scientific research, making possible the identification of the subjects of this research participants;

Thank you for the comment, the introduction section was thoroughly reviewed and revised. (See L 56 to L 95)

Discusses the methods used in the research (semi-structured interview and focus group), uses a software for data analysis (Open Code 3.5), but not an author adopts as a reference for the analysis, this compromises the quality of work;

The Method section was reviewed and detail incorporated

Put a few references in the discussion of the work;

Tried to add few additional references

References contained in the list at the end of the manuscript are not formatted properly. In relation to the guiding questions proposed by the BMC:

Reference list corrected per the recommended style

1. The manuscript does not have well-defined guiding question;

   Areas of guiding questions were included for both the TB patients and for the health care providers (See L 125 to L 131)

2. The methods are well described, but it is suggested not to cite the locations where data collections were made. In addition, it could bring the name of the route used or quoting the items that it contains. As quoted above, the authors could rely on an author as analytical reference (Bardin, for example, who works with the content Analysis – Thematic Mode). Finally, it is suggested that, to raise the quality of work, use the COREQ (Consolidated reporting criteria for qualitative research);
Mentioning exact location of the data collection was omitted and changed by code and COREQ in revising the whole document
3. The data presented (fragments of the speeches of those interviewed) could be demonstrated with a smaller amount of words (the words presented are extensive), which can make the reader get lost in reading;
The whole document was thoroughly reviewed and revised including the quotes
4. The figures submitted are genuine, have no evidence of manipulation. However, it presents formatting errors;
The whole document was thoroughly reviewed for formatting errors and corrected accordingly
5. discusses the liability in connection with the Data Guard, but does not cite standard followed;
This comment is not clear?
6. Discussion and final considerations have relationship with the results. However, does not present the degree of intensification necessary. Uses few scientific articles and focusing more on international guidelines. The articles should have greater prominence;
The whole document was thoroughly reviewed tried to enrich it

7. The manuscript does not discuss the limitations of the study, this compromises the same;
Limitation of this study included (See L 401 to L 404)
8. The authors acknowledge the work that they're building, that are published or not published;
9. The title and the abstract correspond to what was found at work. However, the use of descriptors is inadequate from the moment in which the authors present two of these without being indexed;
The whole document was thoroughly reviewed modified in accordance
10. The writing has typos and inappropriate terminology used at certain times, this compromises the quality of the study.
The manuscript was thoroughly for grammatical and typo errors and correction was made

Despite the manuscript presented reporting a study from a priority country for the control of tuberculosis due to the large number of cases that presents, the same does not meet fully the methodological prerequisites to allow its publication in this periodical. In this way, the same shall be deemed to be denied.

Level of interest: An article of limited interest

Quality of written English: Not suitable for publication unless extensively edited

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.