Decline in the incidence of tuberculosis among HIV-infected patients enrolled in HIV care, treatment and support programme from 2011 to 2014 in Mainland Tanzania

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Abstract
Background Despite improvements in access to antiretroviral therapy (ART), mortality in people living with human immunodeficiency virus (PLHIV) is still high and largely attributed to Tuberculosis (TB) infection. In sub-Saharan Africa, approximately 80% of HIV related mortality cases are associated with TB. Relatively little is known about incidence of TB among PLHIV in Tanzania and the determinant factors. We report incidence rate of confirmed TB and determine association with selected demographic and program related factors based on data in the national HIV care and treatment program from 2011 to 2014.

Methods The Tanzania National AIDS Control Programme, Care and Treatment database was used to obtain information of all HIV clients enrolled in the HIV Care and Treatment Program between January 2011 and December 2014. We analyzed retrospective cohort data to assess TB incidence rate per 1000 person-years. A multivariable Cox proportional hazards regression model was used to estimate hazard ratios and 95% confidence intervals for putative associated factors.

Results Over the period of four years, there were 22,071 confirmed cases of pulmonary TB in 1,323,600 person years. The overall TB incidence was around 16.7 (95% CI 16.4 -16.9) cases per 1000 person years. The annual incidence rate decreased by 12.4% from 17.0 (95% CI 16.5-17.4) in 2011 to 14.9 (95% CI 14.5-15.4) in 2014. TB incidence rate was significantly higher in persons not using ART and in males than females. The incidence of TB was higher in patients with advanced HIV disease and decreased with increasing age. The overall prevalence of TB was 2.2% with peak prevalence of 2.5% in 2013 and being higher among children < 15 years (3.2%) in the same year.

Conclusion The study found an overall decrease of incidence of TB in PLHIV. Our results underline the current recommendations of HIV test and treat and provision of TB preventive therapy for those PLHIV without active TB after intensified TB case-finding.

Introduction
Tuberculosis (TB) and human immunodeficiency virus (HIV) co-infection is a major public health problem worldwide [1–3]. The lifetime risk of developing active TB among people living with HIV (PLHIV) has been reported to be 20 times greater than in people without HIV [4]. Tanzania is among
the 30 countries with high TB burden and TB and HIV co-infection in the world [5]. According to the National Tuberculosis and Leprosy Programme annual report of 2017, about 31% of all TB-notified cases were found to be co-infected with HIV[6]. Despite the increased access to antiretroviral therapy (ART) mortality in PLHIV is still high and TB has been reported to be the main cause [7–9]. It has been noted that TB preventive therapy by using isoniazid reduce the incidence of TB in HIV-infected patients [10, 11]. Conversely, some studies have reported unacceptably high incidence of TB after ART initiation as result of immune reconstitution [12, 13].

In 2004, the World Health Organization (WHO) formulated an interim policy to guide member states in implementing collaborative TB/HIV activities [14] and further addressed the requirement for collaborative effort to address the burden of TB and HIV [15]. Subsequently, the Ministry of Health in Tanzania formed a national TB/HIV coordinating body in 2005 for delivering integrated TB and HIV services to reduce the burden of TB in PLHIV [14]. In this collaborative activities, screening for HIV among TB patients occur in the TB clinics, likewise, the screening for TB at HIV care and treatment clinics.

Previous report from analysis of data corrected between 2004 to 2012 in Dar es Salaam the largest city in Tanzania reported the TB incidence rate of 7.9/100 person-years prior to ART initiation, and 4.4/100 person-years for patients receiving ART[16]. However, the reported TB incidence rates among HIV-infected patients prior to and after ART initiation was from HIV infected cohort in the largest city in the country which might not reflect the countrywide incidence rates. Also, the incidence rate might change with time taking into consideration the implementation of collaborative TB and HIV activities. We therefore analyzed data in the national HIV care and treatment programme corrected from 2011 to 2014 to determine the countrywide incidence of TB and among PLHIV related factors.

Material And Methods
Design, Setting and population
This was a descriptive analytical study of retrospective cohort data routinely collected between 2011 and 2014 from 740 HIV service delivery clinics and archived in the National AIDS Control Programme database. The data include information from all clients attending HIV care and treatment services as
stipulated in the national programme for HIV management[17].

Data management
Primary data generated in the HIV care and treatment clinics (CTC) was captured on facility-held information collection tools designated as CTC2 card. Information from CTC2 cards at health facility level is aggregated either manually or electronically at different levels up to the national level. The manually aggregated data is electronically captured at national level. Moreover, patient-level data from health facilities with electronic CTC2 database is exported to national level. At the end, electronically available aggregated data at national level and patient level data form a macro database designated as CTC3.

Data analysis
Abstracted data were analyzed using StataCorp2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP). Descriptive statistics of TB cases was performed for age, sex, WHO clinical stage and ART status. Patient characteristics at the time of incidence of TB were described by the year using frequencies and percentages for categorical variables. The first episode of TB was determined by following up patients who visited the HIV clinics beginning in each of the years from 2011 to 2014. Incident TB after ART initiation was defined as a new clinically diagnosed or bacteriologically-confirmed case of TB (a biologic specimen positive for Mycobacterium tuberculosis). Patients who were seen in 2011 were followed up until the first episode of TB, or until censored due to death, lost-to-follow-up or at 31st December 2014, with the interval divided into the year to obtain annual TB incidence. The TB incidence rate was calculated by dividing the total number of incidence by the 1000 person-year of observation. A multivariable Cox proportional hazards regression model was used to estimate hazard ratios adjusted for all covariates and 95% confidence intervals (CI) for factors associated with TB incidence. Kaplan-Meier estimation methods were used to calculate the probabilities of cumulative TB incidence after enrolment into the clinic, stratified by baseline characteristics of interest.

Results
Data were extracted and analyzed from records of 1,865,337 individuals with a total of 11,539,844 clinical encounters enrolled on HIV care and treatment services between 2011 and 2014, averaging 6
encounters per year. (Table 1)

Table 1
Number of individuals and clinic encounters in HIV care, treatment and support programme in Tanzania from 2011 to 2014

| Program year | Number of individuals | Total clinic encounters |
|--------------|-----------------------|-------------------------|
| 2011         | 427,117               | 2,560,290               |
| 2012         | 449,114               | 2,565,557               |
| 2013         | 461,857               | 3,004,427               |
| 2014         | 527,249               | 3,409,570               |
| Total        | 1,865,337             | 11,539,844              |

Prevalence of Tuberculosis

The number of cases and prevalence of TB among HIV clients enrolled in care and treatment clinics in the period of 2011 to 2014 are summarized in Table 2. The trend of TB prevalence in this analysis was unpredictable, the overall prevalence was 2.2%, the with the peak of 2.5% in year 2013. Noticeable higher TB prevalence was found among children < 15 years, which peaked at 3.2% in 2013. Overall, TB was more reported in males than in females and the differences were consistent over the four years. The highest prevalence in males was 3.5% observed in 2013. Throughout the four years there was relatively lower prevalence TB among PLHIV on ART than those not on ART.

Table 2
Prevalence of TB among individuals enrolled in HIV care, treatment and support program in Tanzania from 2011 to 2014

| Characteristics | 2011   | 2012   | 2013   | 2014   | Total  |
|-----------------|--------|--------|--------|--------|--------|
|                 | N (%)  | N (%)  | N (%)  | N (%)  | N (%)  |
| Overall         | 8,765  | 9,798  | 11,212 | 9,857  | 39,632 |
| Age group       |        |        |        |        |        |
| < 15 years      | 687 (2.1) | 784 (2.3) | 1066 (3.2) | 854 (2.4) | 3391 (2.5) |
| ≥ 15 years      | 8078 (2.1) | 9014 (2.3) | 10146 (2.4) | 9003 (1.9) | 36241 (2.2) |
| Sex             |        |        |        |        |        |
| Male            | 3858 (2.9) | 4474 (3.2) | 5066 (3.5) | 4681 (2.8) | 18079 (3.1) |
| Female          | 4907 (1.8) | 5324 (1.8) | 6146 (2.0) | 5176 (1.5) | 21553 (1.7) |
| ART Status      |        |        |        |        |        |
| ART             | 1145 (1.5) | 883 (1.4) | 630 (1.2) | 699 (1.2) | 3357 (1.3) |
| Non-ART         | 7620 (2.3) | 8915 (2.4) | 10582 (2.6) | 9158 (2.0) | 36275 (2.3) |

Incidence of Tuberculosis

Over the four years there were more than 22,071 confirmed cases of TB among clients attending CTC (Table 3). The overall incidence of TB was around 16.7 (95% CI 16.4–16.9) cases per 1000 person years. The annual incidence rate was 17.0 (95% CI 16.5–17.4) in 2011 and 14.9 (95% CI 14.5–15.4) in 2014, indicating a 12.4% decrease. The incidence rate was significantly lower among females 13.9 (95% CI 13.7–14.2) than males 22.8 (95% CI 22.4–23.3), which was 2 times higher compared to females. The incidence rate of TB was four fold more common in non-ART patients as compared to
ART patients, being 47.2 (46.1-48.3) versus 12.8 (12.6-13.0). The risk of developing TB was significantly lower in adults compared to children below 15 years and increased with stage of clinical HIV disease (Table 3)

| Variable                        | TB cases | 1000Person years | TB incidence rate/1000 Person years (95%CI) | Hazard Ratio (95% CI) |
|---------------------------------|----------|------------------|-------------------------------------------|-----------------------|
| Overall                         | 22071    | 1232.6           | 16.7 (16.4-16.9)                           | -                     |
| Year of diagnosis               |          |                  |                                           |                       |
| 2011                            | 5366     | 316.2            | 17.0 (16.5-17.4)                           | 1                     |
| 2012                            | 5254     | 317.9            | 16.5 (16.1-17.0)                           | 1.07 (1.02-1.14)      |
| 2013                            | 6356     | 348.5            | 18.2 (17.8-18.7)                           | 1.15 (1.09-1.21)      |
| 2014                            | 5095     | 342.3            | 14.9 (14.5-15.4)                           | 0.84 (0.80-0.89)      |
| Sex                             |          |                  |                                           |                       |
| Male                            | 9306     | 407.7            | 22.8 (22.4-23.3)                           | 1                     |
| Female                          | 12764    | 916.9            | 13.9 (13.7-14.2)                           | 0.65 (0.64-0.67)      |
| ART status                      |          |                  |                                           |                       |
| Non ART                         | 7026     | 148.9            | 47.2 (46.1-48.3)                           | 1                     |
| ART                             | 15045    | 1152.7           | 12.8 (12.6-13.0)                           | 0.47 (0.46-0.49)      |
| HIV clinical stage              |          |                  |                                           |                       |
| 1                               | 844      | 180.0            | 4.7 (4.3-5.0)                              | 1                     |
| 2                               | 2306     | 300.1            | 7.7 (7.4-8.0)                              | 2.31 (2.09-2.55)      |
| 3                               | 13233    | 604.8            | 21.9 (21.5-22.2)                           | 10.2 (9.31-11.09)     |
| 4                               | 5214     | 216.7            | 24.1 (23.4-24.7)                           | 12.3 (11.2-11.45)     |
| Age group (Years)               |          |                  |                                           |                       |
| <15                             | 2034     | 97.5             | 20.8 (20.0-21.8)                           | 1                     |
| 15-24                           | 1210     | 70.4             | 17.2 (16.3-18.2)                           | 0.66 (0.63-0.78)      |
| 25-34                           | 5514     | 323.1            | 16.9 (16.4-17.3)                           | 0.78 (0.75-0.81)      |
| 35-44                           | 7554     | 458.9            | 16.5 (16.1-16.8)                           | 0.93 (0.90-0.97)      |
| 45-54                           | 3990     | 253.9            | 15.7 (15.3-16.2)                           | 0.94 (0.90-0.98)      |
| 55+                             | 1754     | 116.9            | 15.0 (14.3-15.7)                           | 0.87 (0.83-0.92)      |

Cumulative probability of TB incidence

Kaplan-Meier curves were used to assess cumulative probability of TB incidence over time and stratified by baseline variables of age and sex. The probability of TB incidence was 50% by 2 years since enrollment and reached around 65% in 4 years. The hazard of TB incidence was greatest in the first year of enrolment (Fig. 1). The cumulative probability of TB incidences was similar between adult and children in the first six months, progressively increasing more in adult than children after six months. At two years after enrollment cumulative probability for TB incidence was 50% in children while reached around 60% among adults (Fig. 2). There was a clear difference of cumulative probability of TB incidence between males and female. By six months, the cumulative probability of TB incidence among males reached 50% compared to 25% among females, who reached 50% after three years (Fig. 3).
Discussion
We conducted an assessment of the occurrence of a first episode of pulmonary tuberculosis (PTB), involving individuals whose first-visits at HIV care and treatment services occurred between January 2011 to December 2014. As a result, the study included a total of 527,249 individuals with the total of 11,539,844 clinical encounters at health facilities implementing TB and HIV collaborative activities. The observed incidence of TB in PLHIV on ART reported in this study (12.8 per 1000 PY) is on lower side compared to observed incidences in prior studies conducted among adults in Tanzania [16]. The reported incidences in Africa have been described in a range of 0.9–7.9 cases per 100 PY [18–21]. Development of incident TB in the current study was significantly associated with advanced HIV disease defined by WHO clinical stages. Our findings is consistent with previous findings and supports the known benefit of early HIV diagnosis and treatment [22]. There is a much greater risk of HIV and TB co-infected patients to develop active TB either from the latent infection or rapid progression of a new infection especially in advanced HIV disease [23].

As observed in this analysis and reported in other studies, the use of ART has great advantage on reduction of incidence of TB, evidenced by marked low incidence of TB among persons on ART compared to those not on ART [16, 24, 25]. The findings are conceivable because the TB infection and reactivation has been associated with the degree of immune suppression which improve after start of ART [26]. In individuals not on ART, HIV infection increases susceptibility to TB and is the most potent factor in transferring latent or recently acquired TB infection to active clinical diseases[27, 28]. The study found a higher risk of TB among males compared to females, which is comparable to other studies [2, 29, 30]. The most probable reasons to explain this difference could be the biological differences in disease and disease presentation which fevers women [31, 32]. Furthermore, men are more likely to report predisposing factors for TB like smoking than females [33]. PLHIV aged below 15 years had significant higher risk of TB incidence than adults. However, encouragingly the observed overall incidence of TB in children (20.8 cases per 1000 PY) is less compare to finding from a previously reported cohort study in Tanzania (5.2 cases per 100 PY)[34] This signifies the effort in increasing access to paediatric HIV and TB care and treatment in Tanzania [35].
The major strength of this study is that it drew on a large and nationally representative sample from a country with a significant burden of TB and HIV. It has provided some insights on the situation of TB in clinical services for HIV care and treatment in Tanzania. Nevertheless, the TB cases for this analysis excluded those who had no bacteriological confirmation hence the magnitude reported may be underestimated due to the fact that PLHIV have higher tendency for paucibacillary. In addition, many of our facilities may not be able to perform bacteriological diagnostics test which has high sensitivity and specificity, instead depend on radiological and clinical diagnoses. The other limitation is that the data come from the electronic CTC database, which is used in the larger and better run clinics. The situation reported here might not be the same in smaller health facilities that have not provided electronic data.

Conclusion
The study found overall decrease of incidence of TB in PLHIV demonstrated more among those on ART, adult, female and low HIV clinical stage. Our results reinforce known recommendations for HIV test and treat, intensified TB case findings and TB Preventive therapy for those PLHIV without active TB.

Abbreviations
ART
Antiretroviral therapy, CTC:Care and treatment clinics HIV:human immunodeficiency virus,
PLHIV:People living with HIV, TB:Tuberculosis, WHO:World Health Organization

Declarations
Ethics approval and consent to participate
The data was collected by health facilities providing HIV care and treatment services and managed by the Epidemiology Unit of National AIDS Control Programme using the National Guidelines for HIV Care and Treatment, in which ethical issues are strongly advocated.

Consent for publication
Not applicable

Availability of data and material
The raw data supporting the findings can be accessed on reasonable request to the Head of
Epidemiology Unit of the National AIDS Control Programme

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

GS, JN, SV, TJ were involved for preparing the study protocol. GS was the overall coordinator of the study, while JN, SV and TJ performed statistical analyses. MM, MIM, JM, AJ, AR, NM, AR, WM, were involved in various stages of study from reviewing the protocol, reviewing the results and preparation of the manuscript. All authors jointly prepared and approved the final manuscript.

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Figures

Cumulative probability of TB incident after enrollment to HIV care and treatment
Cumulative probability of TB incident after enrollment to HIV care and treatment by age

Figure 2
Figure 3

Cumulative probability of TB incident after enrollment to HIV care and treatment by sex