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TREND OF CASE NOTIFICATION AND TREATMENT OUTCOME IN TB MANAGEMENT UNITS IN REFUGEE SETTLEMENTS IN UGANDA. A FOUR-YEAR RETROSPECTIVE ANALYSIS, 2014-2017
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ABSTRACT

***Background*: Tuberculosis (TB) is a major health challenge in refugee populations. Monitoring the key indicators of TB program performance is essential to improve the effectiveness of TB control in refugee camps.**
***Objective*: To investigate trends of TB case notifications and treatment outcomes in refugee settlements in Uganda, 2014-2017.**
***Design*: Retrospective descriptive cohort study**
***Settings*: Thirty-three health facilities located in 12 refugee settlements**
***Subjects*: All TB cases registered from January 1 2014 to December 31 2017**
***Results*: A total of 794 TB cases of whom 63.4% were of age 15-44 years and 2.9% Extrapulmonary TB (EPTB) were registered. TB case notification increased from 89 in 2014 to 452 cases in 2017. From 2014 to 2017: male to female ratio for notification was ≥ 2.1:1; percentage of bacteriologically confirmed new and relapse pulmonary was 73.5% to 90.5%; and TB treatment success rate remained lower at 56.2% to**

70.8%. On average 32.2% had unfavorable outcomes, including 22% lost to follow-up (LTFU), 4.5% not evaluated, 3.8% died, and 1.5% had treatment failure. Unsuccessful treatment was significantly associated with EPTB (AOR 11.4 95% CI (1.9-66.5).

***Conclusion*: During the study period: TB case notification continuously increased; TB cases were predominately by male and age 15-44 years; frequency of EPTB remained lower than the national data (7.3%); and TB treatment success was far below the global target (≥ 90%) which need to be improved. There was higher LTFU, not evaluated and death. Patients with EPTB who are at higher risk for unsuccessful treatment need special support.**

INTRODUCTION

Tuberculosis (TB) affects millions of people worldwide (1). Uganda is among the 30 high burden countries for TB/HIV. In 2017, the estimated TB incidence and mortality rate (HIV negative) per 100 000 populations in the country was 201 and 26, respectively (1). Overall, the WHO global plan is to end the TB epidemic by 2030 (2).

TB, however, remains to be more challenging in key populations (refugees, immigrants, prisoners, homeless, internally displaced persons), due to overcrowding, poor nutritional status, coexistent illness, and inadequate TB care services (2-5). Studies showed refugees are at higher risk for TB infection and disease progression (4, 5), acquiring or developing multi-drug resistant (MDR) TB (6) and unsuccessful TB treatment outcome (7).

Armed conflicts and population displacements are associated with up to 20-fold increases in the risk of TB (5). In 2018, there were 70.8 million refugees, asylum seekers and persons displaced by wars and conflicts worldwide (8). Majority (> 85%) of refugees originate from and remain within countries with high burdens of TB (9). Others reported, an association between continuous immigration and an increase in prevalence of either PTB or EPTB (10), in TB case notification (11) and in case detection rate (12).

Uganda, with population size of 43 million in 2020 (1), is one of the third top refugee hosting nation in the world, with over 1.4 million refugees as of 2020 hosted in 12 refugee settlements (13). Most of the refugees originate from neighbouring countries where TB is predominant especially from South Sudan (61.7%) and the Democratic Republic of the Congo (29.3%), and from Burundi, Somalia, Rwanda, Eritrea, Ethiopia, Sudan, and Kenya. Nonetheless, the total end year refugee population in Uganda has continuously increased during the timespan of this study, form 335723 refugees in 2014 to 1.3 million by 2017 (13).

The summary of evidence (3-13) indicated TB can be major health challenge in the refugee settlements in Uganda. Thus, monitoring the performances of TB programs in the refugee settlements is essential to improve the effectiveness of TB control activities. In this study, we investigated trends of the key indicators for TB program performance (TB case notification and treatment outcomes) (14) in refugee settlements in Uganda from 2014 to 2017.

MATERIALS AND METHODS

Study settings and participants: In Uganda, the National TB and Leprosy Program (NTLP) is responsible for performing the core functions for TB and Leprosy control services. Similarly, the TB/Leprosy control activities in refugee settlements are led by the NTLP and implemented as per the Uganda national TB guidelines (15).

According to the inclusion criteria, refugee health facilities which have both TB diagnostic and treatment services since january 2017 should be included in this study. Thus, 33 health facilities in 12 refugee settlements (Table 1) which are in 12 Districts were included**.** The study participants were all TB cases of all forms registered in these 33 refugee health facilities from 1 January 2014 to 31 December 2017.

This study was based on secondary data from the unit TB register. Ethical approval (number 150-180) and permission was obtained from Mengo Hospital Research Ethics committee (MHREC), Uganda.

Study design and data collection: In this descriptive retrospective study, demographic and clinical data of all TB case were extracted from the unit TB register. Data collection was done by trained health officers and nurses using pretested data collection forms from January to April 2019.

Data entry and statistical analysis: Data were exported to STATA version 13 for data checking, cleaning and analysis. Multivariate logistic regression analysis was performed to measure the independent effects of each predictor variable on unsuccessful treatment outcomes. The independent variables used were age, sex, baseline weight, type of TB, and HIV and ART status. Odds ratios with 95% confidence interval were used to assess the strength of association between variables. Statistical significance level was considered at a P-value <0.05.

Definitions of variables

The operational definitions are based on the National Manual for TB and Leprosy control in Uganda (15) and the WHO document (16).

TB case notification: TB is diagnosed in a patient and is reported within the national TB surveillance system

TB case: is a patient in whom TB has been diagnosed.

TB treatment outcomes for drug sensitive TB:

Cured: A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion

Treatment Completed: A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative either because tests were not done or because results are unavailable.

Treatment failed: A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.

Lost to follow up: A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.

Died: A TB patient who dies for any reason before starting or during the course of treatment.

Not evaluated: A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" as well as cases for whom the treatment outcome is unknown.

We dichotomized the treatment outcome into: successful (cured and treatment completed) and unsuccessful (died, failed and LTFU)

RESULTS

Characteristics of the study participants

The clinical and sociodemographic characteristics of the total notified TB cases is shown in Table 1. A total of 794 TB cases of whom 2.8% were EPTB, and 96.1% new and relapse patients were registered (2014-2017). Of the 741 (97.1%) new and relapse PTB patients, 78.3% were bacteriologically confirmed. Notified TB cases were predominated by men (67.8%), and age 15-44 years (63.4%).

Overall, 54.3% of the notified cases were from four refugee settlements: Nakivale (17.6%), Kyangwali (14.6%), Rwamwanja (11.2%), and Adjumani (11.0%) (Table 1).

Table 1:

Distribution of notified TB cases by demographic and clinical characteristics in refugee settlements, Uganda, 2014–2017 (N=794)

Characteristic	**2014, N (%)**	**2015, N (%)**	**2016, N (%)**	**2017, N (%)**	**Total (2014-2017) N (%)**
Total TB patients of all Forms	89	82	171	452	794
Mean age, years	35.5	36.8	35.5	35.1	35.7
Age group					
<15	5 (5.6)	7 (8.5)	18 (10.5)	40 (8.8)	70 (8.8)
15-29	29 (32.6)	20 (24.4)	52 (30.4)	125 (27.7)	226 (28.5)
30-44	31 (34.8)	26 (31.7)	52 (30.4)	168 (37.2)	277 (34.9)
45-59	15 (16.8)	21 (25.6)	26 (15.2)	74 (16.4)	136 (17.1)
>= 60	9 (10.2)	8 (9.8)	22 (12.9)	44 (9.7)	83 (10.5)
Not recorded	0	0	1 (0.6)	1 (0.2)	2 (0.2)
Gender,					
Male	61 (68.5)	58 (70.7)	117 (68.4)	302 (66.8)	538 (67.8)
Female	28 (31.5)	24 (29.3)	54 (31.6)	145 (32.1)	251 (31.6)
Not recorded	0	0	0	5 (1.1)	5 (0.6)
M:F ratio	2.2	2.4	2.2	2.1	2.1
Type of TB					
PTB	88 (98.9)	80 (97.6)	166 (97.1)	437 (96.7)	771 (97.1)
EPTB	1 (1.1)	2 (2.4)	5 (2.9)	15 (3.3)	23 (2.9)
Type of TB by diagnostic category:					
PTB+	79 (88.8)	66 (80.5)	137 (80.1)	323 (71.5)	605 (76.2)
Clinically diagnosed PTB*	9 (10.1)	14 (17.1)	29 (17.0)	114 (25.2)	166 (20.9)
EPTB	1 (1.1)	2 (2.4)	5 (2.9)	15 (3.3)	23 (2.9)
TB patient by treatment history:					
New and relapse**	85 (95.5)	78 (95.1)	164 (95.9)	436 (96.5)	763 (96.1)
Treatment after Failure	0	0	1 (0.6)	3 (0.7)	4 (0.5)
Lost to Follow up to Treatment	3 (3.4)	4 (4.9)	6 (3.5)	9 (2.0)	22 (2.8)
Others	1 (1.1)	0	0	1(0.2)	2 (0.3)
Missed	0	0	0	3 (0.6)	3 (0.4)
New and relapse PTB patients	84 (98.8)	76 (97.4)	159 (97.0)	422 (96.1)	741 (97.1)
Bacteriologically confirmed	76 (90.5)	62 (81.6)	132 (83.0)	310 (73.5)	580 (78.3)
cases	8 (9.5)	14 (18.4)	27 (17.0)	112 (26.5)	161 (21.7)

Clinically confirmed cases					
HIV status					
Positive	10 (12.5)	22 (27.2)	27 (16.6)	88 (19.8)	147 (18.5)
Negative	70 (87.5)	59 (72.8)	136 (83.4)	357 (80.2)	622 (78.3)
Not documented	9 (10.1)	1 (1.2)	8 (4.7)	7 (1.5)	25 (3.1)
ART initiation					
Yes	9 (90)	21 (95.4)	26 (96.3)	83 (94.3)	139 (94.6)
No	1 (10)	1 (4.6)	1 (3.7)	5 (5.7)	8 (5.4)
TB cases by refugee settlements					
Adjumani	2 (2.3)	3 (3.4)	17 (19.5	65 (74.1)	87 (11.0)
Palabek	0	0	0	35 (100)	35 (4.4)
Palorinya	0	0	1 (2.8)	35 (97.2)	36 (4.5)
Bidibidi	0	0	5 (6.9)	68 (93.1)	73 (9.2)
Rhino	0	8 (12.9)	17 (27.4)	37 (59.7)	62 (7.8)
Imvepi	0	0	0	38 (100)	38 (4.8)
Kiryandongo	2 (3.8)	4 (7.7)	23 (44.2)	23 (44.2)	52 (6.5)
Kyangwali	35 (30.4)	13 (11.3)	28 (24.4)	39 (33.9)	115 (14.6)
Nakivale	27 (19.3)	20 (14.3)	38 (27.1)	55 (39.3)	140 (17.6)
Oruchinga	7 (41.2)	3 (17.6)	3 (17.6)	4 (23.4)	17 (2.1)
Kyaka II	0	13 (26.0)	14 (28.0)	23 (46.0)	50 (6.3)
Rwamwanja	16 (18.0)	18 (20.2)	25 (28.1)	30 (33.7)	89 (11.2)

PTB+ = Smear-positive pulmonary TB

**Clinically diagnosed PTB: includes smear-negative pulmonary TB and pulmonary smear unknown/not done*

*** New and relapse: includes cases for which the treatment history is unknown (not recorded) and transfer in;*

Trends in case notification by diagnostic category, 2014-2017

Number of notified TB cases has continuously increased from 89 in 2014 to 171 in 2016 and then to 452 cases by 2017 (an increases of 281 cases in one year). From 2014 to 2017, the proportion of PTB remained higher (98.9% to 96.7%), whereas EPTB remained lower in a range 1.1 % to 3.3% **(Table 1)**. By diagnostic category, smear-positive pulmonary TB (PTB+) among total cases decreased from 88.9% to 71.5% **(Fig 1)**, and the percentage of bacteriologically confirmed new and relapse pulmonary patients decreased from 90.5% to 73.5% (**Table 1)**

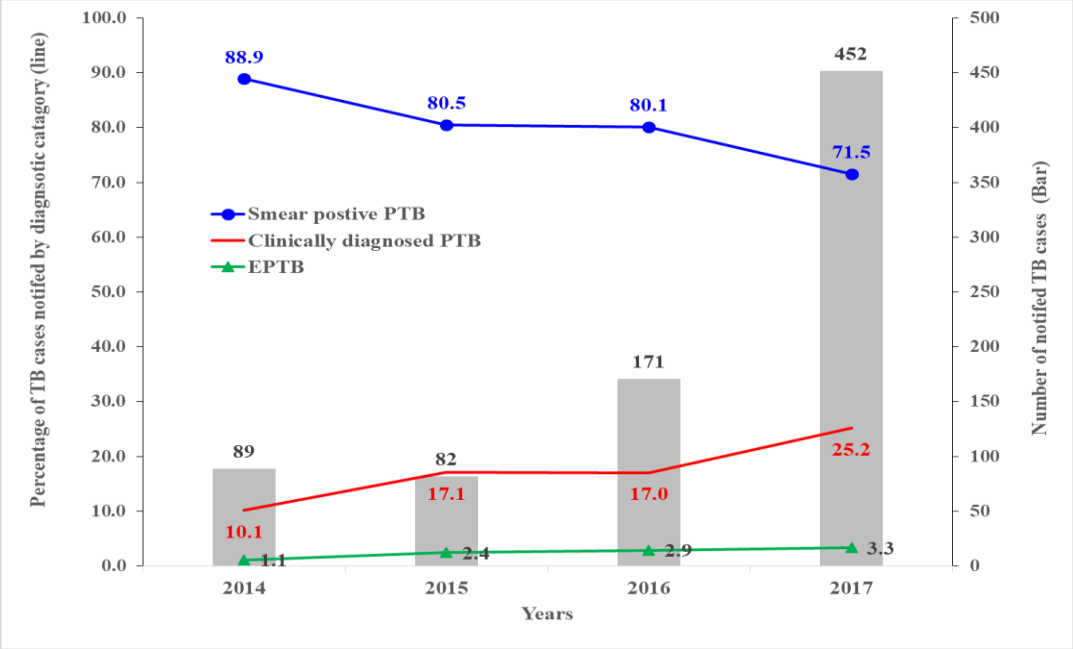

Figure 1. Trends in number of notified TB cases of all forms (bar) by diagnostic category (line) in the refugee settlements, Uganda, 2014-2017.

Trends in cases notification stratified by gender, 2014-2017

From 2014 to 2017, the number, proportion, and male-to-female (M: F) ratio of the notified cases was dominated by men. Hence, the proportion of notified men cases was > 66.8%, with the M:F ratio of notification consistently >2.1:1. The M: F ratio has increased from 2.2 in 2014 to 2.4 in 2015, then declined to 2.1 in 2017(**Table 1**).

Trends in case notification stratified by age categories, 2014-2017

There was a variation in trend of case notification by age categories during the period **(Table 1 & Fig 2)**. The contribution of age groups 30-44 years remained highest at a range 30.4% to 37.2%. The second largest contributor were age group 15-29 years (24.4% to 32.6%). The least contributors were children aged <15 years (increasing gently from 5.9% in 2014 to 8.8% in 2017).

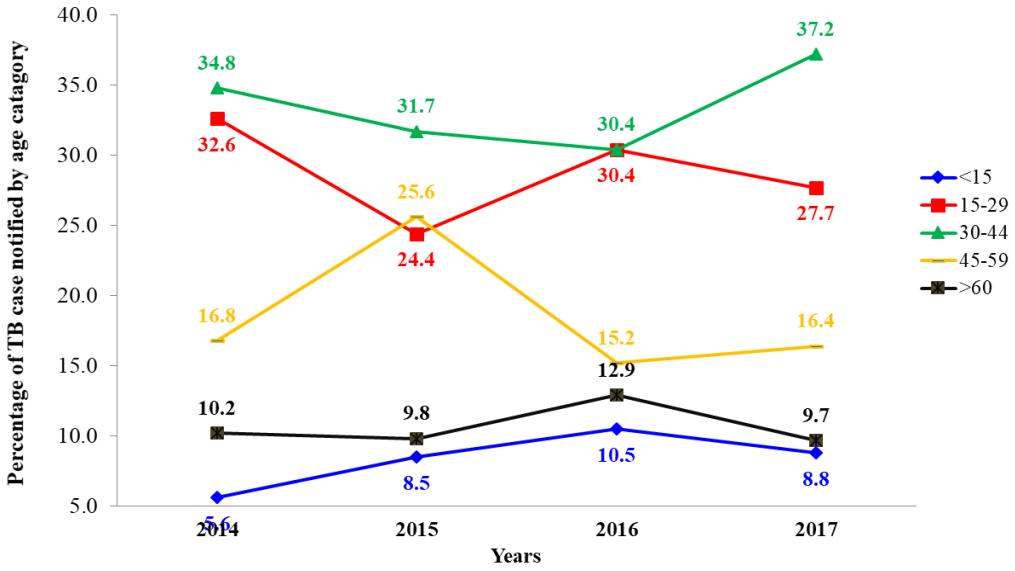

Figure 2. Trends in TB cases notified by age categories in the refugee settlements, Uganda, 2014-2017.

Trends in case notification segregated by gender and age categories, 2014-2017

From the total TB cases, the proportion of men was consistently higher (>54%) in all the age categories and across the study period (2014-2017), except for children <15 years in 2014 and 2015. Importantly, the proportion of women with TB has decreased as age increased across the years (**Fig 3**).

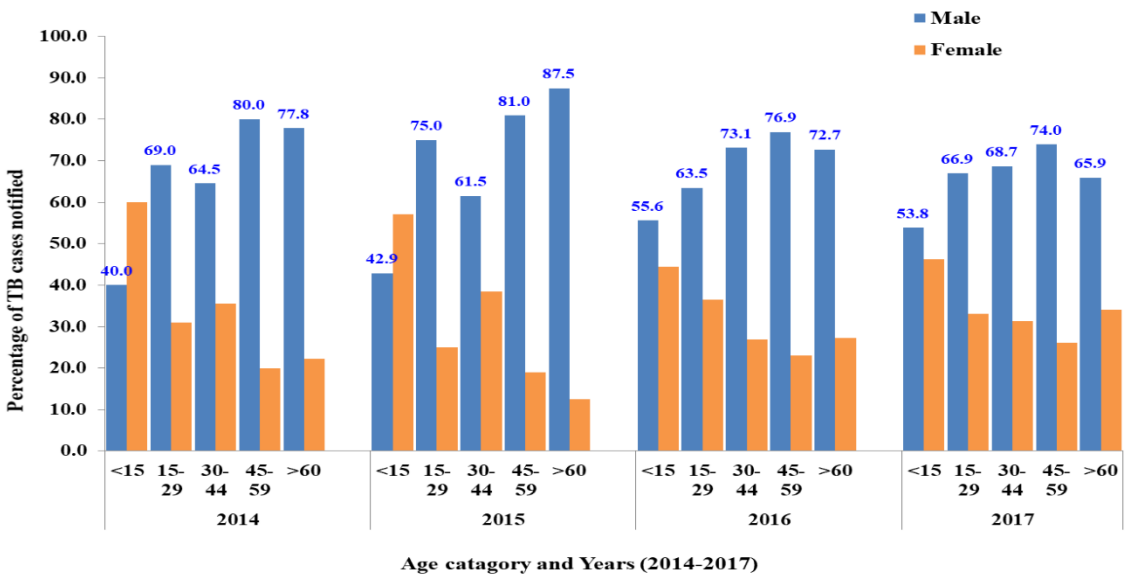

Figure 3. Trends in notified TB cases segregated by gender age categories in the refugee settlements, Uganda, 2014-2017

Trends in TB treatment outcomes, 2014-2017

TB Treatment outcome was evaluated for TB cases of all forms that were notified from 2014 to 2017 (Table 2). Treatment success rate remained lower at a range 56.2% to 70.8% (increasing from 56.2% in 2014 to 69% in 2017). Higher LTFU, followed by death, not evaluated, and treatment failed were the reasons for the lower treatment success rate. On average 32.2% of the patients had unfavorable outcome, including 22% lost to follow-up (LTFU) (decreasing from 31.3% to 22.8%), 4.5% not evaluated (decreasing from 5.6% to 3.1%), 3.8% died (decreasing from 4.5% to 3.5%), and 1.5% treatment failed (decreasing from 2.3% to 1.6%).

Table 2

Treatment outcome of TB cases of all forms registered in refugee settlements, Uganda, 2014–2017 (N=794). Data are presented as numbers (%)

	Years, n (%)				
Treatment outcomes	**2014, n=89**	**2015, n=82**	**2016, n=171**	**2017, n=452**	**Total, n=794**
Cured	24 (27.0)	17 (20.7)	50 (29.2)	157 (34.7)	248 (31.3)
Treatment completed	26 (29.2)	38 (46.3)	71 (41.5)	155 (34.3)	290 (36.5)
Lost to follow-up	28 (31.5)	20 (24.4)	27 (15.8)	103 (22.8)	178 (22.4)
Not evaluated	5 (5.6)	4 (4.9)	13 (7.6)	14 (3.1)	36 (4.5)
Died	4 (4.5)	3 (3.7)	7 (4.1)	16 (3.5)	30 (3.8)
Treatment failed	2 (2.3)	0	3 (1.8)	7 (1.6)	13 (1.5)
Treatment success	**50 (56.2)**	**55 (67.1)**	**121 (70.8)**	**312 (69.0)**	**538 (67.8)**

Data are presented as numbers (%)

Factors associated with unsuccessful TB treatment outcomes

From bivariate logistic regression analysis, history of LTFU to treatment [Odds ratio (aOR) = 10.6, 95% CI: 1.6–68.5, *P = 0.01*] and age 60 years and above (OR) = 2.0, 95% CI: 0.9-4.3, *P = 0.06*] were associated with unsuccessful treatment. However, by multivariate modelling, only EPTB (adjusted odds ratio (aOR) = 10.6, 95% CI: 1.6–68.5, *P = 0.01*] was significantly associated with unsuccessful treatment, which might have been expected given the small numbers in each subgroup.

DISCUSSION

This study provides useful evidence of four-year (2014-2017) trends of TB case notification and treatment outcomes, which can help to improve the effectiveness of TB control in refugee settlements in Uganda.

In countries with less underdiagnosed and underreported TB cases, notifications of TB provide good proxy information on TB incidence (**14**). In this study, TB case notification continuously increased from 82 cases in 2015 to 452 cases in 2017. Similarly, the 2017/18 annual TB report of Uganda showed an increase in 6585 more cases from 2015/16 to 2017/18 **(17).** The possible reasons for the increased trend in TB case notification in the refugee settlements include real increase in TB incidence **(4, 5),** higher TB burden in the surrounding communities of the host country and in country of origin of the refugees **(10),** continuous increase in number of refugee populations **(11-13)**, or improved TB service delivery leading to more TB notification**.** Hence, the increased trend in case notification

in the refugee settlements need to be carefully interpreted and further research is warranted to identify the contributing factors.

Bacteriologic diagnosis of TB allows patients to be correctly diagnosed and started on the most effective treatment regimen. In the refugee settlements, the proportion of bacteriologically confirmed new and relapse pulmonary patients by 2017 (73.5%) was higher than the WHO report for Uganda in 2017 (64%) but lower than the End TB global target for 2020 (80%) **(2).** Level of bacteriological confirmed TB cases in the refugee settlements can be increased by improving the quality-assured TB laboratory diagnostics.

In this study, the proportion of EPTB remained lower at a range 1%-3.3% as compared to the 2017/18 TB report for Uganda (7.3%) **(17),** and the 2018 WHO report for the glob (14%) **(1).** The lower proportion of EPTB in this study, can be due to misdiagnosed or underreported EPTB **(1)**, demographic factors, origin of refugee population, host factors (**18)**, or pathogen factor (**19**). Since EPTB is an important health problem, interventional measures including expansion of advance diagnostics is recommended. In addition, operational research aimed to investigate the factors attributed to the lower EPTB in the refugee settlements is warranted.

We observed, males were almost two times more affected (notified) than females. By 2017, the M:F ratio for notification (2.2:1) was higher than that for Uganda in 2017/2018 (1.9:1) **(17).** The gender disparity in TB case notification, could be due to combination of factors including gender-specific sociocultural factors (**20)**, biological reasons that women are less susceptible to TB infection and reactivation **(20),** or due to that women are less likely to report or show evidence of typical symptoms of pulmonary TB **(21).** Our findings suggest the need of special TB services targeting women.

TB is affects all age groups. In agreement to 2018 WHO report **(1)** and study done by others (**22)**, the highest notified cases in this study was in the age groups 15-44 years (28.5%-34.9%). Thus, as people in 15-44 years represents an active component of the workforce, TB intervention efforts should be focusing on this age group.

Since the source of infection for children is usually an infectious adult in the household, paediatric TB can be served as a sentinel marker for TB transmission (**23**). In this study, the proportion of childhood TB (<15 years) increased from 5.6% in 2014 to 8.8% by 2017. Similarly, 10% of the estimated TB incidence in 2017 in the globe **(1),** and 9% of all TB cases notified in 2017/18 in Uganda **(17)** were children <15 years. It is expected, childhood TB is misdiagnosed, overestimated and/or underreported **(1).**

In countries that have high-performance monitoring and evaluation systems, TB treatment outcomes provide information on the effectiveness of TB treatment program **(14)**. BY 2017, the treatment success rate in the refugee settlements (69.0%) was comparable to the 71% treatment success for all TB cases in Uganda for 2017 cohort (**19**), but lower than the WHO global target (≥ 90%) **(2),** than the global (82%) and national/Uganda (77%) treatment success for new and relapse cases of 2016 cohort **(1).**

The main reasons for the lower TB treatment success rate in this study, was higher unfavorable treatment outcomes (average 32.2%). BY 2017, the percentage of LTFU (22.8%), died (13%), not evaluated (3.1%) and treatment failed (1.6%) in the refugee settlements were higher than the 2018 TB report of Uganda (for adults) which were 13%, 9%, 6% and 1%, respectively, (**17**). In summary,

the TB treatment outcome in the refugee settlements indicate the need to improve TB treatment program, which includes improving follow-up sputum smear/culture examination, recording and reporting system, refresher training, and supportive supervision.

CONCLUSION

This study has provided insights on TB program areas need improvement. From 2014 to 2017: TB case notification has continuously increased; proportion of EPTB remained lower than the national and global data; women cases were less represented; TB cases age 30-44 years were predominant; and TB treatment success rate remained lower than the ≥90% global target.

There are limitations in this study: information about health facility factors, health care worker factors, and patient socioeconomic and lifestyle factors that could be associated with unsuccessful TB treatment outcomes was not recorded in the Unit TB register. Thus, any analysis on the effect of these factors or adjustment for their effect was not possible. Strength of the study: we have provided useful information of four-year timespan on trends in TB case notification and treatment outcomes that will help to guide and improve the effectiveness of TB control efforts in the refugee settlements in Uganda.

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