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# Predictors of Defaulting from Treatment among TB Patients in Baghdad

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## Summary

**Introduction:** Tuberculosis (TB) is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. WHO estimates the burden of TB in Iraq in 2012 (rates per 100,000 population) as 2.9 for mortality, 45 for incidence and 73 for prevalence. NTP Iraq had detected 59% of estimated new cases during this year. During 2009-2011, Success rates of newly treated cases varied between 89% and 90% with undesirable outcomes of 10-11% mostly due to defaulting from treatment (5-6% of patients defaulted from treatment. Tuberculosis is a communicable disease, thus poor adherence to a prescribed treatment increases the risks of morbidity, mortality and drug resistance at both the individual and community levels. Baghdad governorate had higher default rates from all these figures (5.5%, 6.6%, 9.7% and 6.9% respectively). This study aims at identifying predictors of default from TB treatment in Baghdad through estimating rates of Treatment default in Baghdad for new cohorts and identifying predictors of treatment default in Baghdad.

**Methods:** This is a longitudinal study conducted in Baghdad, capital of Iraq, where all national TB patients registered for treatment at district TB coordinators units during April 2013 till the end of December 2013 were requested to participate in this study. A pretested structured questionnaire form collected information about the socio-demographic characteristics, satisfaction with care, presence adverse events of drugs and other potential predictors of non-compliance and defaulting. Patient subjected to follow-up as done routinely in the NTP till the end of their treatment period (6 months), or till default or the specified period of observation (end of March 2014) approached. Defaulted patients were visited at their homes for another interview using another pretested structured questionnaire form which looked in depth for causes of default, beneficiary opinion and presence of coincident events or travels. Statistical package for social sciences version 20 (SPSS 20) was used for data input and analysis. Multivariate binary logistic regression (enter method) used to estimate predictors of default and Kaplan Meier cohort analysis used to further investigate the significance of studied factors on the incidence of default, and predict probabilities of default according to duration of treatment.

**Results:** This study had enrolled 1100 TB patients from Baghdad during the period March- December 2013. Average was 38.2 years, male to female ratio was 1:1, around half the participants (49.5%) have families sized five to 10 persons. Less than 6% of studied patients have education higher than secondary school. Those with fixed income did not exceed 12.4% of total sample. About 86.3% of patients had a monthly income less than ID 500,000 (US\$ 416). Most (89.4%) of patients live in urban settings and similar proportion (89.2%) live in a distance less than 10 Km near to a primary health care center (PHCC). Pulmonary TB patients accounted for 60.4% of study sample, and according to case definition proportions were: 89.5% for new patients, 6.5% for relapsed patients, 2.8% for after failure patients and 1.2% after default patients.

During the period of follow up, 18 patients had defaulted (discontinued treatment for more than two months), one of these treatment defaults was due to death from TB. For defaulted patients, minimum duration of treatment was three weeks and maximum duration of treatment was 17 weeks. 58.8% of defaulted patients suffered from social stigmata of TB. 77.8% of defaulted patients were visiting private physicians for TB disease. 29.4% of defaulted TB patients sold anti-TB from private pharmacies. History of previous default from anti-TB treatment multiplies the risk of default of a current anti-TB treatment by 28.7 times ( $P < 0.05$ ,  $R > 1$ , table 4). Longest period of taking anti-TB before default was 17 week, and according to survival analysis, the probability of survival (survival from default) at week 17 is 0.985 (table 6, figure 2) and hence the cumulative probability of non-survival (defaulting) at this time is 0.015. This study found the highest rates of hazard function in patients of TB who are educated, aged older than 65, employed or retired, monthly income not exceeds ID 500,000 (US\$ 416), and having a history of previous default.

**Conclusion:** Default rate in Baghdad has been improved after 2012. Important factors to be addressed are social stigmata of TB, role of private medical sector in TB control, and close patient education on importance of adherence to treatment.

## **List of Abbreviations**

<b>DTC</b>	<b>District TB Coordinator</b>
<b>TB.....</b>	<b>Tuberculosis</b>
<b>WHO.....</b>	<b>World Health Organization</b>

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## 1. Introduction

Tuberculosis(TB) is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically infects the lungs but can affect other sites as well. The global burden of TB remains enormous. [1] World Health Organization (WHO) declared TB as a global emergency in 1993. [2] In 2011, there were an estimated 8.7 million new cases of TB and 1.4 million people died from TB.[1]

WHO developed the DOTS strategy, a five-component package comprising political commitment, diagnosis using sputum smear microscopy, a regular supply of first-line anti-TB drugs, short-course chemotherapy and a standard system for recording and reporting the number of cases detected by national TB control programs (NTPs) and the outcomes of treatment.[1]This strategy aims at detecting 70% of new smear positive TB cases and cure at least 85% of these detected cases.[3]

The treatment outcome of diagnosed patients is evaluated by cohort analysis. Treatment outcome indicators enable the progress of the NTP towards the global objective; a cure rate of 85% to be measured. They also highlight any weaknesses in the organization of treatment, which can then be remedied. These indicators include cure rate, completed treatment rate, treatment failure rate, defaulted rate and death rate. Treatment success rate equals the sum of both cure rate and completed treatment rate. [4]

WHO estimates the burden of TB in Iraq in 2012 (rates per 100,000 population) as 2.9 for mortality, 45 for incidence and 73 for prevalence. NTP Iraq had detected 59% of estimated new cases during this year.[5]

During 2009-2011, Success rates of newly treated cases varied between 89% and 90% with undesirable outcomes of 10-11% mostly due to defaulting from treatment (5-6% of patients defaulted from treatment) and treatment success rates of retreated TB cases during the same period varied from 75% to 84% and here default rates as well contributed to the undesirable outcomes since 9-12% of retreated cases defaulted from treatment.[5]

According to WHO definitions for drug susceptible TB patients; defaulted is a patient whose treatment was interrupted for two consecutive months or more [4] and this concept is this study concerned with. This term has been recommended to be changed into lost to follow-up starting in 2013 [4] but the term "lost to follow-up" is a broader concept, it includes as well patients who did not start treatment for TB [4] and not used in this study report.

Tuberculosis is a communicable disease, thus poor adherence to a prescribed treatment increases the risks of morbidity, mortality and drug resistance at both the individual and community levels. [9]

One of the major constraints to a successful TB control is treatment default.[6] Patients who default may continue to spread the disease [6,7] and are at risk of developing drug resistance [6,8] and have high post treatment mortality and rates of recurrent disease.[8]



The therapeutic regimens recommended by WHO have been shown to be highly effective for both preventing and treating TB, but poor adherence to anti-tuberculosis medication is a major barrier to its global control. [9]

Adherence to long-term therapies is a multidimensional phenomenon determined by the interplay of five sets of factors (dimensions) namely; social and economic factors, health care team and system-related factors, condition-related factors, therapy-related and patient-related factors.[9]

Improving treatment outcomes and designing effective interventions require understanding of the factors that prevent people from adhering and those that help in treatment completion. [10]

According to literatures, factors that can lead to treatment default of TB patients:

- Several social and economic factors such as low income, lack of social support, low education, financial problems and inability to afford services have been linked to TB treatment adherence. [9]
- Older age, the male sex, inadequate knowledge, ignorance on need for treatment compliance and stigma are among reported patient-related factors that influence default. [10]
- Reported health care system-related factors for default include poor service provider attitudes, negative attitude by tuberculosis patients towards the treatment center, running out of drugs, access to health services and living near to treatment centre.[10,11]
- Side effects, drugs too strong and feeling better are among therapy related factors that influence TB treatment default. [10]
- Major factors leading to non-compliance include patients beginning to feel better, lack of knowledge on the benefits of completing a course, running out of drugs at home and TB drugs too strong. [12]
- Treatment default has been associated with alcohol and other drug abuse, mental illness, poverty and family absence. [6]
- There are many predictors for defaulter to be occurred like Unemployment, being a pensioner, alcoholism, homelessness, low socioeconomic status, Poor communication between health care staff and TB patients. [13]
- Treatment default is known to be associated with previous default, low socioeconomic status, psychiatric illness, unemployment, migration, side effects, long distance to health facility, social stigma, poorly-implemented DOTS but, of course, differ by setting [14].
- High default rate is observed among retreatment cases. [14]

DOT has always meant much more than “supervised swallowing”. Different projects in countries with a high prevalence of TB have shown that removing the socioeconomic barriers to DOT faced by patients, increases adherence and cure rates. [9] Health professionals should ensure that all barriers to TB treatment be removed. [15] If the individuals at risk for poor adherence could be identified early in their

management, health care providers should, in theory, be able to intervene by tailoring the provision of treatment to enable such patients to continue their therapy. [9]

For 2012 treatment cohort, default rates were 3.4% for new smear positive pulmonary TB, 3.9% for all new TB, 7.7% for category II and 4.2% for all registered TB cases. Baghdad governorate had higher default rates from all these figures (5.5%, 6.6%, 9.7% and 6.9% respectively). [16]

Regarding definitions of default (of a TB patient):

A patient previously treated for TB who returns to treatment having previously defaulted [17]. Defaulted: A patient whose treatment was interrupted for 2 consecutive months or more [19].

Defaulter has been replaced by “lost to follow-up” who is a TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more [18].

Defaulter definition had been replaced with Lost to follow-up: A TB patient who did not start treatment or whose treatment was interrupted for two consecutive months or more [20]. Since the new definition is broader and does not fit for this study context; investigators opted to follow WHO definitions used until the end of 2012 and in the global tuberculosis report 2013 [17] where a default [or after loss to follow-up] is defined as patients have previously been treated for TB and were declared ‘lost to follow-up’ at the end of their most recent course of treatment’[17].

Aim of the study: This study aimed at identifying predictors of default from TB treatment in Baghdad.

Objectives:

- 1- Estimate rates of Treatment default in Baghdad for new cohorts.
- 2- Identify predictors of treatment default in Baghdad.

## **2. Patients and Methods.**

**Study Design:** This is a longitudinal study based upon cohort analysis for TB patients enrolled for treatment of TB.

**Settings:** This study was conducted in Baghdad, capital of Iraq, where patients registered for treatment at district TB coordinators units were requested to participate in this study.

**Subjects:** All TB patients registered in study settings during April 2013 till the end of December 2013 were requested to participate in the study.

### **Eligibility Criteria:**

- Inclusion criteria: all TB patients registered for treatment during enrollment period who are Iraqi nationals.
- Exclusion criteria: severely ill or suffering from a debilitating health condition, or suffering from a mental condition, or did not consent to participate in the study.

### **Data Collection:**

All participant were fully informed about the study and if were willing to participate they will be requested to sign an informed consent form in Arabic language (annex 1) (a translated copy to English is available –annex 2). A pretested structured questionnaire form (annex 3) in Arabic language (a translated copy to English is available –annex 4), this form included collecting information about the socio-demographic characteristics, income, housing conditions, accessibility to health care (geographical, financial), satisfaction with care, presence adverse events of drugs and other potential predictors of non-compliance and defaulting. Patient subjected to follow-up as done routinely in the NTP till the end of their treatment period (6 months), or till default or the specified period of observation (end of March 2014) approached. Defaulted patients were visited at their homes for another interview using another pretested structured questionnaire form (annex 5) (a translated copy to English is available –annex 6). This form as well looked in depth for causes of default, beneficiary opinion and presence of coincident events or travels.

### **Sampling Technique:**

Sampling technique of this study was comprehensive sampling; that it targeted all patients registered during the period of data collection.

### **Sample Size:**

According to 2012 data, 2268 patients were registered during the whole year, for 9 months period and expecting 15% non-participation rate, and hence, investigators expected to enroll 1445 patients if work would continue for twelve months (120 patients a month).

### **Definitions:**

Defaulter is a TB patient whose treatment was interrupted for two consecutive months or more. [4]

**End point of observation:**

Was either defaulting from treatment, completing treatment period or reaching the planned date of ending data collection which is the end of March 2014).

**Statistical Analysis:**

Statistical package for social sciences version 20 (SPSS 20) was used for data input and analysis. Discrete variables presented as numbers and percentages, while continuous variables presented as mean $\pm$ SD.

Chi square test for independence used to test the significance of association between discrete variables.

Multivariate binary logistic regression (enter method) used to estimate predictors of default. All variables were adjusted for age and sex.

Kaplan Meier cohort analysis used to estimate the probabilities of defaulting according to duration of treatment and to further investigate the significance of studied factors on the incidence of default, where comparisons were done with the aid of log rank test.

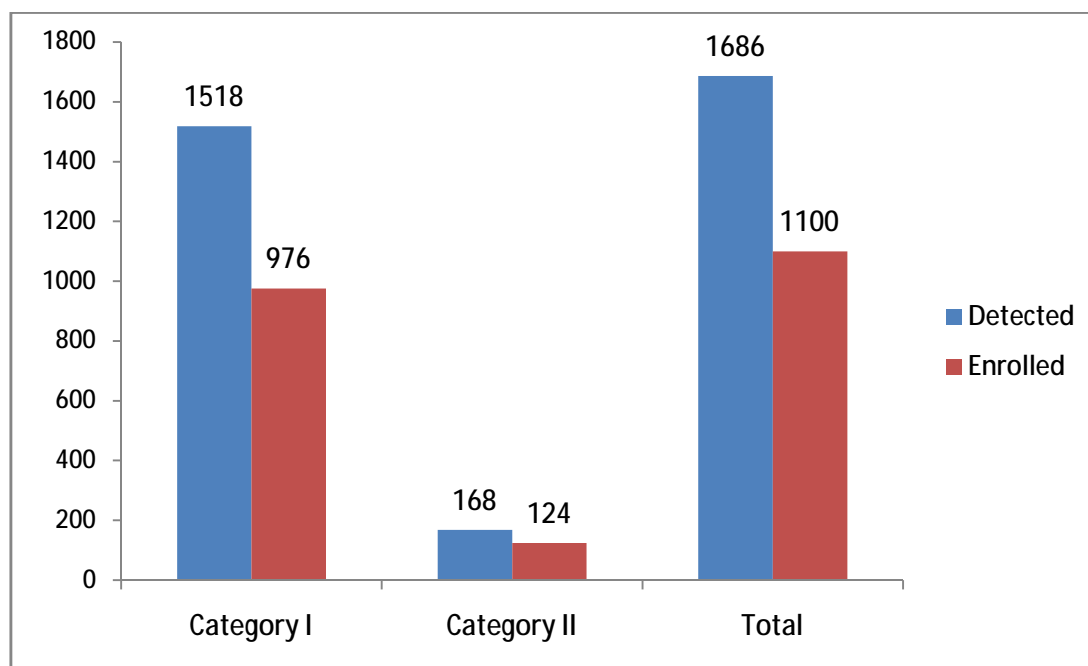
Findings with P value less than 0.05 considered significant.

**Ethical Consideration:**

- 1- Ethical approval was obtained from the Research Ethical Committee in Ministry of Health before conducting the data collection.
- 2- After ensuring confidentiality of data and anonymity, signed informed consent was obtained from each participant.

### 3. Results:

This study had enrolled 1100 TB patients from Baghdad during the period March-December 2013 (i.e. enrollment continued for 10 months). Total TB patients were on treatment during this period is 1686, and this study covered 65.2% of those patients including 64.4% of category I patients and 73.8% of category II patients (figure 1). While investigators expected to enroll around 1445 patients in 12 months (or 1200 patients in 10 months), this study succeeded to enroll 91.6% of the expected sample size for 10 months of enrollment.



**Figure 1: Number of detected and enrolled TB patients in Baghdad, Mar-Dec 2013.**

Enrolled patients were followed during their treatment (end point of observation was either defaulting from treatment, completing treatment period or reaching the planned date of ending data collection which is the end of March 2014). This follow up period, due to its limitation to one year, fully covered treatment period of majority of category I patients (including all patients enrolled in first six months of data collection) and around one third of patients treated under category II (including all patients enrolled in first three months of data collection). Shorter follow up period was for those TB patients detected during December 2013 (minimal follow up period was 14 weeks).

### **Demographic characteristics of enrolled TB patients:**

Age of participants varied from less than a year to 91 years with a mean age of  $38.2 \pm 18.2$  years. Majority (71.7%) of enrolled TB patients aged between 15-45 years (table 1). Males to female ratio approximated 1:1 (males constituted 48.7% of the sample, table 1). More than two thirds (67.5%) of patients are married. Around half the participants (49.5%) have families sized five to 10 persons. Less than 6% of studied patients have education higher than secondary school. Those with fixed income did not exceed 12.4% of total sample (employed and retired people constituted 8.8% and 3.6% of the sample respectively). About 86.3% of patients had a monthly income less than ID 500,000 (US\$ 416). Most (89.4%) of patients live in urban settings and similar proportion (89.2%) live in a distance less than 10 Km near to a primary health care center (PHCC) (table 1).

### **Clinical characteristics of enrolled TB patients:**

Some of patients (12.8%) has a positive family history of tuberculosis and a smaller proportion of patients (4.4%) has diabetes mellitus (table 1).

Pulmonary TB patients accounted for 60.4% of study sample, and according to case definition, proportions were: 89.5% for new patients, 6.5% for relapsed patients, 2.8% for after failure patients and 1.2% after default patients (table 1).

During the period of follow up, 18 patients had been reported as defaulted (discontinued treatment for more than two months). Tracing defaulted cases cleared that one of these treatment defaults was due to death from TB and hence this case was excluded from defaulters group since this study aimed to identify predictors of default from treatment.

Defaulted patients aged from 14 to 85 years, with an average age of  $49.6 \pm 21.9$  years and a median age of 52 years.

For defaulted patients, minimum duration of treatment was three weeks and maximum duration of treatment was 17 weeks. Average duration of treatment prior to default was  $6.4 \pm 4.4$  weeks and a median of five weeks.

More than half the incident defaults (58.8%) occurred within first five weeks of treatment (table 2).

Those 17 patients were distributed as follow (table 1): There were two age peaks for defaulting from treatment; the higher (35.3%) was at age higher than 64 years and the second (23.5%) at age 45-54 years. Males constituted 58.8% of defaulters. About 76.5% of defaulters are married. Family size illustrated about equal distribution among defaulters, 70.6% of defaulters have poor education level (up to primary education).

**Table 1: Characteristics of enrolled TB patients, Baghdad Apr 2013-Mar 2014:**

Variable	Total Sample		Defaulters		P Value <sup>3</sup>
	N=1100	% <sup>1</sup>	N=17	% <sup>2</sup>	
I- Sociodemographic					
Age Group (year)					0.055 <sup>4</sup>
• < 5	28	2.5%	0	0.0%	
• 5-14	44	4.0%	1	5.9%	
• 15-24	227	20.6%	2	11.8%	
• 25-34	222	20.2%	2	11.8%	
• 35-44	178	16.2%	2	11.8%	
• 45-54	162	14.7%	4	23.5%	
• 55-64	116	10.5%	0	0.0%	
• ≥ 65	123	11.2%	6	35.3%	
Sex					0.401
• Male	536	48.7%	10	58.8%	
• Female	564	51.3%	7	41.2%	
Marital Status					0.809 <sup>4</sup>
• Single	292	26.5%	3	17.6%	
• Married	742	67.5%	13	76.5%	
• Divorced/Separated	13	1.2%	0	0.0%	
• Widow	53	4.8%	1	5.9%	
Family Size					0.242
• < 5	385	35.0%	6	35.3%	
• 5-10	544	49.5%	6	35.3%	
• > 10	171	15.5%	5	29.4%	
Education level					0.040 <sup>4</sup>
• Illiterate	225	20.5%	6	35.3%	
• Read & write/primary	471	42.8%	6	35.3%	
• Secondary	340	30.9%	2	11.8%	
• Higher than secondary	64	5.8%	3	17.6%	

<sup>1</sup>percent out of total enrolled patients

<sup>2</sup>percent out of total defaulted patients

<sup>3</sup>Chi-square test for independence

<sup>4</sup>The minimum expected count in this subtable is less than one; chi-square test may be invalid

**Table 1: Continue.**

Variable	Total Sample		Defaulters		P Value <sup>3</sup>
	N=1100	% <sup>1</sup>	N=17	% <sup>2</sup>	
<b>Occupation</b>					<b>0.002<sup>4</sup></b>
• Employee	97	8.8%	4	23.5%	
• Skilled worker	124	11.3%	1	5.9%	
• Unskilled worker	78	7.1%	0	0.0%	
• Farmer	13	1.2%	2	11.8%	
• Retired	40	3.6%	1	5.9%	
• Free work	8	0.7%	0	0.0%	
• Student	117	10.6%	1	5.9%	
• Housewife	425	38.6%	4	23.5%	
• Unemployed	96	8.7%	3	17.6%	
• Others	102	9.3%	1	5.9%	
<b>Monthly income (ID)</b>					<b>0.027<sup>4</sup></b>
• < 250,000	221	20.1%	8	47.1%	
• 250,000-500,000	530	48.2%	7	41.2%	
• 501,000-1,000,000	292	26.5%	1	5.9%	
• > 1,000,000	57	5.2%	1	5.9%	
<b>Residence Area</b>					<b>0.784<sup>4</sup></b>
• Urban	983	89.4%	15	88.2%	
• Rural	97	8.8%	2	11.8%	
• IDP camp	20	1.8%	0	0.0%	
<b>Distance to PHCC</b>					0.891 <sup>4</sup>
• Up to 10 Km	981	89.2%	16	94.1%	
• 11-20 Km	89	8.1%	1	5.9%	
• 21-30 Km	24	2.2%	0	0.0%	
• > 30 Km	6	0.5%	0	0.0%	
<b>Smoker</b>					0.406
• Current Smoker	217	19.7%	5	29.4%	
• Ex-smoker	135	12.3%	3	17.6%	
• Nonsmoker	748	68.0%	9	52.9%	

<sup>1</sup>percent out of total enrolled patients

<sup>2</sup>percent out of total defaulted patients

<sup>3</sup>Chi-square test for independence

<sup>4</sup>The minimum expected count in this subtable is less than one; chi-square test may be invalid



Table 1: Continue.

Variable	Total Sample		Defaulters		P Value <sup>3</sup>
	N=1100	% <sup>1</sup>	N=17	% <sup>2</sup>	
<b>II-Medical History</b>					
<b>Family History of TB</b>					0.548
• Yes	141	12.8%	3	17.6%	
• No	959	87.2%	14	82.4%	
<b>Diabetes Mellitus</b>					0.375 <sup>4</sup>
• Yes	48	4.4%	0	0.0%	
• No	1052	95.6%	17	100.0%	
<b>Site of TB</b>					0.171
• Pulmonary	664	60.4%	13	76.5%	
• Extra-pulmonary	436	39.6%	4	23.5%	
<b>Case Definition</b>					< 0.001 <sup>4</sup>
• New	984	89.5%	13	76.5%	
• Relapsed	72	6.5%	0	0.0%	
• After failure	31	2.8%	1	5.9%	
• After default	13	1.2%	3	17.6%	
<b>Category of Treatment</b>					0.107
• Category I	976	88.7%	13	76.5%	
• Category II	124	11.3%	4	23.5%	

<sup>1</sup>percent out of total enrolled patients

<sup>2</sup>percent out of total defaulted patients

<sup>3</sup>Chi-square test for independence

<sup>4</sup>The minimum expected count in this subtable is less than one; chi-square test may be invalid

Table 2: Distribution of defaulted TB patients according to period of treatment:

Period of Treatment (week)	Frequency	Percent	Cumulative Percent
3	6	35.3	35.3
4	2	11.8	47.1
5	2	11.8	58.8
6	1	5.9	64.7
7	1	5.9	70.6
9	3	17.6	88.2
16	1	5.9	94.1
17	1	5.9	100.0
<b>Total</b>	<b>17</b>	<b>100.0</b>	

Regarding occupation; three peaks of defaults is noticed in this study; 23.5% by employees, 23.5% by housewives, and 17.6% by unemployed patients. Around 88.2% of defaulted patients have a monthly income less than ID 500,000 (US\$ 416). Fifteen patients (88.2%) of those who defaulted were living in urban settings. Sixteen (94.1%) of defaulters live nearby to PHCCs in a distance that does not exceed ten kilometers.

About 53% of defaulters are non-smokers, 82% does have a positive family history of TB, none of them has diabetes mellitus disease, majority (76.5%) of them have pulmonary TB, and as well, majority (76.5%) of defaulted patients are new cases (category I), one (6%) is after failure, and three (17.6%) are after default giving a total of 23.5% as category II treatment patients.

Different default rates were 2% for pulmonary TB and 0.9% for extra-pulmonary TB, 1.3% for new (category I) cases and 3.2% for retreatment (category II) cases, 0% for relapsed cases, 3.2% for after failure patients and 23.1% for after default patients. Overall default rate was 1.6% (0.9%-2.5%) (table 3).

**Table 3: Default rates according to different case characteristics:**

Character	N	Percent	95% Confidence Interval	
			Lower	Upper
Pulmonary TB	13/664	2.0	1.1	3.4
Extra-pulmonary TB	4/436	0.9	0.3	2.5
New TB (category I)	13/984	1.3	0.7	2.3
Relapse	0/72	0.0	0.1	6.3
After failure	1/31	3.2	0.2	18.5
After default	3/13	23.1	6.2	54.0
Category II	4/124	3.2	1.0	8.6
Overall	17/1100	1.6	0.9	2.5

### **Findings obtained during interviews of defaulted TB patients:**

Regarding the opinions and observations of defaulted TB patients about quality of TB services at primary health care settings:

- None of defaulted patients complained unavailability of anti-TB drugs at primary health care settings nor complained from the quality of provided services, and none of them mentioned a delay longer than 15 minutes on obtaining these services or paying money to get anti-TB drugs.
- About 88.2% of defaulted patients were informed about side effects of anti-TB treatment and 94.1% were informed about dates of follow up investigations.

Regarding coincident situations that interfered with adherence to treatment:

- Six defaulters (35.3%) encountered side effects of anti-TB drugs.
- History of hospital admission was positive for four (23.5%) defaulted patients.
- No history of imprisoning among defaulters.
- Three (17.6%) of defaulted patients reported a history of travel during treatment.

Personal and social aspects interfered with adherence to treatment:

- Seven (41.2%) of defaulted patients are not convinced with provided anti-TB treatment.
- 58.8% of defaulted patients suffered from social stigmata of TB
- Only one defaulted TB patient (5.9%) does not believe he is having TB disease.
- Another one patient (5.9%) thinks he is improved and does not need for farther treatment.

Impact of private medical sector on adherence to TB treatment:

- Two patients discontinued anti-TB treatment following the advice of the private physician.
- 77.8% of defaulted patients were visiting private physicians for follow up of their TB disease.
- 29.4% of defaulted TB patients sold anti-TB from private pharmacies.

### **Results of Regression Analysis:**

A- The following factors according to this study found to be less associated with treatment default ( $RR < 1$ ,  $P < 0.05$ , table 4):

- All of age groups:  $< 15$ , 45-64, and  $\geq 65$  compared to age group 15-44 years.
- Single (marital status) compared to married patients.
- Families larger than five persons.
- Education levels up to secondary schools.
- Occupations other than employment & retirement.
- Incomes less than a million (ID) a month.
- Non-urban settings if compared to urban settings.
- Having extra-pulmonary TB compared to pulmonary TB.
- Category I treatment if compared to category II.
- Positive family history of TB.
- Living in a distance 11-20 Km away from a PHCC compared to those living within 10 Km near to a PHCC.

B- History of previous default from anti-TB treatment multiplies the risk of default of a current anti-TB treatment by 28.7 times ( $P < 0.05$ ,  $R > 1$ , table 4).

C- Other factors showed no significant risk estimates according to this study ( $P > 0.05$ ).

**Table 4: Results of multivariate binary logistic analysis:**

Variables	P value	Risk Ratio	95% Confidence Interval	
			Lower	Upper
<b>Age Group (year)</b>	<b>&lt;0.001</b>			
• <15	<b>&lt;0.001</b>	0.024	0.003	0.177
• 15-44	---	---	---	--- <sup>1</sup>
• 45-64	<b>&lt;0.001</b>	<b>0.050</b>	0.018	0.137
• ≥ 65	<b>&lt;0.001</b>	<b>0.114</b>	0.049	0.265
<b>Sex</b>				
• Male	<b>&lt;0.001</b>	<b>0.034</b>	0.018	0.064
• Female	---	---	---	--- <sup>1</sup>
<b>Marital Status</b>	<b>&lt;0.001</b>			
• Married	---	---	---	--- <sup>1</sup>
• Single	<b>&lt;0.001</b>	<b>0.021</b>	0.006	0.073
• Divorced/Separated	0.999	<0.001	<0.001	---
• Widow	0.248	0.275	0.031	2.454
<b>Family Size</b>	<b>&lt;0.001</b>			
• < 5	---	---	---	--- <sup>1</sup>
• 5-10	<b>&lt;0.001</b>	<b>0.060</b>	0.026	0.138
• > 10	<b>&lt;0.001</b>	<b>0.181</b>	0.070	0.467
<b>Education</b>	<b>&lt;0.001</b>			
• Illiterate	<b>&lt;0.001</b>	<b>0.078</b>	0.021	0.285
• Read & write/primary	<b>&lt;0.001</b>	<b>0.039</b>	0.015	0.099
• Secondary	<b>&lt;0.001</b>	<b>0.013</b>	0.003	0.054
• Higher than secondary	---	---	---	--- <sup>1</sup>
<b>Occupation</b>	<b>&lt;0.001</b>			
• Employed/retired	---	---	---	--- <sup>1</sup>
• Other than employed/retired	<b>&lt;0.001</b>	<b>0.044</b>	0.023	0.082
<b>Income</b>	<b>&lt;0.001</b>			
• < 250,000	<b>0.002</b>	<b>0.236</b>	0.095	0.587
• 250,000-500,000	<b>&lt;0.001</b>	<b>0.086</b>	0.036	0.208
• 501,000-1,000,000	<b>&lt;0.001</b>	<b>0.022</b>	0.003	0.165
• > 1,000,000	---	---	---	--- <sup>1</sup>
<b>Residence Area</b>	0.229			
• Urban	---	---	---	--- <sup>1</sup>
• Other than urban	<b>&lt;0.001</b>	0.139	0.072	0.267
<sup>1</sup> Reference level				

**Table 4: Continue.**

Variables	P	Risk	95% Confidence Interval	
	value	Ratio	Lower	Upper
Site of TB				
• Pulmonary	---	---	---	--- <sup>1</sup>
• Extra-pulmonary	<0.001	0.112	0.062	0.201
Treatment Category				
• Category I	<0.001	0.109	0.055	0.216
• Category II	---	---	---	--- <sup>1</sup>
TB type	0.004			
• New	---	---	---	--- <sup>1</sup>
• Relapsed	0.996	<0.001	<0.001	---
• After failure	0.116	0.183	0.022	1.521
• After default	0.001	28.564	3.927	207.751
DM				
• Diabetic	0.997	<0.001	<0.001	---
• Not	---	---	---	--- <sup>1</sup>
Smoking	0.972			
• Current Smoker	0.908	0.938	0.313	2.808
• Ex-smoker	0.848	10.144	0.289	4.533
• Nonsmoker	---	---	---	--- <sup>1</sup>
FH				
• Positive	<0.001	0.105	0.032	0.342
• Negative	---	---	---	--- <sup>1</sup>
Distance	0.162			
• Up to 10 Km	---	---	---	--- <sup>1</sup>
• 11-20 Km	0.023	0.095	0.012	0.726
• 21-30 Km	0.998	<0.001	<0.001	---
• > 30 Km	0.999	<0.001	<0.001	---

<sup>1</sup>Reference level

### Results of Kaplan Meier Survival Analysis:

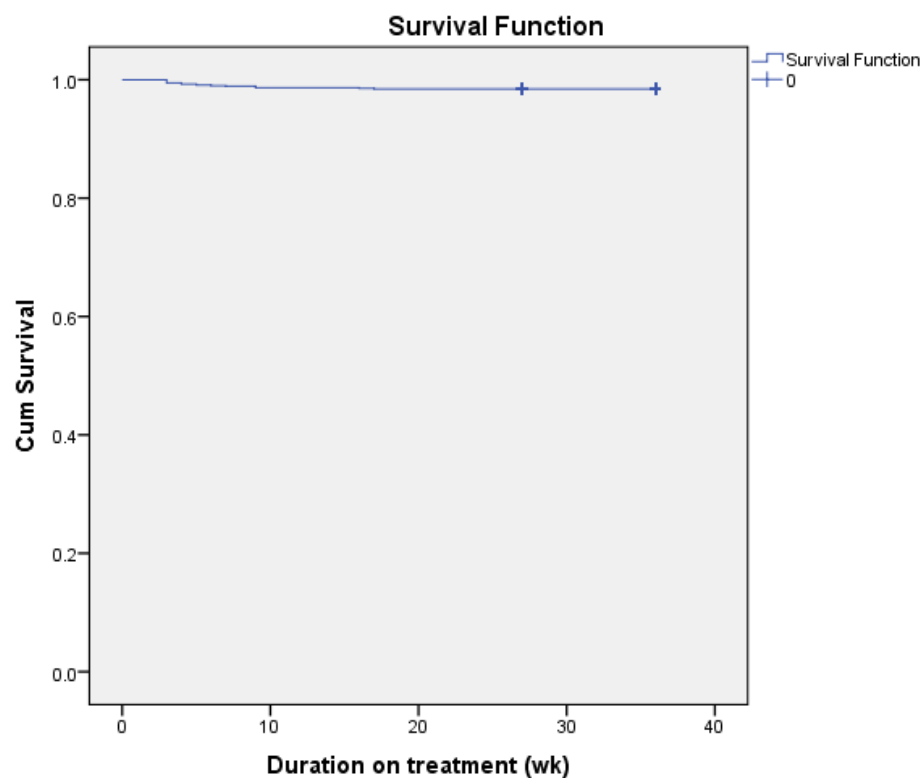
- 1- After comparing factors using Log Rank (Mantel-Cox) Chi-square test, significant factors were age 15-45 year, education, occupation status of employed/retired, monthly income, and case definition (according to treatment history) ( $P < 0.05$ , table 5).
- 2- Longest period of taking anti-TB before default was 17 week, and according to survival analysis, the probability of survival (non-defaulting) at week 17 is 0.985 (table 6, figure 2) and hence the cumulative probability of non-survival (defaulting) at this time is 0.015 (figure 3).
- 3- This study found the highest rates of hazard function in patients of TB who have education higher than secondary (figure 4), aged older than 65 (figure 5), employed or retired (figure 6), monthly income not exceeds ID 500,000 or US\$ 416 (figure 7), and having a history of previous default (figure 8).

**Table 5: Results of Log Rank Chi-square test during Kaplan Meier analysis for the significance of study variables on predicting/causing default:**

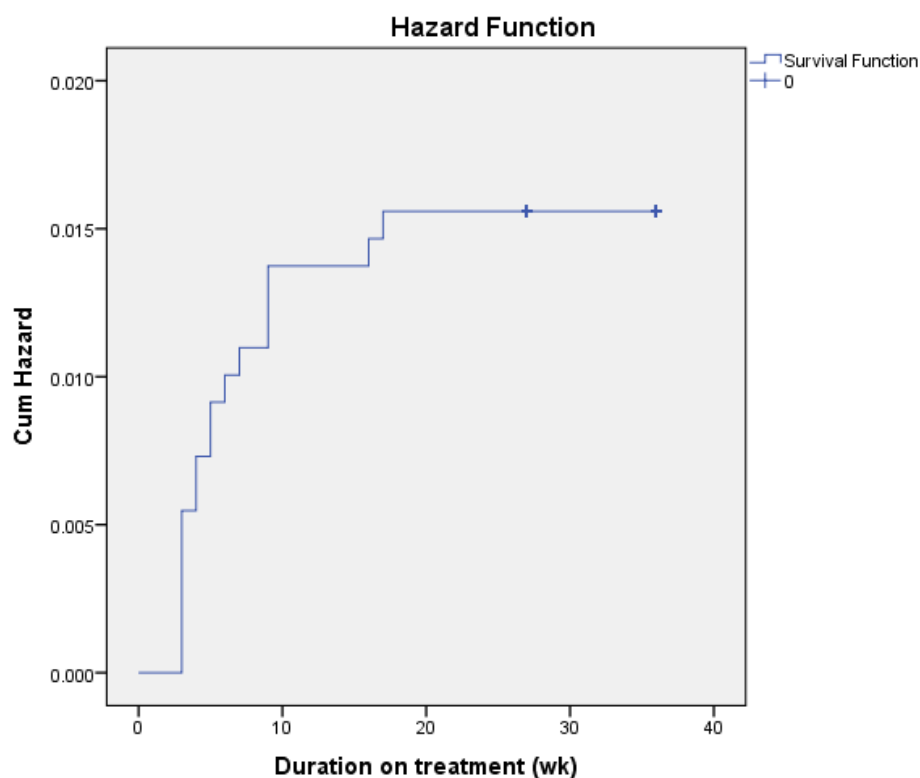
Variables	Log Rank (Mantel-Cox)
Age Group (15-45)	<b>0.014</b>
Married	0.424
Family Size	0.246
Education	<b>0.039</b>
Employed/Retired	<b>0.032</b>
Monthly Income	<b>0.024</b>
Urban Residence	0.881
Site of TB	0.172
Case definition	<b>&lt;0.001</b>
Treatment Category	0.107
Diabetes	0.376
Smoking	0.400
Family history of TB	0.551
Distance > 10 Km	0.507

**Table 6: Survival table for enrolled TB patients:**

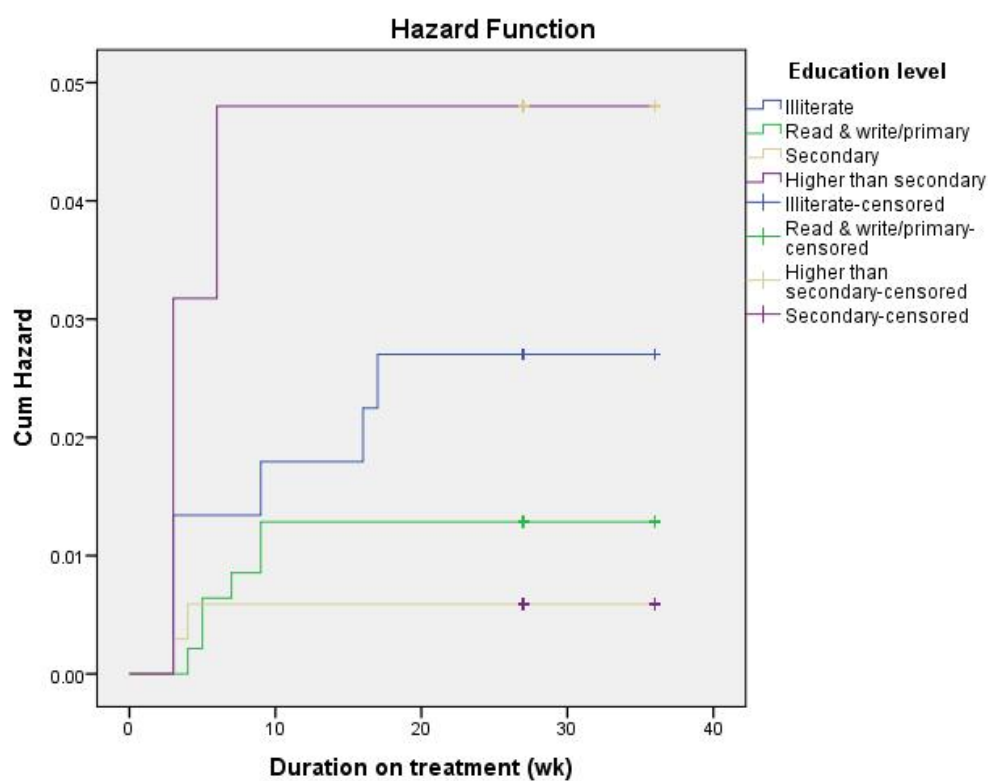
Cumulative N of defaulters	Week of defaulting from Treatment	Cumulative Proportion Surviving at the Time	
		Estimate	Std. Error
6	3	0.995	0.002
8	4	0.993	0.003
10	5	0.991	0.003
11	6	0.990	0.003
12	7	0.989	0.003
15	9	0.986	0.003
16	16	0.985	0.004
17	17	0.985	0.004



**Figure 2: Survival function (non-defaulting) according to duration of treatment with anti-TB.**

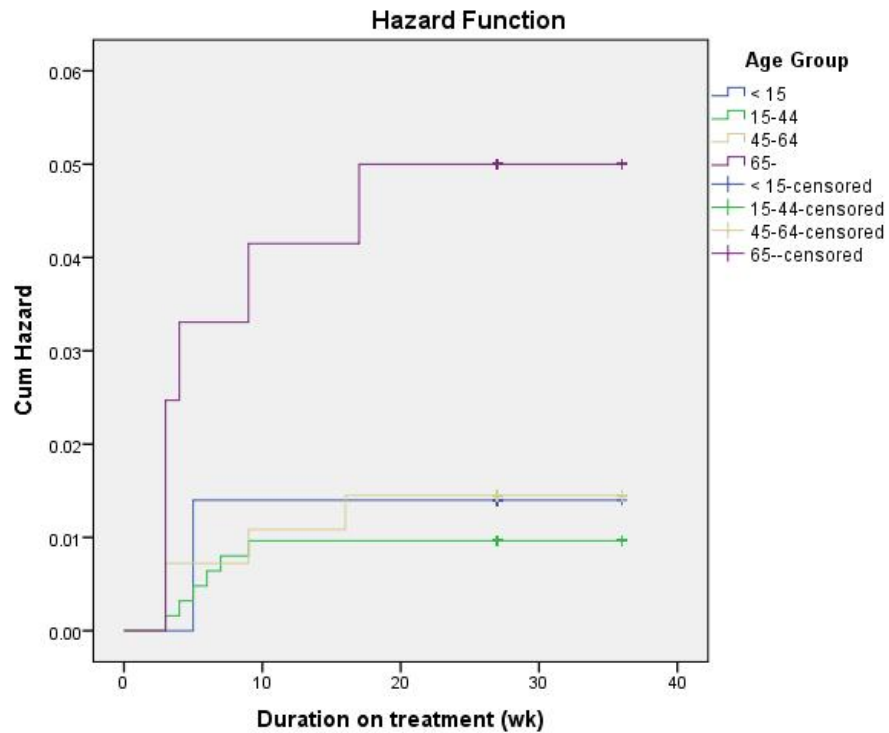


**Figure 3: Hazard (defaulting) function according to duration of treatment with anti-TB.**

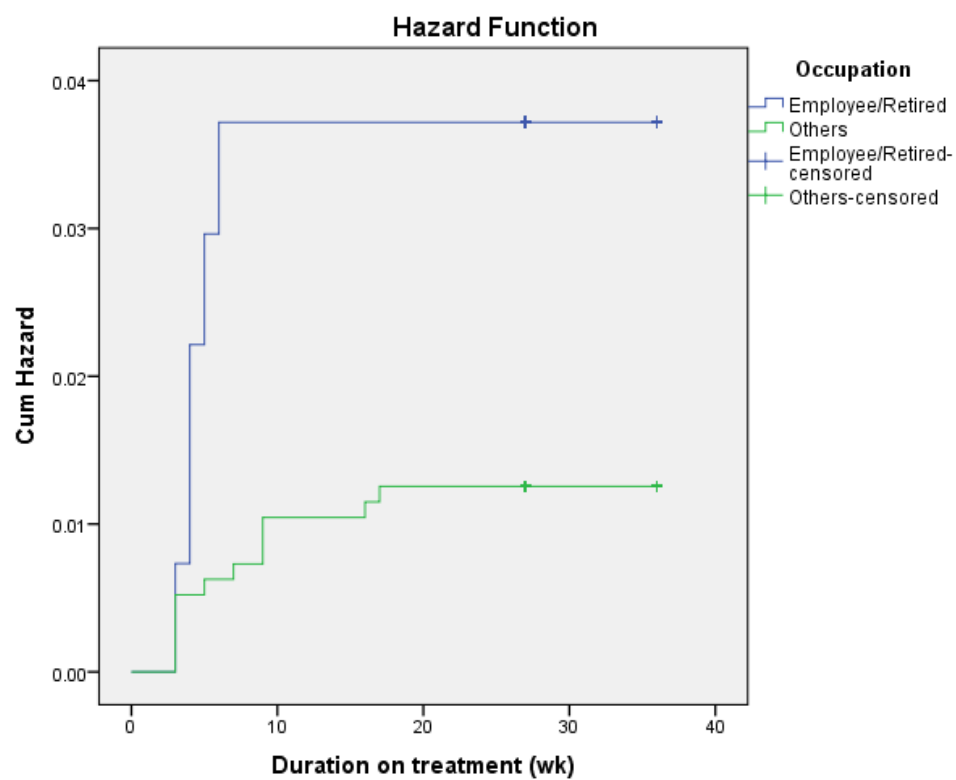


**Figure 4: Hazard (defaulting) function according to education level.**

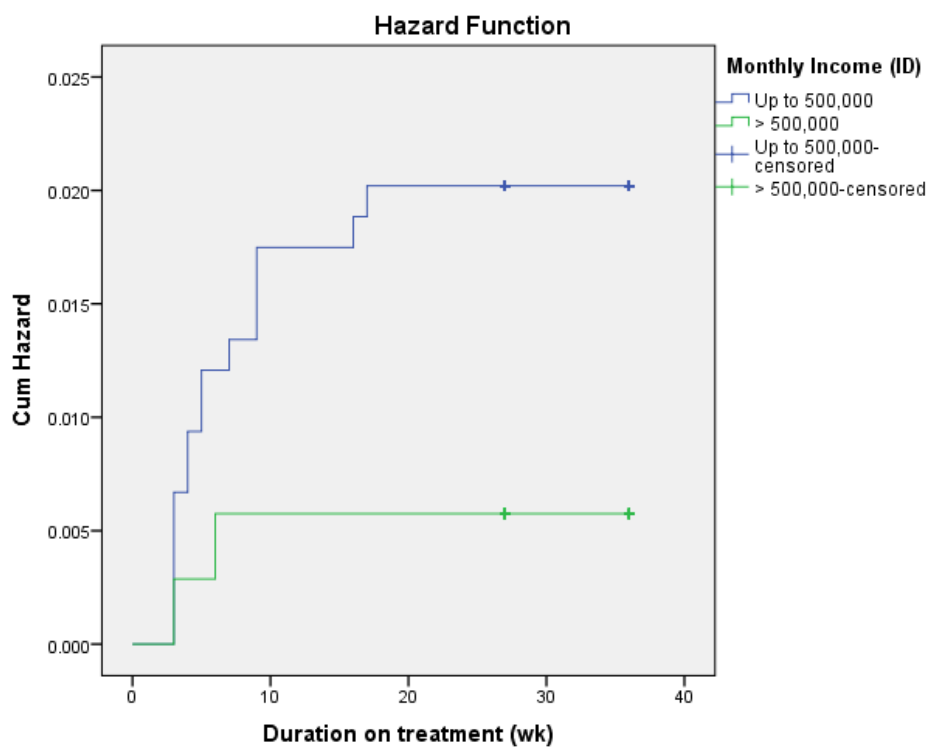




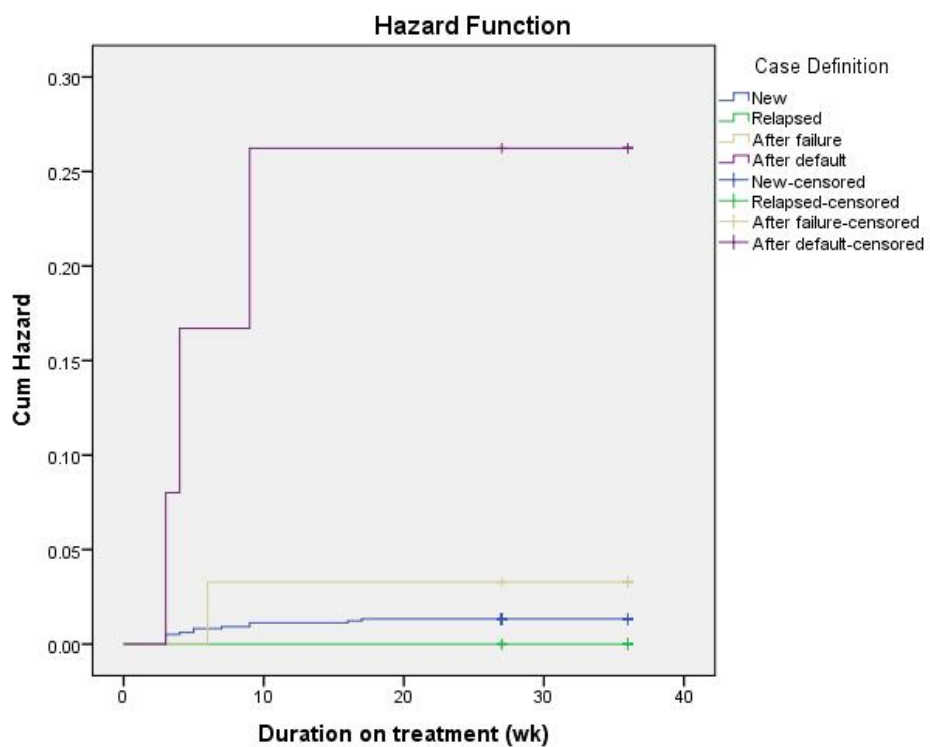
**Figure 5: Hazard (defaulting) function according to age group.**



**Figure 6: Hazard (defaulting) function according to employment.**



**Figure 7: Hazard (defaulting) function according to monthly income.**



**Figure 8: Hazard (defaulting) function according to case definition.**

## 4. Discussion:

Successful treatment of tuberculosis (TB) involves taking anti-tuberculosis drugs for at least six months. Poor adherence to treatment means patients remain infectious for longer, are more likely to relapse or succumb to tuberculosis and could result in treatment failure as well as foster emergence of drug resistant tuberculosis (Muture BN et al. 2011)<sup>21</sup> and persistent infectiousness remains an impediment to the tuberculosis control program (Vijay S. et al 2010)<sup>22</sup>.

Knowing that globally acceptable rate is below 4% (Pinidiyapathirage J et al 2008)<sup>23</sup>, this study showed that default rates among studied sample was within acceptable limits which are 1.3% for new (category I) cases and 3.2% for retreatment (category II) cases, with an overall default rate of 1.6%. By international comparison, Baghdad still having a low default rate compared to Estonia (Kliiman K. el al 2010)<sup>24</sup>, Hong Kong (Chang-Yeung MMW et al 2003)<sup>25</sup>, Nigeria (HAMAYUN A et al 2012)<sup>26</sup> and (Fatireegun AA et al 2009)<sup>27</sup> that had default rates between 5-10% or Kassala in Sudan (Pinidiyapathirage J et al 2008)<sup>23</sup>, Kuwait (Zhang Q et al 2014)<sup>28</sup>, Cameroon (PefuraYone EW et al 2011)<sup>29</sup>, Rio de Janeiro (Orofino Rde L et al 2011)<sup>30</sup> that exceeded a default rate of 10%, or Nairobi in Kenya (Muture BN et al. 2011)<sup>21</sup>, Sri Lanka (Pinidiyapathirage J et al 2008)<sup>23</sup>, Nigeria (Ifebunandua NA et al 2012)<sup>31</sup>, Morocco (Tachfouti N et al 2013)<sup>32</sup>, In Spain 14% defaulted (Cayla JA et al 2014)<sup>33</sup> that exceeded a default rate of 15-20%. In Sri Lanka, a study stated that the default rates were 10.3% and 30.3% among new cases and retreatment cases, respectively, during the intensive phase of treatment and 10.9% and 16.5%, respectively, during the continuation phase (Pinidiyapathirage J et al 2008)<sup>23</sup>.

Majority (76.5%) of defaulted patients in this study had pulmonary TB; this is a similar finding by (Ifebunandua NA et al 2012)<sup>31</sup>. As well as the majority (76.5%) are new cases of TB. In this study, the default rate in pulmonary TB patients was higher (2%) than in extra-pulmonary TB patient (0.9%), and none of relapse patients had defaulted and only one case of after failure was defaulted (6%). Of defaulters, 17.6% were after default which agrees with (Muture BN et al. 2011)<sup>21</sup>, (Pinidiyapathirage J et al 2008)<sup>23</sup>, (Chang-Yeung MMW et al 2003)<sup>25</sup>, (Zhang Q et al 2014)<sup>28</sup> and (Jha UMI et al 2006)<sup>34</sup>, and 23.5% of defaulters were on category II treatment which is as well agrees with other studies (Sylvere TA et al 2015)<sup>35</sup> and (Abuaku B et al 2010)<sup>36</sup>.

Treatment is usually for a minimum of 6 months and requires a high level of compliance (Sultan H et al 2013)<sup>37</sup>. This study found that minimum duration of treatment for defaulters was three weeks and maximum duration of treatment was 17 weeks (119 days). Average duration of treatment prior to default was 6.4±4.4 weeks and a median of five weeks. More than half the incident defaults (58.8%) occurred within first five weeks of treatment, i.e. mostly in the first month of intensive treatment. This agrees with a study in Hong Kong stated that 45% of those who defaulted did so in the first 2 months of treatment (Chang-Yeung MMW et al 2003)<sup>25</sup> and another study in Kuwait stated that 56% of those who defaulted did so in the first

2 months of treatment (Zhang Q et al 2014)<sup>28</sup>. In Cameroon Median duration to treatment discontinuation was 90 days (PefuraYone EW et al 2011)<sup>29</sup>, (Ifibunandua NA et al 2012)<sup>31</sup> found this median default time as 7 weeks, and in a study conducted in India, the median duration of treatment prior to default was 81 days by Category II patients (Jha UMI et al 2006)<sup>34</sup>.

Defaulted patients aged from 14 to 85 years, with an average age of 49.6±21.9 years and a median age of 52 years. There were two age peaks for defaulting from treatment; the higher (35.3%) was at age higher than 64 years and the second (23.5%) at age 45-54 years. Age is a factor associated with default (Cayla JA et al 2014)<sup>33</sup> that default increases with ages equal or older than 30 years (Ifibunandua NA et al 2012)<sup>31</sup>.

Sex is a factor associated with defaulting from treatment (Cayla JA et al 2014)<sup>33</sup>. In this study; Males constituted 58.8% of defaulters and this finding goes with (Ifibunandua NA et al 2012)<sup>31</sup> and (Jha UMI et al 2006)<sup>34</sup>.

Family size illustrated about equal distribution among defaulters, anyhow, no family support is a risk for default (Castelnuovo B. 2010)<sup>38</sup> and this is true for single patients in this study, and family size greater than 5 persons is a risk factor for default (Castelnuovo B. 2010)<sup>38</sup>.

70.6% of defaulters have poor education level (up to primary education). Poor education is reported as a predictor for defaulting of TB patients by (Vijay S. et al 2010)<sup>22</sup>, (Pinidiyapathirage J et al 2008)<sup>23</sup>, and (Zhang Q et al 2014)<sup>28</sup>.

While (Kliiman K. et al 2010)<sup>24</sup> found unemployment is associated with defaulting, this study found all of employees, housewives, and unemployed patients are associated with default as well.

Low house-hold income of defaulters was observed in this study as well as by (Belo MT et al 2006)<sup>40</sup>, (Pablos-Mendez A et al 1997)<sup>41</sup>, knowing that marginalized populations may abandon treatment before being cured (Belo MT et al 2006)<sup>40</sup>.

Fifteen patients (88.2%) of those who defaulted were living in urban settings which agrees with (Kliiman K. et al 2010)<sup>24</sup>, and disagrees with (Ifibunandua NA et al 2012)<sup>31</sup> who found 65% of defaulter were from rural residence.

In Baghdad, 94.1% of defaulters live nearby to PHCCs in a distance that does not exceed ten kilometers. Those who travel in order to get medicine and those who need to travel a distance of more than 30 minute-walk to get medicine are at risk to develop default (HAMAYUN A et al 2012)<sup>26</sup> and (Castelnuovo B. 2010)<sup>38</sup>.

About 53% of defaulters are non-smokers, (Dujaili JA et al)<sup>42</sup> and (Pinidiyapathirage J et al 2008)<sup>23</sup> found TB patients who are ever smoker and regular smokers, respectively, associated with defaulting from treatment.

Strong evidence suggests diabetes may be associated with tuberculosis (TB) and could influence TB treatment outcomes (Faurholt-Jepsen D et al 2013)<sup>43</sup>, as well as previous incarceration (Kliiman K. et al 2010)<sup>24</sup>, history of concomitant diabetes mellitus (Zhang Q et al 2014)<sup>28</sup>, liver disease (Chang-Yeung MMW et al 2003)<sup>25</sup>, (Zhang Q et al 2014)<sup>28</sup>, or lung cancer (Chang-Yeung MMW et al 2003)<sup>25</sup>, and (Zhang Q et al 2014)<sup>28</sup>. In this study, none of reported defaulters was having such diseases.

The following service factors were frequently mentioned by interviewed defaulters: poor to fair-grade communication (Mishra P 2003)<sup>44</sup> and (Vijay S. et al 2010)<sup>22</sup>. “Difficult access to health services” (Brasil PE et al 2008)<sup>45</sup>, “training or support for adherence” (Brasil PE et al 2008)<sup>45</sup> and (Vijay S. et al 2010)<sup>22</sup>, ignorance (Muture BN et al. 2011)<sup>21</sup>, in the same time (Zhang Q et al 2014)<sup>28</sup> and (Chang-Yeung MMW et al 2003)<sup>25</sup> found that around 86.4% and 39%, respectively, of defaulted pulmonary TB patients were still bacteriologically positive at the time of default. None of defaulted patients according to this study complained unavailability of anti-TB drugs at primary health care settings nor complained from quality of provided services, and none of them mentioned a delay longer than 15 minutes on obtaining these services or paying money to get anti-TB drugs.

35.3% of defaulters encountered side effects of anti-TB drugs. This is much more than what (Orofino Rde L et al 2011)<sup>30</sup> encountered (8%) in Rio De Janeiro. Side effects to anti TB drugs are associated with defaulting from treatment according to (Muture BN et al. 2011)<sup>21</sup>, (Vijay S. et al 2010)<sup>22</sup> and (Castelnuovo B. 2010)<sup>38</sup>.

History of hospital admission was positive for 23.5% of defaulted patients. This is also documented by (Hasker E et al 2008)<sup>13</sup>.

No history of imprisoning among defaulters was found in this study. (Abdelhadi MA et al 2015)<sup>46</sup> found imprisonment as a factor associated with default.

17.6% of defaulted patients reported a history of travel during treatment. (Muture BN et al. 2011)<sup>21</sup> notified a proportion of 12.5% to traveling away from treatment site among studied defaulters.

41.2% of defaulted patients are not convinced with provided anti-TB treatment. It is reported that one of the frequent reasons of defaulting from treatment is dissatisfaction with services provided (Vijay S. et al 2010)<sup>22</sup>.

Stigma was also found to be strongly associated with the default rate (Abdelhadi MA et al 2015)<sup>46</sup>. Investigators found that 58.8% of defaulted patients suffered from social stigmata of TB.

Investigators in this study had encountered one patient (5.9%) thinks he is improved and does not need for farther treatment. Feeling better is one of the reported causes of default by TB patients (Muture BN et al. 2011)<sup>21</sup> and (Abdelhadi MA et al 2015)<sup>46</sup>.

Two patients discontinued anti-TB treatment following the advice of the private physician. (Vijay S. et al 2010)<sup>22</sup> mentioned that having other commitments by TB patients during treatment induces default.

29.4% of defaulted TB patients sold anti-TB from private pharmacies, and this finding agrees with (HAMAYUN A et al 2012)<sup>26</sup> found that those who occasionally need to buy medicine are at risk for defaulting from treatment.

Inadequate knowledge of tuberculosis is an associated factor and a predictor for default according to different studies (Muture BN et al. 2011)<sup>21</sup>, (Vijay S. et al 2010)<sup>22</sup> and (Fatiregun AA et al 2009)<sup>27</sup> and we can attribute some of default cases to this reason as in defaulters justify their treatment interruption to presence of side effect of anti-tuberculosis treatment, or due to feeling improved, or following private physician's advice in leaving DOTS treatment or in buying antituberculosis medication from private sector despite its availability at national tuberculosis program facilities.

Longest period of taking anti-TB before default was 17 week, and according to survival analysis, the cumulative probability of default at this time is 0.015. This observed rate of defaulting is much less than what was reported before in Baghdad (4.2% or 0.042) for all registered cases in 2012 (16). Because this study covered all Baghdad and following all recruited patients, this rapid decrease in default rate in one year can be attributed to observational bias that district TB coordinators probably had strictly followed their patients and maintained a higher adherence rate to treatment.

According to this study, predictors for defaulting from treatment are:

1. Previous default from anti-TB treatment multiplies the risk of default of a current anti-TB treatment by 28.7 times. All of (Muture BN et al. 2011)<sup>21</sup>, (Pinidiyapathirage J et al 2008)<sup>23</sup>, (Chang-Yeung MMW et al 2003)<sup>25</sup> and (Zhang Q et al 2014)<sup>28</sup> agree with this finding.
2. Pulmonary TB, a finding agreed with by (Pinidiyapathirage J et al 2008)<sup>23</sup>.
3. History of previous treatment (i.e. enrollment in category II treatment). This is as well a finding by (Abuaku B et al 2010)<sup>36</sup>, (Sultan H et al 2013)<sup>37</sup> and (Berhe G et al 2012)<sup>39</sup>.
4. Age 15-44 years and older than 65 older age. This finding agrees with (Tachfouti N et al 2013)<sup>32</sup>, (Abuaku B et al 2010)<sup>36</sup> and (Sultan H et al 2013)<sup>37</sup> and disagree with (Abdelhadi MA et al 2015)<sup>46</sup> that stated that Age negatively associated with the default.
5. Monthly income not exceeds ID 500,000 or US\$ 416. This finding disagree with (Muture BN et al. 2011)<sup>21</sup> and (Sultan H et al 2013)<sup>37</sup> that stated that low incomes predicts defaulting from treatment.

6. Education higher than secondary. This is unlike (Vijay S. et al 2010)<sup>22</sup>, (Pefura Yone EW et al 2011)<sup>29</sup>, (Abdelhadi MA et al 2015)<sup>46</sup> or (Vijay S. et al 2010)<sup>22</sup> who stated that low education level and illiteracy, respectively, predicts defaulting from treatment.
7. Employed or retired status. This finding disagrees with (Pinidiyapathirage J et al 2008)<sup>23</sup> who stated that skilled and unskilled laborers are at risk to develop default.
8. Living in urban settings. Regarding to this finding, this study agrees with (HAMAYUN A et al 2012)<sup>26</sup>, and disagree with (Tachfouti N et al 2013)<sup>32</sup> who found rural residence predicts defaulting from treatment.

Unlike other studies that found male gender (Muture BN et al. 2011)<sup>21</sup>, (Chang-Yeung MMW et al 2003)<sup>25</sup>, (HAMAYUN A et al 2012)<sup>26</sup>, (Fatireegun AA et al 2009)<sup>27</sup>, (Zhang Q et al 2014)<sup>28</sup> and (Sultan H et al 2013)<sup>37</sup> and smoking (if regular) (Pinidiyapathirage J et al 2008)<sup>23</sup> as predictors of default, this study did not find such relationships significant.

## **5. Conclusions and Recommendations**

Predictors of default found to be previous default, pulmonary tuberculosis, retreatment, age (15-45y and older than 65y), medium to high income, education higher than secondary school, Occupation (employed or retired), and living in an urban setting.

Educating patients at the initiation of antituberuclosis treatment is of paramount importance to reduce default of TB patients in Baghdad, in addition to enhance the peripheral role of national tuberculosis program to strictly follow up TB patient.



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## Annex (1)

### استمارة الموافقة المستنيرة-دراسة العوامل التي تتنبأ بتسرب مرضى التدرن في بغداد

الرقم التسلسلي:

تاريخ المقابلة

اسم القطاع:

عنوان المستجيب (اقرب نقطة دالة):

توقيع القائم بالمقابلة: \_\_\_\_\_ اسم القائم بالمقابلة: \_\_\_\_\_

مكان العمل: \_\_\_\_\_ رقم الموبايل: \_\_\_\_\_

توقيع المشرف الميداني: \_\_\_\_\_ اسم المشرف: \_\_\_\_\_

مكان العمل: \_\_\_\_\_ رقم الموبايل: \_\_\_\_\_

### الموافقة المستنيرة لأفراد المجتمع والمرضى

**عنوان الدراسة:** معرفة اسباب تسرب مرضى التدرن (السل) عن اكمال العلاج في بغداد  
**الغرض من الدراسة:** البحث في معرفة اسباب تسرب مرضى التدرن (السل) عن اكمال العلاج من أجل الحصول على المعلومات لتعزيز اكمال علاجهم بصورة صحيحة وتقليل خطر اصابة المجتمع ومنع انتشار المرض.

**الإجراء:** التعرف على اسباب انقطاع وتسرب مرضى التدرن (السل) عن اكمال العلاج عن طريق استبيان بالمقابلة لغرض الوصول الى المجاميع النتنسبة والمنقطعة عن العلاج  
**المخاطر/المتاعب:** لا توجد مخاطر ناتجة عن مشاركتك في هذه الدراسة حتى وإن قررت عدم الإجابة عن أي سؤال أو قررت إيقاف المقابلة في أي وقت.

**الفوائد:** لا توجد فوائد شخصية لك من المشاركة في الدراسة. ومن المتوقع وجود منافع مجتمعية عن الدراسة حيث ستعمل السلطات الصحية على الاستفادة من معلومات الدارسة لتحسين الخدمات الصحية المقدمة لمرضى السل والمجتمع.

**حقوق المشاركين:** تعد مشاركتك طوعية وقد تختار إيقاف المقابلة في أي وقت ودون شروط. ومن حقك الاستفسار عن أية نقاط غير مفهومة.

**السرية:** لن يتم التصريح عن إجاباتك لأي شخص وستبقى مجهولة الهوية. وسيتم إتلاف البيانات في حال الانسحاب من المقابلة. ويمكن الوصول إلى المعلومات فقط من قبل أعضاء فريق البحث ولأغراض البحث فقط.

**موافقة المشارك:** أعلن أنه قد تم تزويدي بالمعلومات أعلاه وتم شرحها لي وكان لدي كامل الفرصة في طرح الأسئلة وحصلت على إجابات كافية حول كافة الأسئلة التي طرحتها. وأعلن عن مشاركتي الطوعية في هذه الدراسة وأنا على معرفة بحقي الكامل في الانسحاب من الدراسة دون أي شروط.

اسم و توقيع المشارك:-----

توقيع المشارك:-----

في حال عدم قدرة المشارك على قراءة النموذج وحاجته لشخص لشرح/ترجمة النموذج.

اسم و توقيع الشخص الذي قام بشرح/ترجمة النموذج:-----

عنوان الشخص الذي قام بشرح/ترجمة النموذج:-----

## Annex (2)

### Informed consent form

Study Title: Predictors of default of TB patients in Baghdad, 2013.

Date of Interview: SN:

District:

Address of respondent:

Interviewer information:

Name: Signaturer:

Place of work: Mobile:

Field supervisor:

Name: Signaturer:

Place of work: Mobile:

### Informed consent form for TB patients:

**Study title:** Predictors of default of TB patients in Baghdad, 2013.

**Purpose** of the study: study factors predict TB patients default and discontinuation of treatment.

**Methods:** Interviews of TB patients.

**Risks/hazards:** No risk or hazards will result due to participation in this study and you can stop the interview in any time.

**Benefits:** no personal benefits yeild from this participation but public health benefits to TB patients and the community are expected after health authorities utilize results of this study.

**Praticipants rights:** this participation is voluntary and you may stop this interview in any time and you have the right to request the interviewer to explain to you any unclear point or question.

**Confidentiality:** Your responses will be kept confidential and anonymous and accessed only by study team for research purposes.

**Participants' Consent:** I declare that I am well informed about above information and well explained for me and had the chance to ask questions and get sufficient answers, and my participation in this study is voluntary and I am fully knowledgeale of my right to unconditioned discontinue of the interview or withdrawal from this study

Name of the participant:

Signature:

In case of the participant's inability to read the form and needed for someone to read and interpret the informed consent form; the fields below are filled by the person who read the consent form for the participant:

Name:

Signature:

Adress:

### Annex (3)

#### استبانة رقم (١)

اسم الدراسة: العوامل التي تتسبب بتسرب مرضى التدن من العلاج في بغداد، ٢٠١٣  
(تملاً عند تشخيص حالة التدن)

اسم القطاع الصحي	تسلسل الاستمارة	رقم المريض حسب سجل المريض في القطاع	اسم مريض التدن الثلاثي	رقم الموبايل
الاسئلة				
س	رمز الاجابة			
١		العمر (بالسنة)		
٢		الجنس: ١- ذكر ٢- أنثى		
٣		الحالة الزوجية؟ ١- أعزب ٢- متزوج ٣- مطلق/منفصل ٤- أرمل		
٤		عدد أفراد الأسرة؟ ١- أقل من ٥ ٢- بين ٥ الى ١٠ ٣- أكثر من ١٠		
٥		المستوى التعليمي؟ ١- لا يقرأ ولا يكتب ٢- يقرأ و يكتب/تعليم ابتدائي ٣- تعليم متوسط/اعدادي ٤- دبلوم فما فوق		
٦		نوع العمل؟ ١- موظف ٢- عامل ماهر ٣- عامل غير ماهر ٤- فلاح ٥- متقاعد ٦- تاجر ٧- طالب ٨- ربة بيت ٩- عاطل عن العمل ١٠- أخرى		
٧		الدخل الشهري للعائلة بالدينار العراقي؟ ١- أقل من ٢٥٠.٠٠٠ ٢- بين ٢٥٠.٠٠٠-٥٠٠.٠٠٠ ٣- ٥٠١.٠٠٠ الى مليون ٤- أكثر من مليون		
٨		طبيعة مكان الإقامة الحالي؟ ١- حضر ٢- ريف ٣- نازح/مخيم لاجئين		
٩		ما هو نوع التدن الذي مصاب به؟ ١- رئوي ٢- خارج الرئة		
١٠		تصنيف الحالة: ١- جديد ٢- ناكس ٣- بعد فشل ٤- بعد انقطاع		
١١		فئة العلاج: ١- فئة أولى ٢- فئة ثانية		
١٢		هل انت مصاب بأمراض أخرى؟ أذكرها ١- نعم ( ) ٢- لا		
١٣		التدخين: هل انت ١- مدخن ٢- مدخن سابق ٣- غير مدخن		
١٤		هل اصيب احد افراد اسرتك بمرض السل؟ ١- نعم ٢- لا		
١٥		كم يبعد مكان سكنك عن أقرب مركز رعاية صحية أولية يزودك بأدوية التدن؟ ١- ما لا يزيد عن ١٠ كم ٢- ١١-٢٠ كم ٣- ٢١-٣٠ كم ٤- أكثر من ٣٠ كم		
اسم القائم بالمقابلة (Name of Interviewer)		التوقيع (signature)	التاريخ (Date)	
اسم الطبيب المدقق (منسق التدن في القطاع) (Name of Interviewer)		التوقيع (signature)	التاريخ (Date)	

## Annex (4)

### Questionnaire Form -1-

**Study title: Predictors of Default of TB patients in Baghdad, 2013**  
(Filled on Diagnosis of a TB patient)

Health District	SN	Local DTC Registration Number	Full Name	Mobile Number
Q	Code of Response	Question		
1		Age (year)		
2		Sex: 1- Male      2- Female		
3		Marital Status: 1-Single   2-Married   3-Divorced/Separated   4-Widow		
4		Family Size: 1- < 5      2- 5 – 10      3- > 10		
5		Education: 1- Illiterate   2-Read & write/primary   3-Secodary   4- > secondary		
6		<b>Occupation:</b> 1-Employee   2-Skilled worker   3-Unskilled worker   4-farmer      5-Retired 6- Free work   7- Student      8- housewife      9- Unemployed   10- others		
7		<b>Monthly income of the family (in Local Currency-Iraqi Dinar):</b> 1- < 250,000   2- 250,000- 500,000   3- 501,000-1,000,000   4- > 1,000,000		
8		<b>Recent Residence:</b> 1- urban   2- rural   3- Internally displaced camp		
9		<b>Site of TB:</b> 1-Pulmonary   2- Extrapulmonary		
10		<b>Treatment History:</b> 1- New case   2-Relapse   3-After failure   4-After default		
11		<b>Treatment Category:</b> 1- Category I   2- Category II		
12		<b>History of concurrent other diseases:</b> 1- yes (specify _____)   2- no		
13		<b>Smoking history:</b> 1- smoker   2-ex-smoker   3- non-smoker		
14		<b>Family history of TB:</b> 1- yes   2- no		
15		<b>Distance from PHCC provides you with anti-TB treatment:</b> 1- up to 10 Km   2- 11-20 Km   3- 21-30 Km   4-> 30km		
(Name of Interviewer)			(signature)	(Date)
(Name of DTC)			(signature)	(Date)



## Annex (5)

أستمارة رقم (٢)

اسم الدراسة :العوامل التي تتسبب بتسرب مرضى التدن من العلاج في بغداد، ٢٠١٣

( تملأ بعد انقطاع المريض أو تخلفه عن العلاج )

اسم القطاع الصحي	تسلسل الاستمارة	رقم المريض حسب سجل المريض في القطاع	اسم مريض التدن الثلاثي	رقم الموبايل
س	رمز الاجابة	الأسئلة		
١		هل ظهرت عليك أعراض جانبية بعد أخذ العلاج ؟ أذكرها ١- نعم (                      ) ٢- لا		
٢		هل أن الأدوية متوفرة بمركز الرعاية الصحية الاولى ؟ ١- نعم ٢- لا		
٣		هل حصلت على الأدوية من مصادر اخرى؟ أذكرها ١- نعم (                      ) ٢- لا		
٤		هل أن الخدمة المقدمة لك في مركز الرعاية الصحية الاولى جيدة؟ ١- نعم ٢- لا		
٥		ماهي المدة التي انتظرتها في مركز الرعاية الصحية الاولى قبل أستلامك العلاج ؟ ١- أقل من ١٥ دقيقة ٢- من ١٥ الى ٣٠ دقيقة ٣- أكثر من ٣٠ دقيقة		
٦		هل دخلت مستشفى خلال فترة العلاج ؟ ١- نعم ٢- لا		
٧		هل سافرت خلال فترة العلاج ؟ ١- نعم ٢- لا		
٨		هل دخلت سجن أو اصلاحية أثناء فترة العلاج ؟ ١- نعم ٢- لا		
٩		هل أن الأدوية مجانية بمركز الرعاية الصحية الاولى ؟- نعم ٢- لا (التكلفة بالدينار العراقي )		
١٠		هل تعاني أو عانيت من وصمة التدن ؟ ١- نعم ٢- لا		
١١		هل قام مقدمي الرعاية الصحية بتوجيهك قبل البدء بالعلاج عن الفترة اللازمة للعلاج؟ ١- نعم ٢- لا		
١٢		هل قام مقدمي الرعاية الصحية بتوجيهك قبل البدء بالعلاج عن الأعراض الجانبية للأدوية؟ ١- نعم ٢- لا		
١٣		هل قام مقدمي الرعاية بتوجيهك قبل البدء بالعلاج عن مواعيد المراجعة لفحوصات المتابعة؟ ١- نعم ٢- لا		
١٤		لماذا انقطعت عن العلاج؟		
١٥		هل تراجع طبيب خاص ؟ ١- نعم ٢- لا		
		<div style="display: flex; justify-content: space-between;"> <div style="width: 20%;"> <p>التاريخ (Date)</p> </div> <div style="width: 20%;"> <p>التوقيع (signature)</p> </div> <div style="width: 60%;"> <p>اسم القائم بالمقابلة (Name of Interviewer)</p> </div> </div>		
		<div style="display: flex; justify-content: space-between;"> <div style="width: 20%;"> <p>التاريخ (Date)</p> </div> <div style="width: 20%;"> <p>التوقيع (signature)</p> </div> <div style="width: 60%;"> <p>اسم الطبيب المدقق (منسق التدن في القطاع) (Name of Interviewer)</p> </div> </div>		

## Annex (6)

### Questionnaire Form -1-

Study title: Predictors of Default of TB patients in Baghdad, 2013

(Filled after default of a TB patient or discontinuation of treatment)

Health District	SN	Local DTC Registration Number	Full Name	Mobile Number
Q	Code of Response	Question		
1		Did you have side effect of anti-TB drugs? 1- yes (mention_____ ) 2- no		
2		Are anti-TB drugs available in PHCCs? 1- yes                      2- no		
3		Did you get anti-TB from other than PHCC? 1- yes (mention_____ ) 2- no		
4		Is PHCC of treatment provided good treatment service for you? 1- yes    2- no		
5		What is the time spent in PHCC waiting to receive treatment for TB? 1- < 15 min              2- 15-30 min              3- > 30 min		
6		Admitted to hospital during treatment? 1- yes                      2- no		
7		Travel during treatment?                      1- yes                      2- no		
8		Imprisoned during treatment?                      1- yes                      2- no		
9		Treatment given for free in PHCC?    1- yes                      2- no (Cost in ID is _____)		
10		Have you suffered from stigma to TB? 1- yes                      2- no		
11		Had you been informed about duration of treatment? 1- yes                      2- no		
12		Had you been informed about side effects of treatment? 1- yes                      2- no		
13		Had you been informed about dates of follow up examinations? 1- yes    2- no		
14		Why did you discontinue treatment?		
15		Do you visit a private physician clinic for this TB disease? 1- yes                      2- no		
(Name of Interviewer)		(signature)		(Date)
(Name of DTC)		(signature)		(Date)