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Tuberculosis treatment default among HIV-TB co-infected patients in urban Uganda

Sawsan Elbireer[1], David Guwatudde[2], Peter Mudiope[1], Juliet Nabbuye-Sekandi[2] and Yukari C. Manabe[3,4]

1 *Makerere University – Johns Hopkins University Research Collaboration, Kampala, Uganda*
2 *School of Public Health, Makerere University, Kampala, Uganda*
3 *Infectious Disease Institute, Kampala, Uganda*
4 *Division of Infectious Diseases, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA*

Summary

OBJECTIVE To identify health facility and patient-specific factors associated with TB treatment default in HIV-infected patients, in a TB clinic on the campus of Mulago National Referral Hospital in Kampala, Uganda.

METHODS Unmatched case–control study between March and May 2009. Cases were TB patients known to have defaulted on their anti-TB treatment, defined as a TB patient who had documented discontinuation of TB medication for two or more consecutive months due to reasons other than physician's advice and who did not access care at another facility. Controls were TB patients who completed 8 months of anti-TB treatment without interruption of two or more months. Data on health facility-specific factors and individual characteristics were collected using semi-structured questionnaires.

RESULTS Factors associated with defaulting from TB treatment were: distance from home to clinic (OR 2.22; 1.21–4.06); long waiting time at the clinic (OR 4.18; 2.18–8.02); poor drug availability (OR 4.75; 2.29–9.84); conduct of staff (OR 2.72; 1.02–7.25); lack of opportunity to express feelings (OR 3.47; 1.67–7.21). Other patient-related factors were lack of health education, i.e. not being aware of the duration of treatment or the risk of discontinuing it (OR 5.31; 1.94–14.57); not knowing that TB can be cured (OR 44.11; 13.66–142.41); length of TB treatment (OR 10.77; 5.18–22.41), and side effects of treatment OR 5.53 (2.25–13.61).

CONCLUSIONS Defaulting is influenced by health systems, staff factors, and patient misinformation. Health education on TB directed at patients combined with staff sensitization could help to improve adherence to TB treatment.

keywords treatment default, tuberculosis, HIV

Introduction

Tuberculosis (TB) is a major contributor to the global burden of disease, particularly in low and middle income countries due to its association with HIV/AIDS (Corbett *et al.* 2006). In 2009 WHO estimated that there were 9.4 million incident TB cases, and nearly 380 000 TB deaths among HIV-positive people (World Health Organization 2010). In Uganda, 38% of people living with HIV have TB (World Health Organization 2009). Uganda ranks 16th on the list of 22 countries that shoulder the highest tuberculosis burden (USAID 2009).

Defaulting from treatment is a challenge for TB control and one of the major obstacles to treatment management (Brudney & Dobkin 1991). Uganda had a TB default rate of 11% with a treatment success rate of 70% among smear positive patients (World Health Organization 2010). TB treatment defaulters, especially those who are smear positive, comprise an infectious pool that maintains the continued transmission of TB within the community (Daniel *et al.* 2006) and can result in the development of multidrug-resistant TB (MDR-TB) (Sevim *et al.* 2002). Although it has not been shown that HIV infected patients have a higher rate of default than HIV negative patients, failure to complete TB treatment is associated with very high rates of recurrence especially in HIV-infected patients (Korenromp *et al.* 2003).

Factors associated with defaulting from anti-TB treatment are old age (De Albuquerque *et al.* 2007), being male, and low education level (Tissera 2003). Migration for work, perception that TB is incurable and poor knowledge about TB also increase the risk for default (Vijay *et al.*

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2003), as do low income and poor attitude of heath care workers (Dodor & Afenyadu 2005; Holtz *et al.* 2006). Thus knowledge of health systems, patient and clinic staff factors associated with defaulting from TB treatment is crucial in developing strategies to reduce default rates.

In 2007, about 29% of TB patients registered at the Infectious Diseases Institute (IDI) clinic defaulted from treatment (data unpublished), for reasons not well understood. We therefore sought to identify health facility factors and individual patient characteristics associated with defaulting among TB patients receiving TB treatment at the IDI.

Materials and methods

Study population

An unmatched case–control study was conducted from March to May 2009 at the TB clinic of the IDI among HIV-infected patients diagnosed with TB, who were treated between January 2006 and December 2008. The IDI TB-HIV clinic registers and treats approximately 400 active TB patients annually; patients suspected to have active TB are referred internally. All patients who attend the IDI TB clinic are HIV-infected, and some begin highly active antiretroviral therapy (HAART) during the continuation phase of anti-TB treatment. TB diagnosis is based on laboratory sputum smear fluorescent microscopy, and clinical and radiological characteristics of a patient. Patients are provided with adherence counselling and TB health education at the start of TB treatment and at recurrent visits. They are also provided with a card to document the daily intake of TB medication, which adheres to the Uganda National TB treatment guidelines (Ministry of Health 2006). At each clinic visit, adherence is assessed by asking patients about their drug intake and by checking the entries on the patient's card for completeness.

When patients start TB treatment, their names, addresses, TB regimen and HAART status are entered in the TB register. Their outcome status (i.e. either completed treatment, defaulted, died or transferred) is entered on the register regularly. If a patient is not seen in the clinic for two or more consecutive months, the patient is registered as a 'TB treatment defaulter'.

Definition of cases and controls

A case (defaulter) was defined as a TB/HIV co-infected patient, who had documented discontinuation of anti-TB treatment for two or more consecutive months due to reasons other than physician's advice. A control (non-defaulter) was defined as a TB/HIV co-infected patient, who had documented completion of eight months of anti-TB treatment without interruption of two or more consecutive months.

Identification of cases and controls

Using the TB register, patients who started TB treatment between January 2006 and December 2008 were identified. Based on the definition above, a 172 defaulters and 172 non-defaulters were initially identified. Using the patient's contact information, trained research assistants phoned and invited them to participate in the study. At their next clinic visits informed consent was obtained from all participants enrolled into the study. Failure to contact the patients through phone calls required tracing them through IDI visit report, which is an electronic database used to link the patients' number in the TB register with the IDI clinic number and enabling access to former TB patients who were still receiving HIV treatment/care at IDI clinic. Patients too ill to come to the clinic and those who declined to participate were excluded from the study.

After interview 127 patients of the 172 defaulters were confirmed as cases; the remaining 45 patients had accessed treatment elsewhere and thus were re-classified as controls. Hence 127 cases and 217 controls (172 + 45) were included in this study.

Measurements

Data were collected by trained research assistants through face-to-face interviews using a semi-structured questionnaire. The questionnaire collected data on sociodemographic characteristics, average waiting time in the clinic, transport fare to the clinic, views on conduct, attitudes and behaviour of health care providers, satisfaction with clinic staff, health education on duration and risks of discontinuing TB treatment, history of having received counselling, length and frequency of counselling, reminder phone calls, drug availability and clinic working hours/days. Individual patient factors investigated were knowledge about TB transmission and its treatment, employment, discrimination, disclosure, having family support or treatment buddy, concomitant use of HAART and experience of side effects.

Ethical approval

The study was approved by Makerere University School of Public Health (MUSPH)'s Higher Degrees, Research and Ethics Committee. Permission for conducting the study at IDI was obtained from the Scientific Review Committee (SRC) and the management at IDI clinic.

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Data analysis

Participant characteristics were summarized using proportions for categorical variables and means or medians for continuous variables. Characteristics of cases and controls were compared by Pearson's chi-square for categorical variables, and two sample *t*-test for continuous variables. Bi-variable analysis of each independent variable and the defaulting status was initially performed to identify potential individual patient characteristics, and health facility characteristics associated with defaulting on TB treatment. Binary logistic regression analysis was then applied to identify factors associated with defaulting. All variables with a *p*-value less or equal to 0.25 at the bi-variable analysis stage were assessed with the binary logistic regression model. The association was considered significant if the *p*-value was <0.05. Odds ratios and their corresponding 95% confidence interval (CI) were reported as the measures of association. All statistical analysis was performed using STATA version 10.0.

Table 1 Enrolment summary

Year	Total number of patients	Total number eligible*	Total number enrolled in this study	Percentage of eligible patients enrolled
2006	678	576	65	11.3
2007	364	334	138	41.3
2008	253	217	141	65
Total	1295	1127	344	30.5

*Excluding patients who died or were transferred.

Results

Participants

Of all patients started on anti-TB treatment between 2006 and 2008, 1127 were eligible for enrolment into this study. We enrolled 344 (30.5%) were enrolled, of whom 127 were cases and 217 were controls (Table 1). provides a summary of the enrolment figures. 51% were males. The average age of participants was 36.0 years (standard deviation = 8.0, range 27–45). The 42% reported to be married or cohabiting and 35% were single. The rest were divorced, separated or widowed. Only 3% (11) reported not to have attended any schooling, 57% had attended primary school (with 25% completed and 32% not completed), the rest had attended secondary or further education (Table 2). Except for age, where cases were significantly younger (mean age 35) than controls (mean age 37), *P*-value = 0.014, there were no significant

Table 2 Comparison of characteristics of cases and controls at the IDI clinic

Characteristic	*n*	Summary measure	Case	Controls	*P*-value
Age in years mean (SD)	344	36 (8)	35 (8)	37 (8)	0.014
Sex					
Male	176	51.2%	66 (37.5)	110 (62.5)	0.819
Female	168	48.8%	61 (36.3)	107 (63.7)	
Marital status*					
Single	121	35.3%	48 (39.7)	73 (60.3)	0.31
Married/cohabiting	143	41.7%	45 (31.5)	98 (68.5)	
Divorced/separated	64	18.7%	27 (42.2)	37 (57.8)	
Widowed	15	4.4%	7 (46.7)	8 (53.3)	
Highest education					
No education	11	3.2%	1 (9.1)	10 (90.9)	0.152
Primary school, incompleted	110	32%	47 (42.7)	63 (57.3)	
Primary school, completed	87	25.3%	35 (40.2)	52 (59.8)	
Secondary school, incompleted	90	26.2%	32 (35.6)	58 (64.4)	
Secondary school, completed	24	7%	6 (25)	18 (75)	
Tertiary	22	6.4%	6 (27.3)	16 (72.7)	
Alcohol intake†					
History of alcohol	114	(33.3)	45 (39.5)	69 (60.5)	0.527
No history of alcohol	228	(66.7)	82 (36)	146 (64)	

n = total number of cases and controls.
*Respondents, *n* = 343.
†Respondents, *n* = 332.

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differences in the other characteristics measured between cases and controls.

Factors associated with defaulting

The median time to defaulting on anti TB treatment was 5 months, with an inter-quartile range (IQR) of 5–6 months. A number of health facility factors were associated with defaulting: Waiting times at the clinic averaging two or more hours (OR = 4.2 [95% CI: 2.18–8.02]); staff conduct perceived as bad or just fair (OR 2.7 [95% CI: 1.02–7.25]); not having been given a chance to express concerns about TB treatment (OR 3.5 [95% CI: 1.67–7.21]); not receiving adequate health education on the duration of treatment and the risk of discontinuing it (OR 5.3 [95% CI: 1.94–14.57]); and having experienced drug unavailability (OR 4.75 [95% CI: 2.29–9.84]). These results are summarized in Table 3.

Individual patient characteristics associated with defaulting were living at a distance of 10 km or more from the IDI clinic (OR 2.2 [95% CI: 1.21–4.06]); not knowing that TB can be cured (OR 44.1 [95% CI: 13.66–142.41]); and not knowing the duration of TB treatment (OR 10.8 [95% CI: 5.18–22.4]); and a history of side effects during TB treatment (OR 5.5 [95% CI: 2.25–13.61). Employment status, having a family member to remind patient to take their medicine, feelings of discrimination by family, feelings of lack of family support, disclosure status to family members about having TB, and being on HAART during TB treatment were not associated with defaulting. These results are summarized in Table 4.

Discussion

This study investigated factors associated with defaulting from anti TB treatment. Although many studies highlight individual characteristics of patients that contribute to default, in our study, other significant factors were related to the patient–health care provider relationships such as long waiting time, low rating of the conduct of the staff, and not giving patients the chance to express concerns. Health education on duration and the risk of discontinuing TB treatment greatly influenced the attitude of towards coming to the clinic for TB treatment. These findings support suggestions from studies in Ethiopia which concluded that lack of health education is a significant predictor for defaulting (Demissie & Kebede 1994; Michael *et al.* 2004). In a South African study, in-service clinical skills training for nurse practitioners on HIV and lung health led to higher cure and completion rates and lower default rates (Bachmann *et al.* 2010).

More cases than controls reported finding TB drugs out of stock. Our findings were compatible with another study

Table 3 Analysis results of health facility factors associated with TB default status

Characteristic	*n*	Cases	Crude OR (95% CI)	Adjusted OR (95% CI)	*P*-value
Average waiting time*					
<2 h	130	22 (18.2)	1.0		
2–4 h	62	21 (17.4)	2.51 (1.23–5.13)	2.45 (1.07–5.60)	0.034
Above 4 h	140	78 (64.5)	6.18 (3.32–11.48)	4.18 (2.18–8.02)	<0.001
Conduct of staff					
Good	305	99 (77.9)	1.0	2.72 (1.02–7.25)	0.045
Fair	39	28 (22.1)	5.30 (2.46–11.38)		
Received counselling					
Yes	290	95 (74.8)	1.0	1.04 (0.42–2.57)	0.922
No	54	32 (25.2)	2.98 (1.62–5.49)		
Ever given chance to express concerns about anti TB treatment†					
Yes	248	68 (55.7)	1.0	3.47 (1.67–7.21)	<0.001
No	87	54 (44.3)	4.33 (2.51–7.46)		
Received health education on duration & risk of discontinuing treatment‡					
Yes	47	8 (6.6)	1.0	5.31 (1.94–14.57)	0.001
No	289	114 (93.4)	3.17 (1.41–7.13)		
Drugs not available at any one time					
No	279	81 (63.8)	1.0	4.75 (2.29–9.84)	<0.001
Yes	65	46 (36.2)	5.92 (3.15–11.13)		

n = total number of cases and controls.
*Respondents, *n* = 332.
†Respondents, *n* = 335.
‡Respondents, *n* = 336.

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Table 4 Analysis results of individual factors associated with TB default status

Characteristic	*n*	Cases	Crude OR (95% CI)	Adjusted OR (95% CI)	*P*-value
Distance to the TB clinic					
Near (less than 10 km)	235	77 (60.6)	1.0	2.22 (1.21–4.06)	0.010
Far (more than 10 km)	109	50 (39.4)	1.74 (1.09–2.78)		
Knowledgeable that TB has a cure					
Yes	276	65 (51.2)	1.0	44.11 (13.66–142.41)	<0.001
No	67	62 (48.8)	40.25 (12.65–128.10)		
Knowledgeable on duration of anti-TB treatment					
Yes	265	74 (58.3)	1.0	10.77 (5.18–22.41)	<0.001
No	79	53 (41.7)	5.26 (2.96–9.36)		
Being employed at time of TB diagnosis					
Yes	147	44 (34.6)	1.0	1.13 (0.58–2.20)	0.711
No	195	83 (65.3)	1.73 (1.10–2.74)		
Had family member/friend to remind patient to take treatment					
Yes	220	64 (50.4)	1.0	1.0 (0.47–2.13)	0.999
No	124	63 (49.6)	2.52 (1.58–4.02)		
Felt discriminated against by family/community					
No discrimination	309	104 (81.9)	1.0	2.04 (0.52–8.07)	0.307
Discrimination	35	23 (18.1)	3.78 (1.78–8.02)		
Had family support					
Supported	304	101 (79.5)	1.0	1.09 (0.29–4.08)	0.893
No support	39	26 (20.5)	4.02 (1.94–8.31)		
Had disclosed having TB to anybody					
Yes	305	100 (78.7)	1.0	3.27 (0.88–12.12)	0.076
No	39	27 (21.3)	4.61 (2.19–9.70)		
Experienced side effects while on anti-TB treatment					
Yes	250	116 (91.3)	1.0	0.18 (0.07–0.44)	<0.001
No	94	11 (8.7)	0.15 (0.07–0.31)		

in Nigeria which found that continuous uninterrupted supply of anti TB drugs is crucial to the success of TB treatment programmes (Daniel *et al.* 2006). We did not establish the duration TB drug stock-outs, which may range from hours to several days. At the IDI clinic drugs are likely to be out of stock for a few hours during re-stocking from the central pharmacy, especially in the morning. Recall bias may have played a role, but this would affect cases and controls in same direction as we used standard tools for data collection. Nevertheless, for the urban population this result indicates that drug availability plays a central role in TB management irrespective of the duration of stock out.

TB patients taking HAART in addition to TB drugs are more likely to interrupt TB and/or HAART treatment due to adverse events (Dean *et al.* 2002). Indeed we found that more participants who experienced side effects from anti-TB treatment stopped coming to the clinic to collect their medications, but we were surprised that this was not associated with concurrent HAART medications. Further analysis showed no increase in risk of defaulting between patients who developed side effects and were taking HAART compared to those who were not taking HAART. Hence being on HAART was not a predictor of defaulting anti TB treatment in the study population.

Even though this study showed that a case had three times higher odds of not having received counselling than a control at individual level, the association did not reach statistical significance at multivariate level. A South African study using TB register data from 14 trials showed that counselling improved adherence to anti-TB treatment (Volmink & Garner 2000). In Kenya poor counselling was an important factor for defaulting from TB treatment (Wasonga 2002). In our clinic, we had only one TB nurse who was available to both counsel patients and dispense drugs as well as follow-up on side effects during the period studied. Thus, we speculate that these results reflected the conduct and availability of severely limited clinic staff. Integration of TB-HIV care could allow efficient counselling for both TB and HIV simultaneously, as well as reciprocal testing, which should be studied further. In a study of a newly integrated TB-HIV clinic that emphasized TB and HIV testing, there were significant gains in dual therapy for co-infection, but no effect on default (Huerga *et al.* 2010).

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One important factor for defaulting was living 10 km or more away from the TB clinic. Similar findings have been reported in Ethiopia and Malaysia (Naing *et al.* 2001; Michael *et al.* 2004; Shargie & Lindtjorn 2007).

Surprisingly, we found that the median default time from TB treatment was at 5 months, which is contrary to various studies which reported default around 3 months after initiation of TB treatment. In a modified life table analysis of defaulters in India defaulting started in the 3rd month, continued up to the 7th month, then levelled off (Chatterjee *et al.* 2003). Our findings indicate that patients in IDI clinic default later compared to patients elsewhere in the world. This could be attributed to IDI clinic staff efforts to create a good physical setting and social network activities for patients.

This study had a few limitations. Factors associated with defaulting were collected retrospectively, using patient self-reports. Such data are subject to recall bias which we tried to control by using well-structured detailed questionnaires, and employing different questioning techniques. Most of the patients who started their TB treatment in 2006 could not be traced as their contacts were not documented in the TB register. We tried to minimize this potential bias by checking the IDI visit reports which enabled us to interview more year 2006 patients who came for routine check ups and drugs refills at the IDI clinic. Although a calendar effect exists, we believe that these data provide a detailed account on the factors that affect defaulting at IDI.

Excluding very sick patients could lead to potential selection bias pushing the results toward the null since sicker patients may be more likely to default. Therefore, the strength of defaulting that we found in this study could be weaker than what it would have been. History of previous episodes of TB was not investigated.

Conclusions

Defaulting from TB treatment is a complex, dynamic issue with various factors impacting on treatment taking behaviour. General TB health education stressing the duration, side effects and the risk of discontinuing TB treatment should be instituted, perhaps done by community volunteers. Counselling of patients will also be required to reduce TB treatment default. Integration of TB and HIV services especially for counselling may allow for efficient delivery of important information to patients. Finally, ensuring adequate uninterrupted drug supply to TB treatment centres is imperative.

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Corresponding Author Sawsan Elbireer, Makerere University – Johns Hopkins University Research Collaboration (MU-JHU), Upper Mulago Hill Road, Mulago Hospital, PO Box 23491, Kampala, Uganda. Tel.: +256 755 256399; E-mail: sosman@mujhu.org

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