Author's response to reviews

Title: Factors associated with DELAY in diagnosis among Tuberculosis patients in Hohoe Municipality, Ghana

Authors:

   Osei Eric (ericusonline@yahoo.com)
   Akweongo Patricia (akweongo@gmail.com)
   Binka Fred (fred.binka@gmail.com)

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Author's response to reviews: see over
Dear Dr. Amy Greer,

Subject: RESPONSE TO REVIEWERS

“Factors associated with DELAY in diagnosis among Tuberculosis patients in Hohoe Municipality, Ghana”

We are pleased to return the revised version of our manuscript to you for consideration. Please, find below the specific responses to the specific comments made by the two reviewers. We have provided a step-by-step response to each reviewer’s comments. We have also added some useful information that was unintentionally omitted in the results section. All the changes are marked Red in the revised manuscript. Thank you for the opportunity to work with you on this paper and more papers to come.

Reviewer 1 (Chih-Hsin Lee)

1. Is the time to diagnose TB defined as suspecting TB and arranging referral or accepting confirmed diagnosis according to a typical radiological chest x ray or positive acid-fast smear of sputum?

Response: The time to diagnose TB was defined as accepting confirmed diagnosis based on; 1. positive acid-fast bacilli in sputum, or 2. radiological findings, or 3. clinician’s own judgement based on clinical and epidemiological information, including failure to respond to a course of broad-spectrum antibiotic and exclusion of other pathology according to national guidelines. The time anti-TB was initiated was not used in calculating the healthcare services delay because sometimes a patient may be diagnosed but initiation of anti-TB would delay due to reasons such as stock outs of anti-TB drugs. How is multiple healthcare service contact defined for those first visiting public health centers, clinic, and community-based health planning services? Is chest x ray and sputum acid-fast smear available in these public health facilities? Was consulting drug store or traditional healers also considered a healthcare contact?
Response: multiple healthcare service contact was defined for those first visiting health centers, clinics and Community-based Health Planning Services (CHPS) as making more than one contact before TB is suspected and making arrangement for referral to the Hospital for confirmation. Physicians in these facilities can only suspect TB and refer, since there are no diagnostic tools in these facilities. For patients who first visited the hospital, healthcare service contact was defined as making more than one contact before suspecting TB and making arrangement for confirmation either through microscopy or radiology. Consulting drug stores or traditional healers was not considered a healthcare contact. We have redefined Healthcare contact as Public Healthcare contact.

2. The initial radiological findings such as presence of cavitation or zones of involvement, if available should be reported to illustrate the disease severity of pulmonary TB.

Response: Details of radiological findings cannot be reported because this data is not available. The current reporting system in the country do not provide for recording severity of the disease.

3. How is the status of employment defined for those living on farming?

Response: Employment was defined in this study as having income generating job. Thus all patients who lived on subsistence farming were categorized as unemployed, because they do not commercialize their farm products; hence do not generate income from farming.

4. Are sputum acid-fast smear performed in all patients enrolled? For patients diagnosed of TB without positive sputum smear, how many of them were having positive mycobacterial tuberculosis complex culture results?

Response: All patients suspected of pulmonary TB undergo sputum smear examination for acid-fast bacilli. For those whose smear results are negative, chest x ray and/or clinician’s judgement are used to diagnose TB based on clinical history. Culture method for diagnosis was not available at the study site.
5. The table following table 5 are mislabelled as Table 1

Response: The Table following Table 5 was rather mislabelled as Table 15. We have relabelled Tables 3, 4, 5 and 15 as 2, 3, 4 and 5 respectively in the revised manuscript as marked in red ink.

6. The Tables 2, 4, 5 are not referenced in the manuscript

Response: We have referenced the Tables in the manuscript.

7. Was the multiple healthcare contacts due to unawareness of the clinical presentation of TB or due to unavailability of diagnosis facilities for TB?

Response: The cause of multiple healthcare contacts was not investigated in this study. However, we have attributed this to poor clinical suspicions of signs and symptoms by healthcare providers especially, from primary healthcare facilities and failure to request for proper investigations or refer patients to the Hospital for further investigations in the discussion section of the manuscript (you need to provide a reference to support this explanation. Does the Kumasi study or studies done in similar settings have evidence to this explanation). Nevertheless, TB diagnosis facilities were not available at primary healthcare facilities, which could also be the cause for patients making multiple contacts.

Reviewer 2 (Maria de Fatima P.M Albuquerque)

1. The sample size – 73 new TB patients – is very small and could have jeopardised the internal validity of the study. The authors should discuss this study limitation and its consequences on the findings presented.

Response: we have discussed this limitation of the study as below: the most obvious limitation of this study is its small sample size. Therefore firm conclusions about the relationships between and among variables cannot be drawn. Thus interpretation of the results must be done with caution. Research studies with much larger sample size would therefore be required to ensure appropriate generalization of the findings of the study. This was affected by the time period available to review the records (i.e. 1st June, 2013 to 31st May, 2014). We limited ourselves to a one-year period in other to minimize recall bias.

2. It would be of interest to indicate details of how the variable “stigmatization” was constructed in the “operational definitions” section.
Response: Stigma was constructed using social and psychological constructs of stigma (shame, moral value of blame, responsibility, and guilt) associated with Tuberculosis at both community and patient/individual levels. This has been included in the operational definitions section (indicate the page number and the section number). Details can also be found in the data analysis section of the manuscript.

3. The time delays among the smear positive and smear negative pulmonary TB individuals need to be reported to achieve better understanding of the study.

Response: we have now reported the time delays among the smear positive and smear negative pulmonary TB individuals at the results section of the revised manuscript (page number?).

4. It would be of interest if the delay patterns of 21 (28.8%) cases of TB microbiologically confirmed in this study were compared with the delay patterns reported in the population studied by Lawn et al (1998)

Response: We have made the comparison in the discussion section of the manuscript (page number and section number?)

5. One interesting finding was that the median healthcare services delay verified (45 days) is shorter than that reported by Lawn (1998) for healthcare services delay (60 days). What is the author’s interpretation of that? it would be expected that a population study including 2/3 of smear negative pulmonary TB, as reported in the present study, would present a longer healthcare services delay than a study population of only smear-positive pulmonary TB cases.

Response: we have interpreted this difference in the discussion section as below: Lawn’s study was conducted a year after establishing a new TB control programme in the country and since then the National Tuberculosis Control Programme has been implementing activities towards improving quality of TB care, which includes extensive training of health personnel, decentralization of diagnosis and treatment services, community TB-DOTS, and provision of “enabler” package to health providers and TB patients as well, aiming at providing a quality integrated TB services to people at all levels by means of standardised diagnosis, treatment and community-based care and support. These measures are expected to reduce diagnostic delays. This could explain the shorter median healthcare services delay in the current study (indicate page number where this explanation can be found in the manuscript).

6. Did the HIV positive patients present longer patient delays, perhaps as a result of atypical TB clinical presentation?

Response: slightly longer patient delay (59 days) was noted for HIV sero-negative patients than (57 days) for HIV positive patients. HIV positive patients were 0.99 times less likely to delay seeking TB care compared to HIV negative patients, however this difference did not
reach statistical significant (p=0.985, CI: 0.25-3.85). This information has been included in the results section (page number??)