

# Risk Factors for DOTS Treatment Default Among New HIV-TB Coinfected Patients in Nalgonda (Dist.) Telangana (State): A Case Control Study

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## ABSTRACT

**Background:** The therapeutic regimens as recommended by the Revised National TB Control Programme (RNTCP) have been shown to be highly effective for both preventing and treating tuberculosis, but poor adherence to medication is a major barrier to its global control. **Aim and Objectives:** The study was conducted to assess the influence of patient related factors for DOTS Treatment Default among HIV-TB Co-infected cases. **Setting and Design:** This was a case control study conducted in Nalgonda, Telangana. **Materials and Methods:** All new HIV-TB coinfected and DOTS-defaulted patients registered under RNTCP for the period from January 2010 to December 2012 were selected. Of the 154 patients, 23 had died and 11 could not be traced, and these were excluded. Thus the total number of available cases were 120 for those age- and sex-matched controls (HIV-TB coinfected patients and those who had completed the DOTS regimen successfully) were selected. **Results:** The mean age was  $36.5 \pm 9$  years; the majority (23.3%) of patients defaulted during the second month of treatment. Significant risk factors associated with defaulting included unskilled occupation [adjusted odds ratio (AOR): 3.56; 95% confidence interval (CI): 1.1-11.56], lower middle class socioeconomic status (AOR: 17.16; 95% CI: 3.93-74.82), small family size (AOR: 21.3; 95% CI: 6.4-70.91), marital disharmony (AOR: 6.78; 95% CI: 1.93-23.76), not being satisfied with the conduct of health personnel (AOR: 7.38; 95% CI: 2.32-23.39), smoking (AOR: 8.5; 95% CI: 2.31-31.21), and side effects of drugs (AOR: 4.18; 95% CI: 1.35-12.9). **Conclusion:** Unskilled occupation, marital disharmony, small family size, lower middle class socioeconomic status, not being satisfied with the conduct of health personnel, smoking, and drug side effects were significantly associated with defaulting. Information on the pattern of tuberculosis (TB), the outcome of anti-tuberculosis treatment (ATT), and the factors associated with it will help in planning interventions to improve adherence to DOTS treatment.

**Keywords:** Directly observed treatment, short-course (DOTS), extrapulmonary tuberculosis (TB), human immunodeficiency virus-tuberculosis (HIV-TB), Nalgonda, Revised National TB Control Programme (RNTCP)

## Introduction

Human immunodeficiency virus-tuberculosis (HIV-TB) coinfection is a condition where a person has both HIV infection and tuberculosis (TB) disease.<sup>(1)</sup> The

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dual epidemics of TB and human immunodeficiency virus (HIV) infection constitute a major public health problem, particularly in resource-limited settings such as India.<sup>(1)</sup> TB is the most common opportunistic infection in HIV-infected patients, particularly in developing countries.<sup>(1)</sup> Patients with HIV-TB coinfection frequently have advanced HIV disease and are at an increased risk of death and new opportunistic infections.<sup>(1)</sup> The HIV-TB coinfection has been aptly described as the “cursed duet.”<sup>(1)</sup> The World Health Organization (WHO) estimated 8.8 million incident cases of TB globally in 2010, with 12-14% of cases among people with HIV.<sup>(1)</sup> India accounted for the maximum number of incident cases of TB (2-2.5 million) worldwide, with an estimated 5.0% (3.3-7.1%) having HIV coinfection.<sup>(1)</sup> The directly observed treatment, short-course (DOTS) default rate was around 8.1% among HIV-TB coinfecting patients in the northern states of India.<sup>(1)</sup> Despite the high burden of disease, there is a paucity of data from India on response to anti-tuberculosis treatment (ATT) in patients with HIV-TB coinfection.<sup>(1)</sup> Information on the pattern of TB, the outcome of ATT, and the factors associated with it will help in planning interventions to improve outcomes in these patients.

India has established cross-referral mechanisms in 14 states, where the National AIDS Control Project (NACP) has implemented intensified TB case-finding at its Integrated Counselling and Testing Centres (ICTCs) for HIV.<sup>(2)</sup> As TB is the most common opportunistic infection among the HIV-infected, HIV counselors screen clients for TB and refer TB suspects to the nearest Revised National TB Control Programme (RNTCP)-Designated Microscopy Centre (DMC) for testing. In a recent report from India, of 100,000 clients referred, 76% reached DMCs.<sup>(2)</sup> The proportion of clients who did not visit a DMC or did not complete investigations for TB (dropouts) ranged 5-30% in the different states.<sup>(2)</sup> There are complex economic and environmental conditions, including high levels of urban migration and unemployment, and unique sociocultural risk factors that may have important influences on TB treatment adherence.<sup>(2)</sup> The relative contribution of these factors to the problem of defaulting from TB treatment is not known.<sup>(2)</sup> The aim of this study was to assess and study the risk factors of DOTS treatment defaulting among HIV-TB coinfecting cases as compared to controls in Nalgonda district, Telangana, and the primary objective was to identify patient-level risk factors associated with defaulting from TB treatment.

## Materials and Methods

### Study design

Case control study design.

### Study period

January 2010 to September 2013.

### Study area

Nalgonda district, Telangana.

### Study population

Patients defaulting from TB treatment (2 months or more) among HIV-TB coinfecting patients registered under the RNTCP<sup>(1)</sup> were considered as “cases” and those having completed DOTS treatment successfully (6 months) among HIV-TB patients were treated as “controls.” All DOTS centers (139) and all tuberculosis units (7) of Nalgonda district covered under the RNTCP were selected. The periodicity of TB drug collection in the district was monthly.

### Sample size (census survey method)

Figure 1: All new HIV-TB coinfecting and DOTS-defaulted patients registered under the RNTCP Nalgonda district for treatment during the period January 2010 to December 2012 were selected. Total number of New HIV-TB co-infected patient registered under DOTS during January 2010 to December 2012 were 1927. Of the 154, 23 had died and 11 could not be traced, and these patients were excluded. Therefore the total number of available cases was 120 for those

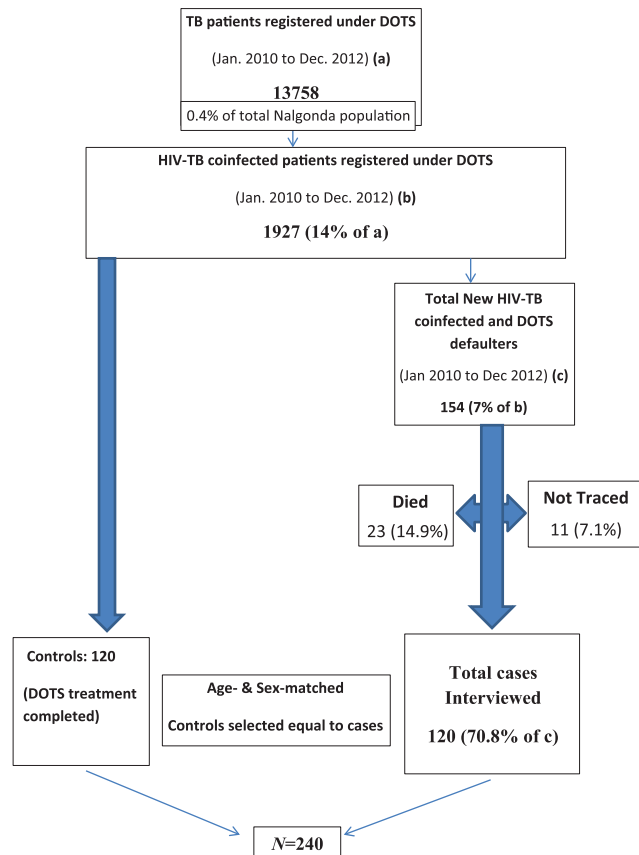


Figure 1: Flow chart on selection of study subjects

age- and sex-matched controls (HIV-TB coinfecting patients and those who completed the DOTS regimen successfully) were selected.

### Study variables

Age, gender, level of education, occupation, duration of residence in the treatment area, socioeconomic status, per capita monthly income, size of family, type of TB, marital status, smoking and alcoholism, and drug side effects.

### Tools used

Pretested semistructured interview schedule and TB registers available at the district TB center.

### Data collection

Data were collected through patient interviews using pretested questionnaire and review of TB registers and treatment cards. Enrolled patients were traced and interviewed by trained field investigators. Interviews were conducted in the regional language 2-4 months after the declaration of treatment outcome by the field investigators in the presence of a field supervisor. The questionnaires were checked for consistency and correctness by the field supervisors on completion of the respective interviews. Canvassing of the interview schedule was standardized by practical exercises and field training of the staff. Prior to interviews, a formal introduction was given to the patients regarding the purpose of seeking information, and informed oral consent was obtained. The questionnaire had built-in checks to ensure the reliability and consistency of the information obtained. Specific guidelines were provided for filling up the questionnaire to avoid ambiguity. To ensure adequate coverage, a minimum of three attempts were made to trace each patient.

### Ethical consideration

The purpose of seeking information was explained in detail, individually to all patients. Only informed verbal consent was obtained prior to each interview, as there was no other intervention/procedure involved. Patients' consent to participate in the interview was recorded on the individual interview schedule, which was signed by the interviewer. The data collected were presented as an aggregate and not linked to any individual in the study. Patients were assured that nonparticipation in the interview would not jeopardize their access to any government health center subsequently. As a service component, the patients were informed about the disease and its treatment to bridge the observed gap in their knowledge, and defaulting patients were motivated to resume treatment. The data obtained from patient records and interviews were securely held and confidentially maintained by the study staff. The research activity was approved by the Institution

Ethics Committee of Kamineni Institute of Medical Sciences, Narketpally, Nalgonda district and the State Tuberculosis Office, Telangana state.

### Knowledge score

The study subjects were assessed on their awareness for causation, clinical manifestations, duration of treatment, preference in medical care, and prevention of TB by an interview schedule. This schedule contained seven close-ended questions, for which the scoring system was given where one mark was given for each question if answered correctly. No negative marking was done for incorrect answers. Scoring was done by giving due weightage to answers related to the knowledge questions answered. The subjects were then classified as follows: Those scoring less than or equal to 4 had poor knowledge and those scoring more than 4 had good knowledge, respectively. The attainable maximum and minimum scores were 7 and 0, respectively.

### Inclusion criteria

HIV-TB coinfecting patients 15 years and above in age, who had received and defaulted from TB treatment under DOTS (2 months or more), and registered during the period from January 2010 to December 2012.

### Exclusion criteria

Patients who had died, patients who could not be traced, relapse, category II defaulters, and multidrug resistant (MDR) and extreme drug resistant (XDR).

### Data analysis

Data were entered in Excel sheet and analyzed for proportions. Mean and standard deviation were calculated, risk was estimated by using odds ratio (OR), and 95% confidence intervals (CIs) were set by using the SPSS Version 16.0 package. Chi-square test was used to know the statistical significance ( $P < 0.05$ ), multivariate logistic regression was used to know the interactions, and adjusted odds ratios (AORs) were calculated. Graphical presentations in the form of line bar charts and pie charts were used where needed.

### Results

The total number of HIV-TB coinfecting patients registered under DOTS was 1,927, out of which the number of study subjects including new HIV-TB coinfecting patients and DOTS defaulters was 154. Of the 154 cases, only 120 (78.0%) patients and an equal number of age- and sex-matched controls (120) were selected, for a total of 240. Most of the patients (23.3%) defaulted from treatment during the second month, 22.5% defaulted in the first month, and 17.5% defaulted in the third month of treatment, followed by 14.2% in the fourth month, 12.5% in the fifth, and 10% in the sixth month.

It was observed that the majority of study subjects were linked to Chivemla [24 (20%)], followed by Nidamanoor [22 (18.3%)], Chilkur [20 (16.7%)], Yadagirigutta [17 (14.2%)], Chintapally 16 (13.3%), Voligonda [11 (9.2%)], and Nalgonda 10 (8.3%) TB units. Age- and sex-matched controls (DOTS treatment completed) were selected similar to the cases (DOTS treatment defaulters). Of the defaulters, 85.84% belonged to the economically productive age group (16-45 years). A smaller proportion of study population 34 (14.16%) were in the older-than-46 years age group. The mean age was  $36.5 \pm 9$  years and range was 18-60 years. In the study population, 144 were males (the majority at 60%) and 96 were females (40%).

Table 1: The proportion of DOTS defaulters [85 (70.83%)] with primary education was found to be high when compared to controls [52 (43.33%)]. The proportion of unskilled workers was higher among DOTS treatment defaulters [85 (70.83%)] as compared to controls [62 (51.67%)]. More individuals of lower socioeconomic status discontinued DOTS treatment [110 (91.67%)] as compared to controls [85 (70.83%)]. A higher proportion of cases [100 (83.33%)] had small family size compared to controls [46 (38.33%)]. A higher proportion of patients who defaulted had lived for less than 2 years in the treatment area [47 (39.17%)] as compared to controls [23 (19.17%)]. Extrapulmonary TB prompted more patients to default 28 (23.33%) as compared to controls [10 (8.33%)]. As expected, a higher proportion of DOTS

defaulters [49 (40.83%)] were of separated/disrupted marital status as compared to controls [20 (16.67%)]. A higher proportion of DOTS defaulters [79 (65.83%)] were not satisfied with the conduct of health personnel in DOTS centers as compared to controls [22 (18.33%)]. Table 2 shows that among DOTS defaulters, a higher proportion of cases [76 (63.33%)] were alcohol abusers compared to controls [30 (25%)]. Likewise, 68 (57%) were smokers compared to 20 (17%) controls. Among the cases, 90 (75%) HIV-TB coinfecting and DOTS defaulters had experienced drug side effects compared to 60 (50%) controls. Among the cases, 60% had poor knowledge scores compared to 17 (14%) controls.

Multiple logistic regression analysis revealed that the following risk factors had strong and significant association with DOTS defaulting:

1. Unskilled occupation.
2. Living alone (single/divorced/widowed).
3. Small family size.
4. Not being satisfied with the conduct of health personnel.
5. Smoking.
6. Drug side effects.
7. Poor knowledge score.

## Discussion

Of 1927 HIV-TB coinfecting patients registered under DOTS, 7.99% (154) defaulted from DOTS treatment,

**Table 1: Risk factors of study subjects (N = 240)**

Risk factors	HIV-TB coinfecting patients		Total (N = 240) n (%)	AOR (95% CI)
	DOTS defaulters (N = 120) n (%)	DOTS completed (N = 120) n (%)		
Level of education				
Primary	85 (70.83)	52 (43.33)	137 (57)	1.69
Secondary and above	35 (29.17)	68 (56.67)	103 (43)	(0.4-7.13)
Occupation				
Unskilled	85 (70.83)	62 (51.67)	147 (61.3)	3.56*
Skilled	35 (29.17)	58 (48.33)	93 (38.7)	(1.1-11.56)
Socioeconomic status				
Lower middle class	110 (91.67)	85 (70.83)	195 (81.25)	17.16*
Middle class	10 (8.33)	35 (29.17)	45 (18.75)	(3.93-74.82)
Family members				
≤5	100 (83.33)	46 (38.33)	146 (60.9)	21.31*
>5	20 (16.67)	74 (61.67)	94 (39.1)	(6.4-70.91)
Duration of residence in treatment area				
≤2 years	47 (39.17)	23 (19.17)	70 (29)	1.71
>2 years	73 (60.83)	97 (80.83)	170 (71)	(0.5-5.88)
Type of TB				
Extrapulmonary	28 (23.33)	10 (8.33)	38 (16)	1.81
Pulmonary	92 (76.67)	110 (91.67)	202 (84)	(0.39-8.33)
Marital status				
Single/divorced/widowed	49 (40.83)	20 (16.67)	69 (28.75)	6.78*
Married	71 (59.17)	100 (83.33)	171 (71.25)	(1.93-23.76)

\*P < 0.05 was statistically significant

**Table 2: Risk factors of study subjects (N = 240)**

Risk factors	HIV-TB coinfecting patients		Total (N = 240) n (%)	AOR (95% CI)
	DOTS defaulters (N = 120) n (%)	DOTS completed (N = 120) n (%)		
Alcohol abuse				
Yes	76 (63.33)	30 (25)	106 (44)	2.52
No	44 (36.67)	90 (75)	134 (56)	(0.79-7.98)
Smoking				
Yes	68 (57)	20 (17)	88 (37)	8.5*
No	52 (43)	100 (83)	152 (63)	(2.31-31.21)
Experience of drug side effects				
Yes	90 (75)	60 (50)	150 (62.5)	4.18*
No	30 (25)	60 (50)	90 (37.5)	(1.35-12.9)
Conduct of health personnel				
Not satisfied	79 (65.83)	22 (18.33)	101 (42)	7.38*
Satisfied	41 (34.17)	98 (81.67)	139 (58)	(2.32-23.39)
Knowledge levels				
Poor ( $\leq 4$ score)	72 (60)	17 (14)	89 (37)	9.31*
Good ( $>4$ score)	48 (40)	10 (8)	151 (63)	(2.83-30.56)

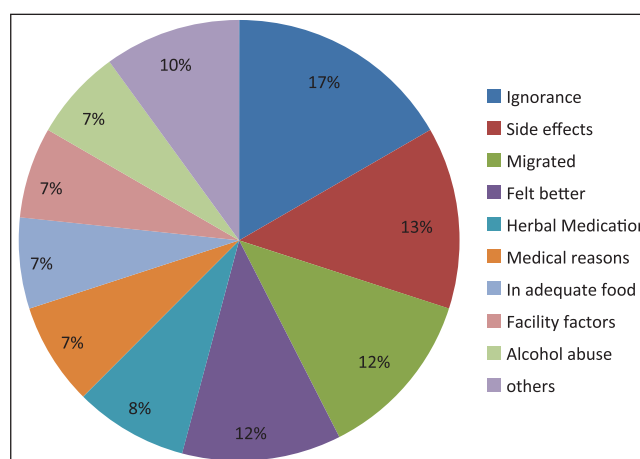
\*P < 0.05 was statistically significant

and this is consistent with other studies from resource-constrained settings.<sup>(1)</sup> High rates of defaulting are a major problem in the management of these patients in the program. The majority were in the economically productive age group (18-45 years) and defaulted during the intensive phase of DOTS treatment (23.3%), especially during the second month of treatment.

Figure 2: It is observed that of the cases, 17% defaulted due to lack of knowledge regarding the disease and/or duration of the treatment; 13% defaulted due to drug side effects; 12% because they migrated to other places for their livelihoods; 10% due to other reasons (2.5% imprisoned, 2.5% too sick, 5% because of stigma); 8% due to herbal medication; and 7% due to medical causes, inadequate food, facility factors, and alcohol abuse. These observations are consistent with other Studies.<sup>(9)</sup>

A higher proportion of patients who defaulted had lived for less than 2 years in the treatment area (39.17%) as compared to controls (19.17%), and it is statistically significant (OR: 2.75); this finding was consistent with other Studies.<sup>(9)</sup> Extrapulmonary TB prompted patients to default more (23.33%) as compared to controls (8.33%) and it is significant (OR: 3.34); this was consistent with other Studies.<sup>(8)</sup> A higher proportion of cases (63.33%) were alcohol abusers compared to controls (25%), and there is strong and significant association (OR: 5.18); this finding was consistent with the other Studies.<sup>(9)</sup>

Multiple logistic regression analysis revealed that the significant risk factors associated with defaulting included unskilled occupation (AOR: 3.56; 95% CI: 1.1-11.56) and this is consistent with the literature.<sup>(7,10)</sup> For classification of socioeconomic status, Udai Pareek's scale was considered because many of those interviewed



**Figure 2:** Reasons for DOTS treatment defaulting among HIV-TB coinfecting cases: (N = 120)

were reluctant to reveal their income status and the fact that they were of lower middle class socioeconomic status (AOR: 17.16; 95% CI: 3.93-74.82); this is consistent with three other studies<sup>(9,11,14)</sup> that had revealed that 77.4%, 58.4%, and 50.7% of the subjects were of low socioeconomic status, respectively. Patients belonging to small families were more likely to default (AOR: 21.3; 95% CI: 6.4-70.91) compared to patients from joint families, and this finding is consistent with other studies.<sup>(4,12)</sup> Marital disharmony was also a contributing factor for defaulting (AOR: 6.78; 95% CI: 1.93-23.76), which is consistent with other studies.<sup>(11)</sup> The employees at the DOTS center discriminated against HIV-TB coinfecting patients, compared to other TB patients (AOR: 7.38; 95% CI: 2.32-23.39); this finding was consistent with other studies.<sup>(6,12)</sup> The majority were smokers (AOR: 8.5; 95% CI: 2.31-31.21) and this finding was consistent with other studies.<sup>(8,11)</sup> Likewise, drug side effects were also associated with DOTS treatment defaulting (AOR:

4.18; 95% CI: 1.35-12.9) and this is consistent with other studies.<sup>(3,12,13)</sup> Similarly, poor knowledge (AOR: 9.31; 95% CI: 2.83-30.56) regarding the course of treatment and prevention of disease was also associated with DOTS defaulting and is a finding consistent with other studies.<sup>(5)</sup>

## Conclusions

Unskilled occupation, living alone, small family size, lower middle class socioeconomic status, and adverse attitude of DOTS provider towards HIV-TB co-infected patients are factors found to have significance influence on defaulting, while smoking, experience of drug side effects, and poor knowledge regarding disease were found to have statistically significantly associations with defaulting compared to other risk factors. Information on the pattern of TB, the outcome of ATT, and the factors associated with it will help in planning interventions to improve adherence to DOTS treatment.

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## Conflicts of interest

There are no conflicts of interest.

## References

- Sharma SK, Soneja M, Prasad KT, Ranjan S. Clinical profile and predictors of poor outcome of adult HIV-tuberculosis patients in a tertiary care centre in north India. *Indian J Med Res* 2014;139:154-60.
- Ramachandran R, Chandrasekaran V, Muniyandi M, Jaggarajamma K, Bagchi A, Sahu S. Cross-referral between HIV counselling and testing centres and smear microscopy centres in Tamil Nadu. *Int J Tuberc Lung Dis* 2009;13:221-5.
- Awofeso N. Anti-tuberculosis medication side-effects constitute major factor for poor adherence to tuberculosis treatment. *Bull World Health Organ* 2008;86:B-D.
- Mutare BN, Keraka MN, Kimuu PK, Kabiru EW, Ombeka VO, Oguya F. Factors associated with default from treatment among tuberculosis patients in Nairobi province, Kenya: A case control study. *BMC Public Health* 2011;11:696.
- Vijay S, Kumar P, Chauhan LS, Vollepore BH, Kizhakkethil UP, Rao SG. Risk factors associated with default among new smear positive TB patients treated under DOTS in India. *PLoS One* 2010;5:e10043.
- Sinha T, Tiwari S. DOTS compliance by tuberculosis patients in District Raipur (Chhattisgarh). *Online J Health Allied Sci* 2010;9:12.
- Rajasekaran S, Jeyaseelan L, Chandrasekar C, Madhavan K, Mahilmaran A, Francis T. Effectiveness of management of HIV-TB patients under programme conditions in India. *JK Science* 2008;10:70-3.
- Gopi PG, Vasantha M, Muniyandi M, Chandrasekaran V, Balasubramanian R, Narayanan PR. Risk factors for non-adherence to directly observed treatment (DOT) in a rural tuberculosis unit, South India. *Indian J Tuberc* 2007;54:66-70.
- Vijay S, Balasangameswara VH, Jagannatha PS, Saroja VN, Kumar P. Defaults among tuberculosis patients treated under dots in Bangalore city: A search for solution. *Indian J Tuberc* 2003;50:185-96.
- Finlay A, Lancaster J, Holtz TH, Weyer K, Miranda A, van der Walt M. Patient- and provider-level risk factors associated with default from tuberculosis treatment, South Africa, 2002: A case-control study. *BMC Public Health* 2012;12:56.
- Maruza M, Albuquerque MF, Coimbra I, Moura LV, Montarroyos UR, Miranda Filho DB, *et al*. Risk factors for default from tuberculosis treatment in HIV-infected individuals in the state of Pernambuco, Brazil: A prospective cohort study. *BMC Infect Dis* 2011;11:351.
- Boateng SA, Kodama T, Tachibana T, Hyoui N. Factors contributing to tuberculosis (TB) defaulter rate in New Juaben Municipality in the Eastern Region of Ghana. *J Natl Inst Public Health* 2010;59:291-7.
- Kaona FA, Tuba M, Siziya S, Sikaona L. An assessment of factors contributing to treatment adherence and knowledge of TB transmission among patients on TB treatment. *BMC Public Health* 2004;4:68.
- Buu TN, Lönnroth K, Quy HT. Initial defaulting in the National Tuberculosis Programme in Ho Chi Minh City, Vietnam: A survey of extent, reasons and alternative actions taken following default. *Int J Tuberc Lung Dis* 2003;7:735-41.