

“Treatment adherence status of the TB patients notified from private sector and its associated factors: Findings of a secondary data analysis from West Bengal, India.”

Short title: - “Treatment adherence status of Privately treated TB patients of West Bengal”

Authors: Abhijit Dey^{1*}, Arista Lahiri², Sweety Suman Jha³, Vivek Sharma¹, Parthiban Shanmugam¹, Arup Kumar Chakrabartty⁴

1. *Tuberculosis Health Action Learning Initiative (THALI), SukrishnaBhawan757/1, Madurdaha Main Road, Madurdaha, Hussainpur, Kolkata, West Bengal, Pin- 700107*
2. *Department of Community Medicine, College of Medicine & Sagore Dutta Hospital, Kamarhati, North 24 Paraganas, West Bengal, India. Pin-700058*
3. *Department of Preventive Social Medicine, All India Institute of Hygiene Public Health, Kolkata, West Bengal, India, Pin- 700 073*
4. *Hony. Secretary, Health Vision Research, Jessore Road, Kolkata 700089*

***Correspondence:** - Abhijit Dey, Senior Medical Consultant, Tuberculosis Health Action Learning Initiative (THALI) project, USAID-India; 404 Kalikapur, Live Valley Apartment, Mukundapur (PO), Kolkata- 7000099. Mail- drabhijitdey@gmail.com Phone: +918100650578(M)

Details of the Authors

sl no.	Name	Professional Qualification	Affiliation during research	Current affiliation	Addresss	Mobile no.	Email
1	Abhijit Dey	MBBS, D.Epi, MPH	Sr Medical Conusltant, World Health Partners, THALI Project ,USAID-India	NTEP Medical Consultant, WHO-India	404 Kalikapur, Live Valley Apartment, PO-Mukundapur, Kolkata, Pin- 700099, India	8100650578	drabhijitdey@gmail.com

2	Arista Lahiri	MBBS, MD(Community Medicine)	Senior Resident, Dept. Of Community Medicine, College of Medicine and Sagore Dutta Hospital	Senior Resident, Dept. Of Community Medicine, College of Medicine and Sagore Dutta Hospital	37/3/1, Jaffarpur Road, 1st Lane Barrackpore, Kolkata, India. PIN- 700122	80132635 40	arista_rg kar2008 @hotmai l.com
3	Sweety Suman Jha	MBBS	Junior Resident, Dept. Of Preventive and Social Medicine, All India Institute of Hygiene and Public Health, Kolkata	Junior Resident, Dept. Of Preventive and Social Medicine, All India Institute of Hygiene and Public Health, Kolkata	110, Chittaranjan Avenue, Kolkata – 700 073	90510102 15	swty.jha0 6@gmail .com
4	Vivek Sharma	MSc (Math), MPS, PGDPHN	MEL Advisor, John Snow Inc, THALI Project ,USAID-India	MEL Advisor, SFT Gujarat	A 201, Vrundalaya Greens, Atladara, Vadodara, Gujarat 390012	98353527 84	vivekiips @hotmai l.com
5	S Parthiban	MBBS, MPH, AFIH, NFPM, FHM	Deputy Project Director, World Health Partners, THALI Project ,USAID-India	Public Consultant- Freelance	No.40, Kamaraj street, near Axis Bank, West Tambaram, Chennai-45, Tamil Nadu State, pin code: 600045	94448348 71	sparthiba nmph@g mail.com
6	Arup Kumar Chakrabartty	MBBS, MPH, PHD	Hony. Secretary, Health Vision Research, Kolkata	Hony. Secretary, Health Vision Research, Kolkata	Jessore Road, Kolkata 700089	90513533 96	arup.publ ication@ gmail.co m

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Abstract

Objective: In India, yearly, estimated one million TB cases are missing from notification, mostly from private sector. The large number of patients in private sector has raised concerns for suboptimal quality of care. This study was conducted to find out the treatment adherence status among the private TB patients and factors associated with poor adherence.

Data Source: Secondary project data, obtained through adherence monitoring house visit by NGO workers. Data collected by reviewing different records available with the patients & data was entered into the CommCare HQ, an open-source mobile platform designed for data collection.

Methods: Descriptive observational study.

Results: Default rate among private patients was 5%. Commonest reasons stated for being a defaulter were 'Medicine is not good' (30%), 'Travel' (28.6%), 'Cost of treatment' (21.8%) and 'Side effects' (11.6%). Despite best of efforts only 36.9% defaulter could be retrieved. Higher default rate was associated with 15-59 years age, males, earning member of the family, addiction, DR-TB, continuation phase of treatment, previous history of TB, presence of symptoms and inability to walk.

Conclusion: Privately treated TB patients are vulnerable to non-adherence. Once defaulted, it is difficult to retrieve them. Economically productive age group is at higher risk of being defaulter. Strict adherence monitoring for private TB patients and extensive advocacy communication & social mobilization program in the community, workplaces and institutions is a need of hour.

1. Introduction:

Tuberculosis (TB) is one of the world's most neglected health crisis. In spite of its alarming danger, surprisingly little action has been taken to address the TB Epidemic. The World Health Organization (WHO) declared TB a global public health emergency in 1993 recommends what specific steps should be taken to address the epidemic¹. TB is a communicable disease requiring prolonged treatment, poor adherence to a prescribed treatment increases the risk of morbidity, mortality spread of disease in the community. The

therapeutic regimens given under direct observation as recommended by WHO have been shown to be highly effective for both preventing treating TB but poor adherence to anti-TB drugs (ATD) is a major barrier to global control².

India notified 1.9 million TB cases in 2016 of which, 1.6 million were from public sector 0.3 million from private sector. A staggering one million TB cases are missing from notification, most of them being diagnosed treated in private sector. That is what makes the engagement with the private sector so very vital. The large number of patients in private sector has raised concerns about: delayed diagnosis; suboptimal quality of care; incorrect diagnostic treatment protocols; lack of systems for treatment adherence patient support; a high drop-out rate, thus raising the risk of drug resistance to first-line /or second-line drugs³.

The United States Agency for International Development (USAID) funded Tuberculosis Health Action Learning Initiative (THALI) project launched its activity in 6 revenue districts of West Bengal viz Kolkata, Howrah, Hooghly, North 24 Parganas, South 24 Parganas & Purba Medinipur with an aim to improve the quality of TB care by introducing innovative solutions⁴⁻⁹. With the help of THALI project these districts were able to notify nearly 8000 10000 privately treated TB patients respectively during 2017 2018^{10,11}. After notification, taking public health action especially monitoring treatment adherence was a real challenge for the TB patients notified from the private sector. The project devised a plan to monitor the treatment adherence of private TB patients through house visit by the trained field workers of THALI.

There are numerous studies to assess the factors associated with poor TB treatment adherence, but most of them analysed data from public sector^{2,12-17}. There is a dearth of scientific literature reporting the treatment adherence status for private sector. There is no study on treatment adherence of private TB patients in West Bengal .The current study was

conducted to find out the status of TB treatment adherence in private sector & to identify the factors associated with poor TB treatment adherence. Now as India is moving towards TB elimination, strict treatment adherence, especially for those patients who have been seeking care from private sector, is a need of hour. Therefore, identifying the major thrust areas, bears policy relevance.

2. Methods

2.1. Study Design, Settings & Study Population:

A secondary data analysis was performed on the data that was obtained through adherence monitoring house visit by THALI field workers during the period of July 2018 – June 2019. Data was collected by visiting household of the notified TB patients from six districts of West Bengal namely Kolkata, Howrah, Hooghly, North 24 Parganas, South 24 Parganas & Purba Medinipur who were notified during January 2018 to June 2019. Along with the private patients few of the public patients, who were residing at hard to reach area or whose required details had not been collected by the system yet. The line-list with complete address, contact details of all private patients & selected public patients has been shared to THALI by the respective District TB Officers (DTO). THALI field worker targeted to visit all privately notified TB patients who were on treatment from any peripheral health institute (PHI) of these six districts. During the visit period from July 2018 to June 2019 twenty field workers visited & collected adherence information of more than 15000 TB patients. After excluding the details of public patients incomplete details of private patients we had 7505 patients' details for the secondary analysis for the study.

2.2. Data Collection, Definitions & Analysis:

Data collected by reviewing the TB treatment card, medical records available with the patients & interview with the patients or the care giver. Collected data was entered into the CommCare HQ (<https://www.commcarehq.org/accounts/login/>) application based structured proforma. For quality assurance 10% patients house whose house had been visited by the field workers, was re-visited by supervisors & senior managers of the project (district coordinator, medical consultant & deputy project director & director). Information from the CommCare was extracted into Microsoft® Excel® (2016) was analyzed after cleaning validation. Stata 14.2 (StataCorp LP, College Station, TX, USA) was used for statistical analysis. Key analytic outputs were the number proportion of TB patients with difference socio-economic & clinical background.

A Private TB patient was considered as one who has been diagnosed & treated by a Private (non-government) health Care facility. However, a private health care facility may use Government diagnostic facility Government supply ATD for that Private TB patients. A TB patient was considered as Defaulter if s/he was not taking ATD for 28 days or more, consecutively after starting treatment. This outcome is called Lost to Follow Up (LTFU). To define regular use of alcohol, one who takes alcohol at least twice a week, was considered as alcohol user. On the other h, who used any forms of tobacco at least once per day was considered as a tobacco user. Reasons for missing of drugs is tabulated dividing into two categories namely number of proportions of defaulter retrieval done & number & proportion who remain defaulted. Nonrom association of the reasons measured using Fisher's exact test. Association with socio-demographic & clinical factors for being a defaulter was measured through the Odds ratio (OR) using Generalized linear model (Poisson regression with robust stard errors) 95% Confidence Interval (95% CI) for each OR was obtained from the models. A P-value of <0.05 was taken as statistically significant.

3. Results

3.1. *Socio Demographic profile of the Private treated TB Patients:*

Table-1 is showing the socio-demographic & clinical profile of the privately treated TB patients as well as the treatment defaulters. Default rate among the Private Patients was 5%.

The median age of the Privately notified TB patients was 40 yrs (25-53). Among them 81.6% were in the age bracket of 15-59 years (Economically productive age). 68.6% were males, 20.7% were illiterate, 45.1% were earning family members, 3.8% belongs to a migratory family, 22.3% tobacco user, 10.4% alcohol user, 98.1% non-veg eater, 4.8% were Drug resistant TB (DR-TB), 66.3% were in their Intensive Phase of therapy (IP), 16.2% had history of TB before, 15.1% were known diabetic, 0.7% were PLHIV (People Living with HIV/AIDS), 63% patients had some symptoms 7% were unable to walk.

The median age of the defaulter TB patients (subset of the private TB patients) was 38 yrs (25-50). Among them 87.3% were in the age bracket of 15-59 years, 72.9% were males, 22.6% were illiterate, 53.3% were earning family members, 4.2% belongs to a migratory family, 36.3% tobacco user, 19.9% alcohol user, 98.7% non-veg eater, 11.1% were DR-TB, 54.1% were in their Continuation Phase of therapy (CP), 22.3% had history of TB, 16.5% were diabetic, 0.8% PLHIV, 73.5% patients had some symptoms 9.5 % were non-ambulatory.

3.2. *Reasons for Lost to Follow-up:*

3.3. Table-2 is showing different reasons (as stated by the patients &/ primary care giver) leading to discontinuation of ATD & becoming a treatment defaulter. The table is also

showing the number & proportion of each category who has been reinstated to the treatment with counseling & motivation by THALI field workers.

Commonest reason for being a defaulter was the impression of 'Medicine is not working' (30%). Other reasons were 'Travel' (28.6%), 'Cost involved in the treatment' (21.8%), 'Side effects of ATD' (11.6%), 'Anxiety or Depression' (7.2%) & 'Feeling of completely cured' (0.8%). Proportion of default retrieved was 36.9%.

3.4. Risk factors associated with Lost to follow-up:

Table-3 is showing the association of *Socio Demographic & clinical factors of the TB Patients* for 'being a defaulter'.

Economically productive age group (15-59 yrs) were associated with more than 5 times risk of being defaulter when compared with below 15 years age group. Other factors associated with increased risk were male sex {OR 1.3 (1.0 -1.6)} , being earning member of the family {OR 1.3 (1.1 -1.6)}, being tobacco user {OR 2.1 (1.7 -2.6)}, Alcohol use {OR 2.3 (1.7 -2.9)}, DR-TB {OR 2.7 (1.9 -3.8)}, being in the CP {OR 2.4 (2.0 -3.0)}, previous history of TB {OR 1.5 (1.2 -2.0)}, presence of any symptoms {OR 1.7 (1.3 -2.1)} & inability to walk {OR 1.4 (1.0 -2.1)}.

4. Discussion:

4.1. Key findings in light of relevant literatures:

The current article is unequivocally the first article which described the treatment adherence status of the TB patients notified from private sector of West Bengal. Our study has few key findings which may have significant implication in National TB Programs (NTP).

Default rate among the Private Patients was 5%. Which was same as the aggregate default rate of privately treated TB patients of whole country during the year 2020. The private sector default rate is slightly higher than public sector TB patients (4%)¹⁸. The default rate was better than the default rates among private TB patients elsewhere¹⁹. Among the private TB patients 81.6% & among the defaulter 87.3% were in the age bracket of 15-59 years (Economically productive age). As per census 2011 the age group 15-59 contributes 62.5 percent of total population²⁰. Over representation of the age group for contracting TB might be due to more outdoor activity exposure, addictions, carrier, or work-space related stress. Our study also found that the economically productive age group were associated with more than 5 times risk of being defaulter when compared with below 15 years age group earning family members were associated with 30% increased risk of being defaulter. In most of the families, males are earning members, naturally study showing 30% increased risk of being defaulter among males. These findings might partially explain how TB can put economic burden to the affected family the society.

Commonest reason for being a defaulter was the impression of 'Medicine is not working' (30%). Other two most stated reasons were 'Travel' (28.6%), 'Cost involved in the treatment' (21.8%). A similar study which was conducted for public patients reported that three most common reason for being defaulter is side effects of ATD (42.2%) , a feeling of early improvement (33.3%) Travel for work (9.6%)². The study also found that once defaulted, retrieval is tough among the private TB patients. Despite best of efforts only 36.9% defaulter could have been retrieved. Tobacco & Alcohol use was associated with increased risk of being a defaulter. Several other studies also reported similar association^{13,21-25}. There was increased risk of being defaulter among the DR-TB patients & who have previous history of TB. Studies also reported similar findings^{21,26}. The study

also found that ‘persistence of symptom & inability to walk was also associated with higher risk of getting defaulted.

The study found that among private TB patients who were on Continuation Phase of their treatment were at more than 2 times higher risk of getting defaulted. Though Most of the studies on Public sector patients of India & abroad ^{13,27,28} reported that Intensive Phase is associated with higher risk of getting defaulted, there is a study at Tajikistan which reported similar findings²⁶. This is particularly important because it has a significant public health implication. Non-adherence in the presence of high bacillary loads typically seen in the intensive phase is likely to have greater impact than the same degree of non-adherence later during the continuation phase, when bacillary loads are generally several logs lower²⁹.

4.2. Strengths Limitations:

The study was conducted under programmatic settings reflects the field realities. The study had a relatively large sample size for a secondary data analysis possibility of selection bias was minimized by virtue of the systematic selection criteria used in the program. Quality of the source data (treatment card) had been controlled & assured through cross-checking & validation by the field supervisor. Entry errors were also checked by inbuilt logical checking & consistency checking system in the CommCare Apps. However, despite the best efforts, the study had a few limitations. Potential confounders like distance from referred health facility, socio economic status, fees structure of treating private health facility, marital status, were not adjusted for during regression analysis. Thus, the factors associated with “being a defaulter” should be interpreted with caution. It can be argued that to explain the outcomes of the quantitative

analysis, qualitative interviews could have been of help, but the current article limited its reach within the bounds of quantitative analysis of the secondary data.

4.3. Recommendations based on the findings:

Based on the study's findings, there are few implications recommendations for adherence monitoring of privately treated TB patients. Privately treated patients are most vulnerable to become defaulter, so more attention is needed, unfortunately which is, till now, missing in the program. It is also evident that once defaulted it is very difficult to back them into the track. So early counseling & regular follow-up is a must for all TB patients especially for the privately treated TB patients.

Economically productive & most active age group is more vulnerable of having TB. This group are at higher risk of being a defaulter. This may be due to stigma associated with TB in workspace &/ due to work pressure. De-stigmatization activity including awareness program, periodic TB screening, IEC may be carried out in the offices, schools, other private & public sector enterprises. Paid-leave until end of the Intensive Phase of TB treatment can be a way forward.

Commonest reason for lost to follow up was wrong impression about TB medicine.

Burden of treatment cost was the reason for more than one fifth of the defaulter, whereas TB diagnosis & treatment is freely available at Government Hospitals. Both the reason indicates for extensive awareness program, IEC & repeated counseling of the private TB patients. To implement these, sensitization program for the private providers is required in order to build capacity of these private sector providers.

5. Conclusions

Privately treated TB patients are highly vulnerable for becoming a defaulter. Once defaulted, it seems to be difficult to retrieve them. Economically productive & most active age group is at higher risk of being defaulter. Commonest reason for lost to follow up is wrong impression about TB medicine. The study clearly identified the high-risk group where risk of loss to follow up is higher. NTP managers should consider three things- i)extensive engagement & sensitization drive for the private providers; ii) Strict adherence monitoring of the privately treated TB patients, especially for the high-risk groups and iii) implementation of extensive advocacy communication & social mobilization program in community including workplaces & educational institutions.

6. Declarations

6.1. **Ethics approval consent to participate:** The study has been approved & actively supported by the Project Director, THALI. As the analysis involved review of patient records (secondary program-data), so issue of clearance from institutional ethics committee was waived.

6.2. **Consent for publication:** Not applicable

6.3. **Availability of data materials:** The datasets used /or analysed during the current study are available from the corresponding author on reasonable request. Also, the datasets are included in the supplementary information files of the article.

6.4. **Competing interests:** The authors declared no competing interests

6.5. **Funding:** No fund involved in this study

6.6. **Authors' contributions:** All authors have contributed to data curation, manuscript writing, proof reading &all have given approval for publication.

6.7. **Acknowledgements:** We acknowledge the hard work of the THALI Field officers who have visited the patient's house to collect this data. We also acknowledge the

support from the NTP staff of the six districts, without which this study was not possible. We are thankful to the patients who have shared their documents & information with the THALI volunteers. We are also thankful to THALI project director for his active support & encouragement.

6.8. Table 1: Socio Demographic & Clinical profile of the Private TB Patients (N) & among those who missed dose of 28 days or more (n) as identified by the THALI project, West Bengal, during Jul'18-June'19. N=7505; n= 377

Characteristics	Total Number of TB patients (%)	Number of TB patients who missed dose (%)
Total	7505 (100)	377 (5.0%)
Age in years		
0-14	193 (2.6)	2 (0.5)
15-29	2253 (30.0)	119 (31.6)
30-44	1948 (26.0)	109 (28.9)
45-59	1918 (25.6)	101 (26.8)
60 and above	1193 (15.8)	46 (12.2)
Gender		
Male	5145 (68.6)	275 (72.9)
Female	2359 (31.4)	102 (27.1)
Transgender	1 (0.0)	0 (0.00)
Education		
Illiterate	1556 (20.7)	85 (22.6)
Primary School	3955 (52.7)	217 (57.6)
High School	1548 (20.6)	59 (15.6)
Graduate & Above	446 (6.0)	16 (4.2)
Occupation		
Student	704 (9.4)	21 (5.6)
Dependent Family Members	3414 (45.5)	155 (41.1)
Earning Family Members	3387 (45.1)	201 (53.3)
Migratory Family		
No	7218 (96.2)	361 (95.8)
Yes	287 (3.8)	16 (4.2)
Tobacco usage		
No	5831 (77.7)	240 (63.7)
Yes	1674 (22.3)	137 (36.3)
Alcohol usage		
No	6723 (89.6)	302 (80.1)
Yes	782 (10.4)	75 (19.9)
Type of Diet		
Veg	145 (1.9)	5 (1.3)
Non-veg	7360 (98.1)	372 (98.7)
Type of TB		
DS-TB	7147 (95.2)	335 (88.9)
DR-TB	358 (4.8)	42 (11.1)
Phase of Treatment		
IP	4974 (66.3)	173 (45.9)
CP	2531 (33.7)	204 (54.1)
History of TB		
No	6287 (83.8)	293 (77.7)
Yes	1218 (16.2)	84 (22.3)
Diabetes status		
Non-diabetic	5446 (72.6)	279 (74.0)

Diabetic	1133 (15.1)	62 (16.5)
Unknown	926 (12.3)	36 (9.5)
HIV status		
Negative	6324 (84.3)	320 (84.9)
Positive	53 (0.7)	3 (0.8)
Unknown	1128 (15.0)	54 (14.3)
Current Symptoms		
No Symptoms	2774 (37.0)	100 (26.5)
Have some symptoms	4731 (63.0)	277 (73.5)
Ambulatory		
No	522 (7.0)	36 (9.5)
Yes	6983 (93.0)	341 (90.5)

Numbers within the parentheses indicate column percentages for each category.

Table 2: Reasons for “being a defaulter”, as stated by the private TB patients or care giver during patient’s house visit by the volunteer of THALI project, West Bengal during Jul’18-June’19. n= 377

Reasons for missing dose of anti-TB drugs	Number patients who remained defaulter (%)‡	Number of default patients who were retrieved (%)‡	Total Number (%)‡	p-value
Medicine is notworking	75 (31.51)	38 (27.34)	113 (30.0)	0.794
Travel	67 (28.15)	41 (29.50)	108 (28.6)	
Cost involved in the treatment	49 (20.59)	33 (23.74)	82 (21.8)	
Side effect of drugs	28 (11.76)	16 (11.51)	44 (11.6)	
Anxiety/Depression	16 (6.72)	11 (7.91)	27 (7.2)	
Feeling of completely cured	3 (1.26)	0 (0.00)	3 (0.8)	
Total (%)#	238 (63.1)	139 (36.9)	377	

‡ Numbers within the parentheses indicate column percentages; # Numbers within the parentheses indicate row percentages; LTFU: Lost to follow-up (Missed dose for more than 1 month); P-value obtained by Fisher’s exact test.

Table 3: Association of Socio Demographic & Clinical factors of the Private TB Patients for “being a defaulter” as identified by the THALI project, West Bengal, during Jul’18-June’19. N=7505; n= 377

Characteristics	Total Number of TB patients (N)	Number of defaulters (n, % #)	OR (95% CI)
Age in years			
0-14	193	2 (1.0)	(base)
15-29	2,253	119 (5.3)	5.3 (1.3 -21.7)
30-44	1,948	109 (5.6)	5.7 (1.4 -23.1)
45-59	1,918	101 (5.2)	5.3 (1.3 -21.7)
60 and above	1,193	46 (3.9)	3.8 (0.9 -15.9)
Gender			
Male	5,145	275 (5.3)	1.3 (1.0 -1.6)
Female	2,359	102 (4.3)	(base)

Transgender	1	0 (0.0)	(empty)
Education			
Illiterate	1,556	85 (5.5)	1.6 (0.9 -2.7)
Primary School	3,955	217 (5.5)	1.6 (0.9 -2.6)
High School	1,548	59 (3.8)	1.1 (0.6 -1.9)
Graduate & Above	446	16 (3.6)	(base)
Occupation			
Student	704	21 (3.0)	0.7 (0.4 -1.0)
Dependent Family Members	3,414	155 (4.5)	(base)
Earning Family Members	3,387	201 (5.9)	1.3 (1.1 -1.6)
Migratory Family			
No	7,218	361 (5.0)	(base)
Yes	287	16 (5.6)	1.1 (0.7 -1.9)
Tobacco usage			
No	5,831	240 (4.1)	(base)
Yes	1,674	137 (8.2)	2.1 (1.7 -2.6)
Alcohol usage			
No	6,723	302 (4.5)	(base)
Yes	782	75 (9.6)	2.3 (1.7 -2.9)
Type of Diet			
Veg	145	5 (3.5)	(base)
Non-veg	7,360	372 (5.1)	1.5 (0.6 -3.7)
Type of TB			
DS-TB	7,147	335 (4.7)	(base)
DR-TB	358	42 (11.7)	2.7 (1.9 -3.8)
Phase of Treatment			
IP	4,974	173 (3.5)	(base)
CP	2,531	204 (8.1)	2.4 (2.0 -3.0)
History of TB			
No	6,287	361 (5.7)	(base)
Yes	1,218	16 (1.3)	1.5 (1.2 -2.0)
Diabetes status			
Non-diabetic	5,446	279 (5.1)	(base)
Diabetic	1,133	62 (5.5)	1.1 (0.8 -1.4)
Unknown	926	36 (3.9)	0.8 (0.5 -1.1)
HIV status			
Negative	6,324	320 (5.1)	(base)
Positive	53	3 (5.7)	1.1 (0.4 -3.6)
Unknown	1,128	36 (3.2)	0.9 (0.7 -1.3)
Current Symptoms			
No Symptoms	2,774	100 (3.6)	(base)
Presence of Symptoms	4731	277 (5.9)	1.7 (1.3 -2.1)
Ambulatory			
No	522	16 (3.1)	1.4 (1.0 -2.1)
Yes	6,983	361 (5.2)	(base)

Numbers within the parentheses indicate row percentages. (base): reference categories.

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