Magnitude and factors associated with pre-diagnosis loss to follow-up among tuberculosis presumptive patients in the Cycle of Health Care, Musoma, Tanzania: Cross-sectional study

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Abstract

**Background:** Despite National Tuberculosis (TB) Program efforts on tuberculosis control in the country, pre-diagnosis loss to follow-up is still a major problem. The study aims at exploring the magnitude and risk factors of presumptive TB cases who either do not submit a second sputum sample or do not show up for their laboratory results.

**Methods:** The study included presumptive TB registered at the Musoma Regional Referral Hospital between May and November 2014. Lost to follow up presumptive TB were then traced and interviewed from December 2014 to April 2015. One hundred and thirty-two among those who submitted both samples and showed up for their results were randomly selected as a comparison group.

**Results:** A total of 620 presumptive TB was registered at the Musoma Regional Referral Hospital of which 521 (84.0%) completed TB testing in accordance with the national TB diagnostic algorithm while 99 (16.0%) did not complete. Out of those who did not complete, 65 (65.7%) submitted only one spot sample and 34 (34.3%) submitted both but all of these did not pick-up their results. The Mean age of participants was 45.3 years. The main reasons for loss to follow-up were: 23 (23.2%) opted to go to other health care facilities; 23 (23.2%) lack of transport fare; and 20 (20.2%) long distance to the hospital. Males were 1.6 more likely to complete TB diagnostic algorithm.

**Conclusions:** The magnitude of TB pre-diagnosis loss is very high. Lack of transport fare and long distance to healthcare facilities were the main reasons. Active tracing of pre-diagnosis loss to follow up to presumptive TB individuals to bring them back to care is highly recommended.

**Key Words:** loss to follow up, Pre-diagnosis loss to follow up, Tuberculosis (TB), presumptive TB, Musoma regional referral hospital (MRRH), laboratory results.

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**BACKGROUND**

Tuberculosis (TB) is an important public health problem worldwide. Delays in case detection not only worsen the disease and increase TB transmission, but also a challenge to the National TB and Leprosy Programme (NTLP). Low case detection either due to the health system and/or patient’s delays is still a problem in majority of Sub-Saharan African countries including Tanzania (Ngadaya et al. 2009).

TB kills about 1.4 million people worldwide (WHO 2020). The East African region bears the brunt of TB burden. Tanzania is ranked 14th among the 30 WHO-identified high TB burden countries with the incidence ranging between 112 and 408 per 100,000 populations (WHO 2020). Effective treatment is Possible if TB infected persons are detected early and put on timely appropriate
management. However, with the high amount of pre-treatment loss to follow up this may not be possible. Rapid (Dye et al. 2008).

The available guidelines in the country advocates for the passive case finding in which an individual present to the health facility with symptoms suggestive of TB, and promoted as part of Direct Observed Therapy (DOT) strategy model of passive case finding that has been adapted by National TB programme. All TB presumptive individuals are supposed to submit two sputum samples; spot and morning for smear microscopy and in case they fall under diagnosis category that requires diagnosis by MTB Rif assay they only submit spot sample (MDR Guideline, 2018). TB treatment is then initiated based on either smear microscopy results or MTB Rif assay results. Pre-treatment loss to follow-up among TB patients who does not start treatment is a global public health problem and represents an important failing of the provision of care because such patients are highly infectious and experience high mortality (Htwe et al. 2019).

Efforts to bring back these individuals into care are of paramount importance as it could help to reduce TB transmission (Square et al. 2005). WHO changed its policy from three to two sputum specimens, the changes allow treatment initiation even with only one positive sample. Despite WHO policy changes of spot-morning sputum samples and only Spot in GeneXpert technology, the MRRH experienced situations where; (i) some TB Presumptive persons submitted only a spot sputum sample and did not come back to the hospital to submit the morning sample the following day (s); (ii) some TB Presumptive persons submitted both sputum samples (i.e. spot and morning) but did not come back to pick up their laboratory results thus not start treatment. Characteristics of these individuals and the reasons for not bringing in the second sputum sample or to pick up their laboratory results are yet to be known and therefore need to be investigated.

Thus, this study explored the characteristics of these individuals and reasons for not turning up either for morning sample submission and or their results. This study will inform the programme of the relevant measures for these individuals and putting them into appropriate management.

METHODS
Study Design and Population
A cross-sectional study among adult participants (≥18 years of age) who were lost to care before completing a TB diagnosis from May 1st to November 30th, 2014 at the MRRH was conducted. This period was chosen to reduce possibility of recall biases and increase the probability of locating these individuals when traced considering relocation factors (i.e. people moving to other places). MRRH is located in Musoma municipal in Mara region on the eastern edge of Lake Victoria close to the international borders of Tanzania and Kenya at 1° 30' 0.00"S, 33° 48' 0.00"E (Latitude: -1.5000; Longitude: 33.8000).

According to the 2012 national census, Mara region had a population of 1,743,830 with 2.5 percent average annual population growth rate (Tanzania Population and Housing Sensor 2012). Being a regional hospital, Musoma received patients from all over the region. The hospital has a specialized TB ward and clinic, and a TB laboratory which is integrated into the general hospital laboratory building.

Ethical consideration
The protocol for this study was approved by the National Ethics Review Board of Tanzania (NIMR/HQ/R.8a/Vol. IX/1838, 2014). Information explaining the aim of conducting this study was provided orally and in writing to the participants. Study participants were informed that their participation was confidential and voluntary and information used would be anonymous. The participants then signed informed consent forms or verbally consented to participate in the study,
including being interviewed. Participants were free to withdraw or decline to participate in the study at any point in time without giving reason(s) for withdrawal.

Individuals under 18 years of age and presumptive TB persons with a psychiatric disorder or who were physically disabled and those who refused to consent were excluded from the study.

Data Collection
Data collection and interviews were conducted from December 2014 to April 2015; thus, all eligible loss to follow up (LTFU) presumptive TB persons together with control group were traced and interviewed using semi structured questionnaire in person at their household or through phone calls. LTFU TB presumptive individuals were identified by reviewing the TB laboratory registers to confirmation of treatment status with TB District Register.

Trained field staff under supervision of the study principal investigator looked for all the eligible presumptive individuals who were lost to follow-up to participate in the study. The contact information of each of these individuals available at the facility was used to aid tracing. Semi-structured questionnaires were used to collect the desired information; demographic, TB knowledge, perceptions about the health care settings and social factors associated with not-showing up for morning sputum submission or results collection.

Data management
Completed questionnaires were coded and double entered into a computer software Epi-data version 3.1. Data were cross-checked and cleaned, then transferred to the Statistical Package for Social Sciences (SPSS) version 23.0 windows (SPSS Inc, Chicago, USA) for analysis. The predictor variables were categorized based on its distribution while the dependent variables were coded 1 for completing algorithm and “0” for incomplete, then the chi2 test was used to assess the association between the two.

The associated variables were then regressed logistically to estimate the Risk magnitude using ODD Ratio, Risk factors were estimated using logistic regression, with 95% confidence interval (CI) given for odds ratios (OR) and a P value of 0.05 was considered statistically significant

Definitions
The NTLP guideline in defining some terminologies was used; In this study, Individual diagnosed with tuberculosis on the basis of at least one positive sputum smear, but did not start tuberculosis treatment is defined as pre-treatment loss to follow-up (LTFU). This includes individuals who died before treatment initiation. Individuals diagnosed with tuberculosis on the basis of at least one negative or/and two sputum sample but did not come back for laboratory results are defined as pre-diagnosis loss to follow-up.

Results
A total of 620 TB presumptive individuals were registered at MRRH out of which 521 (84.0%) completed TB diagnostic algorithm aspects and 99 (16.0%) did not complete all the TB diagnostic algorithm aspects. Out of those 65(65.65%) submitted only spot sample and 34(34.34%) submitted second sputum but did not pick up the smear results). To ascertain risk factors for TB pre-diagnosis loss, 132 participants were randomly selected among those who completed TB programme diagnostic algorithm aspects to represent the control group. Fourteen out of 99 (14.1%) TB presumptive individuals who did not complete TB diagnosis algorithm had positive TB smear results. Two participants died before completing TB diagnosis algorithm and one participant could not be located due to wrong map so they were not included in data analysis.
The Mean age of the 231 study participants was 45.3 years (Standard Deviation 17.7), ranging from 18 to 96 years; 136 (58.9%) were males; 147/231 (63.6%), were married/cohabited; 84 (36.4%) divorced/single/widowed and most of them 157 (68.0%) were farmers (i.e., peasants, livestock and fisheries).

Table 1: Distribution of Demographic information of study participants in relation to completeness of algorithm

| Variable                        | Complete algorithm; N=132; n (%) | Incomplete algorithm; N=99; n (%) | p-value |
|---------------------------------|----------------------------------|-----------------------------------|---------|
| **Sex**                         |                                  |                                   |         |
| Male                            | 85 (64.4)                        | 51 (51.5)                         | 0.04    |
| Female                          | 47 (35.6)                        | 48 (48.5)                         |         |
| **Age group**                   |                                  |                                   |         |
| <26                             | 24 (18.2)                        | 13 (13.1)                         | 0.67    |
| 26-35                           | 4 (18.2)                         | 18 (18.2)                         |         |
| 36-45                           | 29 (22.0)                        | 20 (20.2)                         |         |
| ≥46                             | 55 (41.7)                        | 48 (48.5)                         |         |
| **Marital status**              |                                  |                                   |         |
| Single/widow/divorced           | 41 (31.1)                        | 43 (43.4)                         | 0.05    |
| Married/cohabiting              | 91 (68.9)                        | 56 (56.5)                         |         |
| **Education level**             |                                  |                                   |         |
| Primary/no formal education      | 37 (28.0)                        | 37 (37.4)                         | 0.13    |
| Secondary/advanced/collage      | 95 (72.0)                        | 62 (62.6)                         |         |
| **Occupation status**           |                                  |                                   |         |
| Farm/livestock/fisher           | 86 (65.2)                        | 71 (71.7)                         | 0.25    |
| Business/petty trader           | 27 (20.5)                        | 12 (12.1)                         |         |
| Jobless/house wife              | 19 (14.4)                        | 16 (16.2)                         |         |

Males and those living with partners (i.e., married/cohabiting) were 1.6 (95%CI1.02-2.90) more likely to complete TB diagnostic algorithm. Where Males 85 (64.4%) completed the TB diagnosis algorithm as compared to females 47 (35.6%) (p=0.04) there was no significant difference in age groups among loss to follow up (LTFU) participants and those who completed TB algorithm. Additionally, there was no significant difference in occupational status and education level among the participants.

Table 2: Factors contributing to not completing sputum algorithm N=231

| Variable                        | Total N | Factor contributing for not Completing sputum algorithm |
|---------------------------------|---------|-------------------------------------------------------|
| **Sex**                         |         |                                                       |
| Male                            | 136     | 85 (64.4)                                             |
| Female                          | 95      | 47 (35.6)                                             |
| **Marital status**              |         |                                                       |
| Living alone                    | 83      | 41 (31.1)                                             |
| Living with partner             | 148     | 91 (68.9)                                             |

In ascertaining the knowledge and awareness of TB transmission, prevention and treatment among the participants, there was a significant difference in knowledge and awareness among LTFU participants (those who did not complete the algorithm) and those who competed. Strikingly, there was a significant relationship with where the participant heard of TB for the first time and not completing the TB programme, algorithm; 38 (45.8%) who heard about TB for the first time at a health facility did not complete TB algorithm (p=0.05).
The main reasons for not submitting morning samples as well as not picking up results were as follows: lack of transport fare 23 (23.2%); long distance to the hospital 20 (20.2%); opted to go to other health care facilities 33 (33.3%) and 10 (10.1%) were busy with other economic activities, the rest 13/99 (13.3%) gave reasons such as; not informed to come back, fear of HIV testing and moving to other residential places, mostly for farming reasons.

![Figure 1: Chart showing Distribution of reasons for not completing sputum diagnosis algorithm](image)

Ascertaining health facility factors associated with pre-diagnosis loss to follow-up; 48 (48.5%) were not satisfied with the services available the day they first presented at the hospital. Among those not satisfied with the health services 32 (32.3%) complained of long waiting times at the hospital; 8 (8.1%) Poor rapport from health care providers; 6 (6.1%) unnecessary bureaucracy at the hospital; and 2 (2.0%) did not give any reason.

| Table 3: Factors associated with not completing sputum algorithm; N=99 |
|---------------------------------------------------------------|
| **Reasons**                               | **n (%)**  |
| How many samples where you instructed to submit?             |            |
| Two                                                                              | 81 (81.8)  |
| Others (one, three, four)                                      | 18 (18.2)  |
| Were you satisfied with the health services when you submitted the first sample? |            |
| Yes                                                                               | 51 (51.5)  |
| No                                                                                | 48 (48.5)  |
| If not satisfied, why?                                          |            |
| Long waiting time at the hospital                                 | 32 (32.3)  |
| Poor rapport from health care provider                           | 8 (8.1)    |
| Stigmatization from health care provider                         | 2 (2.0)    |
| Unnecessary bureaucracy at the hospital                          | 6 (6.1)    |
| Why you did not come back for treatment?                         |            |
| Long distance to the hospital                                    | 20 (20.2)  |
| Doing other economic activities | 10 (10.1) |
| Did’nt have bus fare | 23 (23.2) |
| Treated at other health facility | 33 (33.3) |
| Not informed | 1 (1.0) |
| Fear of HIV testing | 5 (5.1) |
| Migration to other residential area | 4 (4.0) |
| Others | 3 (3.0) |

**Do you know that for not completing treatment you are risking others getting TB?:**

| | |
|---|---|
| Yes | 70 (70.7) |
| I don’t know | 29 (29.3) |

**Discussion**

There are several programme implications from this study. Rapid case identification of individuals with sputum smear-positive tuberculosis and rapid initiation of anti-tuberculosis chemotherapy are critical to controlling tuberculosis and are promoted as part of the DOTS strategy model of passive case-finding that has been adopted by the national tuberculosis programme (WHO, 2011). From the patients’ perspective, the tuberculosis diagnostic and care pathway begin with recognition of symptoms that prompt care seeking. Individuals may drop out of care during the diagnostic process (“loss to follow-up during diagnostic period”), before initiating treatment (“pre-treatment loss to follow-up”) or after treatment has begun (Zacharia et al. 2012).

This study was conducted to determine the Magnitude and Factors Associated with Pre-Diagnosis loss to follow up (LTFU) in the Cycle of Health Care for Tuberculosis presumptive in Musoma, Tanzania. In this study, 99 (16.0%) of all TB presumptive individuals registered at MRRH between May and November 2014 were LTFU. A similar rate of LTFU among TB patients was documented in a study conducted in Chongwe-Zambia by Chilembo et al 2020, where by 71 out of 145 LTFU (33%) were not put into treatment. The same study indicated that those who were diagnosed using smear microscopy were two times more likely to be LTFU before treatment as compared to those who were diagnosed by Xpert (Chilembo et al 2020).

Another study by Kizito et al. 2011 in Kenya reported that 146 (13%) of 1094 TB registered patients were LTFU from treatment. This finding also corrrelates with a systematic review and meta-analysis by MacPherson et al. 2013 which reported the pre-treatment LTFU ranging from 4 to 38%, and which is higher in sub-Saharan Africa (18%) than in Asia (13%).

Further data analysis noted that 33 (33.3%) of TB pre-treated LTFU opted to go to other health facilities (Table 2). This finding is consistent with a study conducted in Asia, where transfer to private clinics for tuberculosis treatment was the commonest reason for pre-treatment LTFU; from 0 to 62% of patients were found to have been treated at private clinics (Geremew et al. 2015). This finding also correlates with the study from Myanmar which traced individuals who initiated treatment elsewhere, it was reported that of the 1365 bacteriological confirmed patients who were initially classified as PTLFU, 200 (15.6%) were referred for treatment to other health facilities and 114 (8.4%) did not initiate anti-TB treatment (Htwe et al. 2019).

Long distance to the hospital was pronounced by 20/99 (20%) as among factors for LTFU in this study. This finding correlates with the study conducted by Geremew et al. 2015 in Ethiopia who reported that TB patients residing in the rural area were 4.4 times at greater risk of being lost to follow-up as compared to patients in urban areas. This may be explained by the fact that patients living in the rural area have limited access to treatment centre due geographical locations as well as limited active public transport. Patients have to pay for public transport (incurring catastrophic costs) to reach treatment centres, which is always not possible due to poor economic income of the
people particularly in rural areas. Another study by Nataprawira & Wonoputri 2014 on “Obstacles Facing Tuberculosis Treatment in Children from a Developing Country in Indonesia” reported that far dwelling encompassing 16.5% of the TB LTFU children, however this finding is in contrast to the study conducted by Afutu et al. 2012 in Ghana which reported that distance to treatment centre was not associated with the risk of treatment LTFU among TB patients.

Financial related factors were also among the factors pronounced by LTFU participants, where 23/99 (23.2%) reported to have no transport fare back to the hospital. The finding is consistent with the findings from the study conducted by Nataprawira & Wonoputri 2014 in Indonesia, which reported that 22.7% of the TB children LTFU were due to financial problems.

Health system related factors, particularly those relating to long waiting time to see a doctor, the need for repeated visits and delays in receiving the results of sputum smears, par rapport from health care providers as well as unnecessary bureaucracy was also reported to be important contributors to pre-treatment LTFU in this study. Long waiting time at the hospital was pronounced by 32/99 (32.3%), par rapport from health care provider 8/99 (8.1%) and Unnecessary bureaucracy at the hospital 6/99 (6.1%).

These findings correlate with the findings of the studies by Squire et al. 2005 and Buu et al. 2003 which reported that health-system-related obstacles like dissatisfaction with long waiting times in health services, the need for repeated visits, and delays in receiving the results of sputum smears were associated with not starting treatment for tuberculosis. These findings also relate to a systematic review and meta-analysis of pre-treatment LTFU among TB patients in low and middle-income countries by McPherson et al. 2013 which reported the LTFU rates ranging from 4 to 38%, among the reasons reported was non-user-friendly health system.

This study also found that even though health care and diagnostic tests for TB are free, the diagnosis and care pathway is often costly and long (in terms of time and catastrophic costs). Findings from this study call for TB programme and other stakeholders to consider for replacing “spot-morning” sputum collection with two spot sputum samples one hour apart (front loading). WHO is recommending on the use of automated molecular diagnostic testing (Xpert Assays) which simultaneously detects Mycobacterium tuberculosis and rifampicin resistance and associated with reduced time to diagnosis and lower pre-treatment loss to follow-up (WHO 2016).

Males were 1.6 (95%CI1.02-2.90) more likely to complete TB diagnostic algorithm (Table3). This is true probably due to males are mostly income earners, so they have a high chance of presenting to hospital as compared to females who depends to their married couples for transport and other health related costs. This finding is supported by the truth that most females are home keepers so they sometimes have to take care of the domestic activities and family related issues increasing the treatment defaulting chance.

Despite the effectiveness of DOTS services in Tanzania, a 16% loss to follow up rate is higher than the WHO recommended target of less than 5%. The magnitude of TB pre-diagnosis loss is very high, this calls for more comprehensive approaches to reduce LTFU among TB presumptive individuals by targeting risk factors for pre-diagnosis LTFU. Pre-diagnosis LTFU could be a source of under reporting and underestimating the magnitude of TB in the country patients lost from care before treatment initiation (pre-treatment loss to follow up) are not included and thus not reported. Lack of transport fare and long distance to health facilities are among factors that needs adequate interventions to reduce pre-diagnostic LTFU. Active tracing TB presumptive individuals who are lost and bring them back to care is highly recommended.

**Study Limitations and Strength**

Failure to locate some participants due to incomplete demographic information, difficulty in locating participants from distant location, especially those who shifted outside the study area and recall
biases to some the participants were some limitations in this study. So, the information obtained cannot be generalized as some participants were not involved in the study, perhaps their information could add up significant reasons for not showing up for laboratory results.

Despite of the limitations encountered the study team tried much to minimize errors, e.g. recall biases by frequently reminding participants using commonly occurring events like holidays, weekends depending on the date/day the participant first presented to the hospital.

Conclusion and Recommendations
The magnitude of TB pre-diagnosis loss is very high. Long distance to the healthcare facilities, long waiting time at the hospital, lack of transport fare (catastrophic costs) and treated to another health facility were the main reasons mentioned by the majority. The findings in this study call for the urgent need for intervention measures to actively tracing presumptive TB presumptive individuals who lost to follow up and bring them back to care. Improving and bringing TB health services closer to people is also highly recommended to curb the burden of the disease.

Competing interests
The authors declare no competing interests.

Authors’ contributions
All the authors listed in this article made contributions during the design of the study, data collection and interpretation, intellectual content and approved the final manuscript.

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