

## CHAPTER IV

### RESULT

The study was conducted from 1 to 31 February 2005 in Bangkok Urban Areas, Thailand. Four government DOTS treatment centers including Bangkok Chest clinic under Ministry of Public Health and 3 public health centers under Bangkok Metropolitan Administration were involved in this study. The main purpose of the study was to assess the effectiveness of different types of DOT observers including self administration group on treatment outcome among new smear positive pulmonary TB patients, while controlling/adjusting other confounding factors such as the socio-economic and demographic characteristics, medical services, and health condition of TB patients. This study also aimed to identify relationships between these variables and treatment outcome. There were 518 subjects in the study. Family member supervised patients totaled 180, health personnel supervised patients 167, and self administration patients 171. The patient treatment card, TB register and laboratory register books were examined to collect the data.

#### **4.1 Descriptive Data**

##### **4.1.1 General Data**

**Frequency and percentage of study subjects by different types of DOT observers and location**

There were 518 subjects in the study and Family member supervised patients: 180 (34.7%), health personnel supervised patients: 167 (32.2%), and self administration patients: 171 (33.0%) by different types of DOT observers (Table 1).

**Table1. Frequency and percentage of study subjects by different types of DOT observers**

<b>Types of DOT observer</b>	<b>Frequency</b>	<b>Percentage</b>
Family member	180	34.7
Health worker	167	32.2
Self administration	171	33.0
<b>Total</b>	<b>518</b>	<b>100.0</b>

**Table 2. Frequency and percentage of study subjects by Location**

<b>Location</b>	<b>Number</b>	<b>Percentage</b>
Bangkok chest clinic of MoPH	320	61.8
Health center 7 of BMA	76	14.7
Health center 23 of BMA	67	12.9
Health center 16 of BMA	55	10.6
<b>Total</b>	<b>518</b>	<b>100.0</b>

**Frequency and percentage of patients by different health center**

According to location, Bangkok Chest clinic was 320 (61.8%), health center 7 was 76 (14.7%), health center 16 was 55 ( 10.6%) and health center 23 was 67 (12.9%), respectively (Table 2).

#### 4.1. 2 Socio-Demographic Data

##### Frequency and percentage of patients by Age group.

This section showed different kinds of variables of socio-demographic factors. The age of the research subjects ranged from 12 to 85 years with a mean, 37.7 and median, 34.5. Ages of the patients were classified into five groups, Table 3 indicated that more than 70 % of study subjects belonged to the age group 15-44, and 86 % in the 15-54 age group, which is the economically most productive age group. A very small proportion were at the range of age 55 and above (13.9%).

**Table 3. Frequency and percentage of patients under different types of DOT observers by age**

Age group (years)	Types of DOT observers						Total	
	Family member		Health worker		Self administration		N	%
	N	%	N	%	N	%		
1-24	40	23.3	31	18.6	30	17.5	101	19.5
25-34	51	28.3	58	34.7	49	28.7	158	30.5
35-44	41	22.8	34	20.4	40	23.4	115	22.2
45-54	19	10.6	19	11.4	34	19.9	72	13.9
55 and over	29	16.1	25	15.0	18	10.5	72	13.9
Total	180	100.0	167	100.0	171	100.0	518	100.0

Mean=37.7/Median=34.50, SD=14.41 Min=12 Max=85  $X^2=13.824^*$ , df=10 p-value:0.181,

##### Frequency and percentage of patients by gender

Regarding gender, male patients accounted for more than two thirds (69.7 %) of study subjects, whereas females accounted for only one third (30.3 %) of the total study subjects. The ratio of male to female is 2.3: 1.

**Table 4. Frequency and percentage of patients under different DOT observers by gender**

Gender	Types of DOT observers						Total	
	Family member		Health worker		Self administration		N	%
	N	%	N	%	N	%		
Male	121	67.2	122	73.1	118	69.0	<b>360</b>	<b>69.7</b>
Female	59	32.8	45	26.9	53	31.0	<b>157</b>	<b>30.3</b>
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 1.452$   $df=2$   $p\text{-value}=0.484$

#### Frequency and percentage of patients by marital status

Regarding the marital status, the result showed that more than half (55%) of patients belonged to the married group, (Table 5).

**Table 5. Frequency and percentage of study subject by marital status**

Marital status	Number	Percentage
Unmarried	187	<b>36.1</b>
Married	285	<b>55.0</b>
Widow/widower/ separate	46	<b>8.9</b>
<b>Total</b>	<b>518</b>	<b>100.0</b>

#### Frequency and percentage of patients by Occupation

Concerning the occupation of study subjects, over one fourth of study subjects (28.8%) were involved in laboring and farming, 23.7% were in private services, 23.9% of study subjects were unemployed, and only few were students/children(13.7 %), housewife (8.3%) and government officials (1,5%).

**Table 6. Frequency and percentage of patients by occupation and DOT observers**

Occupation	Types of DOT observers						Total	
	Family Member		Health worker		Self administration		N	%
	N	%	N	%	N	%		
Farmer/laborer	47	26.1	53	31.7	49	28.7	<b>149</b>	<b>28.8</b>
Unemployed	47	26.1	47	28.1	30	17.5	<b>124</b>	<b>23.9</b>
Private sector Employee	34	18.9	27	16.2	62	36.3	<b>123</b>	<b>23.7</b>
Other(student/children)	35	19.4	21	12.6	15	8.8	<b>71</b>	<b>13.7</b>
Housewife	14	7.8	15	9.0	14	8.2	<b>43</b>	<b>8.3</b>
Government officials	3	1.7	4	2.4	1	0.6	<b>8</b>	<b>1.5</b>
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 32.057$ ,  $df = 10$   $p$ -value: < 0.001

#### 4. 1. 3 Patients Behavior Data

##### Frequency and percentage of patients by Compliance status

Regarding the compliance of study subjects, 429 subjects (82.8%) had never missed any drug taking and the remaining (89 cases -17.2%) had missed drug taking between 1 to 109 days with a mean of 21.5, median of 10.0, and Std. Deviation of 26.5.

**Table 7. Frequency and percentage of patients by compliance status**

Compliance	Number	Percentage
Never missed treatment	429	82.8
Ever missed treatment	89*	17.2
<b>Total</b>	<b>518</b>	<b>100.0</b>

\* Range: 1 to 109 days, Mean: 21.5 days, Median: 10.0 days, SD: 26.5

### Frequency and percentage of patients with habit of alcohol drinking.

Among the total study subjects, 125 cases (24.1%) had a information about alcohol consumption and among those 125 cases, more than half of the patients (66.4 %) had a habit of drinking alcohol.

**Table 8. Frequency and percentage of patients\* with habit of alcohol drinking by different DOT observers**

Habit of drinking alcohol	Types of DOT observers						Total	
	Family Member		Health Worker		Self Administration		N	%
	N	%	N	%	N	%		
No	6	37.5	32	38.6	4	15.4	42	33.6
Yes	10	62.5	51	61.4	22	84.6	83	66.4
<b>Total</b>	16	100.0	83	100.0	26	100.0	125*	100.0

\* 125 subjects from total 518 study subjects because 164 subjects did not have the information on alcohol drinking.  $X^2 = 4.889$ ,  $df=2$ ,  $p\text{-value} = 0.087$

### Frequency and percentage of patients with habit of smoking

Among the total study subjects, only 138 patients' smoking status (26.6 %) were available in medical records, and among those 138 patients, more than half of the patients (57.2 %) had a habit of smoking, when they registered as a TB patients.

### Frequency and percentage of defaulters according to the phase of treatment

Table 10 showed that among 81 defaulters, 55.5% was defaulted at the continuous phase, while 44.5% occurred at the intensive phase. According to the different DOT observers, 44.1% of defaulters supervised by family member and 50.0% defaulters under self administration occurred at the intensive phase, while

only 27.3% defaulters under the supervision of health personnel occurred in intensive phase (Table 10).

**Table 9. Frequency and percentage of defaulters according to the phase of treatment by different DOT observers**

Default period	Types of DOT observers						Total	
	Family member		Health worker		Self administration			
	N	%	N	%	N	%	N	%
Intensive phase*	15	44.1	3	27.3	18	50.0	<b>36</b>	<b>44.4</b>
Continuous phase**	19	55.9	8	72.7	18	50.0	<b>45</b>	<b>55.6</b>
<b>Total</b>	<b>34</b>	<b>100.0</b>	<b>11</b>	<b>100.0</b>	<b>36</b>	<b>100.0</b>	<b>81</b>	<b>100.0</b>

df : 2, p-value: 0.414

\* The first two or three months of treatment

\*\* The third or fourth month to sixth or seventh month of treatment

#### 4.1. 4 Health Service Related Data

**Frequency and percentage of patients according to DOT and non-DOT.**

Concerning the DOT and non-DOT group, 347(67%) were under DOT and 171(33%) were under non-DOT (Self- administration group).

**Table 10. Frequency and percentage of TB patients by DOT and Non-DOT (Self administration).**

DOT & Non DOT	Frequency	Percentage
DOT	347	67.0
Non-DOT (Self –administration group)	171	33.0
<b>Total</b>	<b>518</b>	<b>100.0</b>

### **Frequency and percentage of study subject by different drug supply intervals**

According to the different drug supply intervals, 129 (24.9 %) were supplied drugs on a daily basis, 216 (41.7%) were on a weekly basis, 135 (26.1%) were on a monthly basis and 38 cases (7.3 %) were in the interval of every two weeks. As shown in table 13, health personnel supervised DOT group, 18.6% got drugs on the weekly basis and 16.2% at the fourteen days interval instead of daily supply. And family member supervised DOT group, 7.2% got drugs on the monthly basis in stead of weekly basis, and among the self administration group, 24% was on the weekly basis instead of monthly basis (Table 13).

### **Frequency and percentage of study subject by treatment regimen**

According to the treatment regimen, 515 (99.4%) were treated with daily regimen and only 3 (0.6 %) were treated with intermittent regimen.

### **Frequency and percentage of study subject according to the formulation of tuberculosis drugs**



**Table 11. Frequency and percentage of study subjects by different drug supply intervals and DOT observer**

Drug supply interval	Types of DOT observers						Total	
	Family Member		Health worker		Self administration		N	%
	N	%	N	%	N	%		
Daily	20	1.1	109	65.3	0	0.0	129	<b>24.9</b>
Weekly	144	80.0	31	18.6	41	24.0	216	<b>41.7</b>
Monthly	13	7.2	0	0.0	122	71.3	135	<b>26.1</b>
Others*	3	1.7	27	16.2	8	4.7	38	<b>7.3</b>
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 493.114$ ,  $df=6$ ,  $p$ -value:  $<0.001$  \* Others: Once every two weeks

According to the formulation of tuberculosis drugs, 340 study subjects (65.6%) were treated with separated drugs (non-combination form), and 178 cases (34.4%) were treated with a 4-drug combination in one tablet. Majority of TB patients of Chest clinic of MoPH were treated by separate drugs and the patients of BMA were treated by combination drugs form. This might be the reason of different policies between MoPH and BMA.

#### **Frequency and percentage of study subject by the duration of directly observed treatment (DOT)**

As for the Frequency and percentage of study subjects according to the different DOT duration are as the below table 15.

**Table 12. Frequency and percentage of study subjects according to the formulation of tuberculosis drugs and types of DOT observers**

Formulation of drugs	Types of DOT observers						Total	
	Family member		Health Worker		Self administration			
	N	%	N	%	N	%	N	%
Separate drugs	143	79.4	32	19.2	165	96.5	340	65.6
Combination form drugs	37	20.6	135	80.8	6	3.5	178	34.4
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$\chi^2 = 247.316$ ,  $df:2$ ,  $p\text{-value}:0.001$

As shown in the table 15, among 180 family member supervised patients, 101 patients (56.1%) changed into non-DOT after two month intensive phase treatment, while 10.2% health personnel supervised patients (17 of 167 patients) became non-DOT after intensive phase treatment.

**Table 13. Frequency and percentage of study subjects according to the duration of directly observed treatment (DOT) by DOT observer**

DOT duration	Types of DOT observers						Total	
	Family Member		Health worker		Self administration			
	N	%	N	%	N	%	N	%
Intensive phase	101	56.1	17	10.2	0	0	118	22.8
Whole course of treatment	78	43.3	147	88.0	0	0	225	43.4
Never DOT	1	0.6	3	1.8	171	100.0	175	33.8
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$\chi^2 = 620.426$   $df=4$ ,  $p\text{-value}<0.001$

#### 4. 1. 5 Patients' Physical Condition Related Data

##### Frequency and percentage of study subject as per the initial acid fast bacilli (AFB) status

As per the initial AFB status, 172 cases (33.2%), 140 (27%), and 206 (39.8%) were in one plus (+), two plus (++) and three plus (+++) status, respectively. Nearly half of the patients under health personnel DOT was one plus sputum smear, while majority of patients under family member DOT and self administration were in three plus sputum smear.

**Table 14. Frequency and percentage of study subject according to the initial acid fast bacilli (AFB) status by different DOT observers**

Initial AFB status before starting treatment	Types of DOT observers						Total	
	Family member		Health worker		Self administration		N	%
	N	%	N	%	N	%		
+	58	32.2	74	44.3	40	23.4	172	33.2
++	49	27.2	34	20.4	57	33.3	140	27.0
+++	73	40.6	59	35.3	74	43.3	206	39.8
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 17.866$ ,  $df = 4$   $p$ -value=0.001.

##### Number and percentage of study subject according to the sputum conversion status at the end of the second month of treatment and DOT observers

According to the sputum conversion status, the sputum of 357 cases (68.9%) were converted into the smear negative at the end of the intensive

phase treatment, 114 cases (22.0%) were still smear positive and 47 cases (9.1%) did not have an examination of sputum among 518 cases in total.

According to different type of DOT observers, self administration group had a lowest conversion rate (62.8%), compared to other two groups, while they had a highest positive rate (26.8%) than others. As for the proportion of no tested patients by different DOT observer, health personnel supervised DOT group reported lowest rate (5.4%), compared to family member group(10.6%) and self administration group (11.1%).

**Table 15. Frequency and percentage of study subjects according to the sputum conversion status at the end of the second month of treatment and DOT observers**

Sputum status at the 2nd month of treatment	Types of DOT observers						Total	
	Family member		Health worker		Self Administration		N	%
	N	%	N	%	N	%		
AFB negative	129	71.1	121	72.5	107	62.8	357	68.9
AFB positive	32	17.8	37	22.2	45	26.8	114	22.0
No tested	19	10.6	9	5.4	19	11.1	47	9.1
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 8.123$      $df=4$      $p\text{-value}=0.087$

#### **Frequency and percentage of drug resistant patients among study subjects**

Among the total study subjects, 88 patients (17%) were tested for the drug resistance and 430 were not tested. Among those tested for drug resistance, 7 (1.3%) had drug resistance and among those who had drug resistance, 6 cases (1.2%) were non-MDR TB, while one case (0.2%) was MDR-TB.

**Frequency and percentage of study subjects with side effects of drugs and frequency and percentage of each side effect**

Concerning the side effects, 118 study subjects (22.8%) had side effects. According to the different DOT observers, family member supervised DOT group and self administration group had higher side effect rates (30.0% and 29.8%), compared to health personnel supervised DOT group (7.8%). According to the types of side effect, itching was 34 cases (28.8%), nausea or vomiting—27 (22.9%), rash--29 (24.6%), joint pain or numbness—17 (14.4%), Jaundice—8 (6.8%), blue vision—2 (1.7 %), and loss of hearing-- 1 (0.8%).

**Table 16. Frequency and percentage of study subjects by side effects and types of DOT observers**

Side effect	Types of DOT observers						Total	
	Family member		Health Worker		Self administration		N	%
	N	%	N	%	N	%		
No side effect	126	70.0	154	92.2	120	70.2	400	77.2
Side effect	54	30.0	13	7.8	51	29.8	118	22.8
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

df:2 p-value:0.001

**Number and percentage of study subject with co-morbidities and Frequency and percentage of each co-morbidity**

Concerning the co-morbidities, among 518 study subjects, 76 patients (14.7%) had co-morbidity along with tuberculosis.

**Table 17. Frequency and percentage of study subjects by side effects**

<b>Side effect</b>	<b>Frequency</b>	<b>Percent</b>
Itching	34	6.6
Rash	29	5.6
Nausea/ vomiting	27	5.2
Joint pain/numbness	17	3.3
Jaundice	8	1.5
Vision Problem	2	0.4
Loss of hearing	1	0.2
<b>Total</b>	<b>118</b>	<b>22.8</b>

The most common was diabetes mellitus (61.3%), followed by HIV/AIDS (26.7%), liver disorder (4.3%), hypertension (2.7%), and others including asthma, allergy, stomach disorder and nerve system disorder (1.3%, each).

**Table 18. Number and percentage of study subjects according to other co-morbidity**

<b>Existence of Co-morbidity</b>	<b>Frequency</b>	<b>Percent</b>
No	443	85.5
Yes	75	14.5
<b>Total</b>	<b>518</b>	<b>100.0</b>

#### **Frequency and percentage of each symptom among study subjects**

The clinical information of 518 new smear positive pulmonary tuberculosis patients is presented in the following table.

**Table 19. Distribution of each co-morbidity**

<b>Kind of Co-morbidity</b>	<b>Frequency</b>	<b>Percentage</b>
Diabetes	46	8.9
HIV/AIDS	20	3.9
Liver disorder	3	0.6
Hypertension	2	0.4
Allergy	1	0.2
Stomach disorder	1	0.2
Nerve system disorder	1	0.2
Asthma	1	0.2
<b>Total</b>	<b>75</b>	<b>14.5</b>

More than half of the patients had classic symptoms such as cough (97.7%), and fever (58.1%), while other common symptoms were chest pain (45.6 %), dyspnoea (37.6%), blood stained sputum (24.9%), loss of weight (22.2%), night sweats (15.8%), loss of appetite (15.6 %), and hemoptysis (6.9%).

**Table 20. Frequency and percentage of each symptom among 518 study subjects**

<b>Symptom</b>	<b>Frequency</b>	<b>Percentage</b>
Cough	506	<b>97.7</b>
Fever	301	<b>58.1</b>
Chest pain	236	<b>45.6</b>
Dyspnoea	195	<b>37.6</b>
Blood stained sputum	129	<b>24.9</b>
Loss of weight	115	<b>22.2</b>
Night sweats	82	<b>15.8</b>
Loss of appetite	81	<b>15.6</b>
Hemoptysis	36	<b>6.9</b>

### Severity of disease of study subjects

Severity of the disease of study subjects was measured by using a scoring method. Nine questions for measuring the severity of disease were used. The data collectors were requested to choose a “yes” or “no” answer by ticking in each question. The questions were graded as yes=1, and no=0. Severity level were categorized based on the total scores. Subjects who got >80% of total score were most severe cases, and subjects who got 60%-80% of total score belonged to the moderate and subjects who got less than 60% of total score belonged to the less severe group.

Table 23 showed, regarding the severity level of diseases, 31(6.0%) of subjects belonged to the most severe group, 79 (15.3%) belonged to the moderate level of severity of the disease, and 408 (78.8%) belonged to the less severe level of disease.

**Table 21. Frequency and percentage of study subjects by severity of disease**

<b>Severity level *</b>	<b>Frequency</b>	<b>Percent</b>
Low	408	78.8
Moderate	79	15.3
High	31	6.0
<b>Total</b>	<b>518</b>	<b>100.0</b>

Mean:72.12 days, Median: 30.0, SD:117.9, Max:1,400, Min:0

\* Low level is the score less than 60% of total score, moderate level is the score of 60-80% of total score and high severity level is the score more than 80% of total score.



### Frequency and percentage of overall treatment outcome

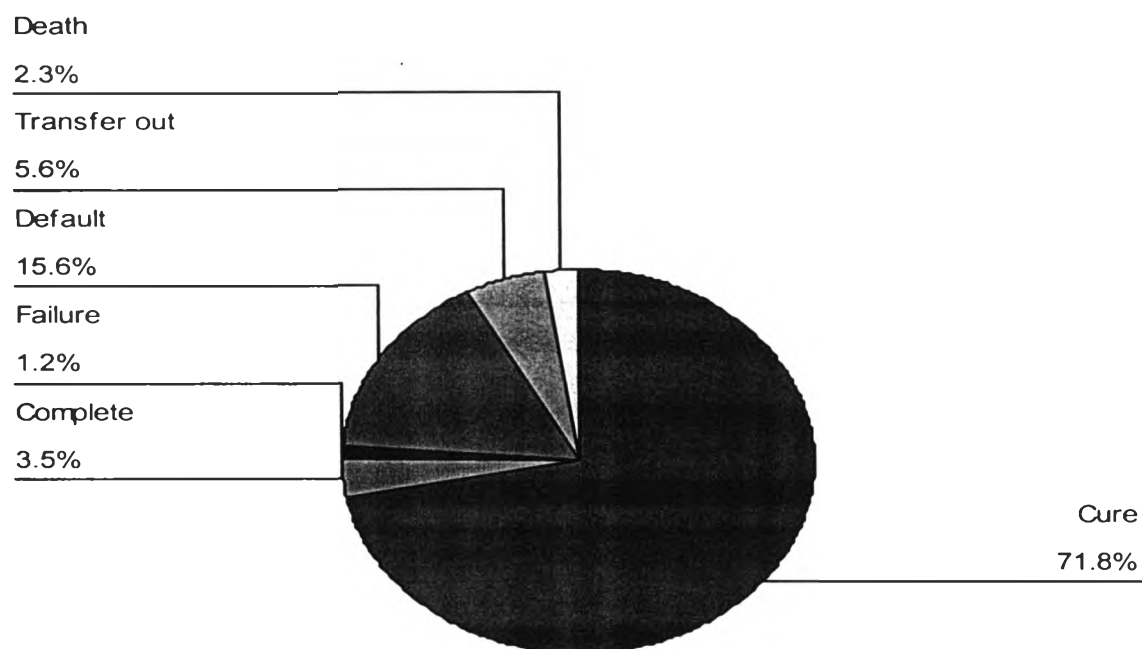
Outcomes are as following table 22.

**Table 22. Treatment outcome of 518 study subjects**

Outcome of treatment	Frequency	Percentage
Success*	390	75.3
Failure	6	1.2
Default	81	15.6
Transfer out	29	5.6
Death	12	2.3
<b>Total</b>	<b>518</b>	<b>100.0</b>

\* Success = Cure + Complete

### Proportion of each treatment outcome



**Figure 3. Frequency and percentage of each treatment outcome**

### Treatment outcome of TB patients with HIV/AIDS

Among those 20 TB patients with HIV/AIDS, 17 cases (85%) were cured, 1 case (5.0%) failed and 2 cases (10.0%) transferred out. Result showed that

HIV co-infected TB patients have similar treatment outcome with those HIV non-infected TB patients (Table 24-2).

**Table 23. Treatment outcome of TB patients with HIV/AIDS**

Outcome of treatment						Total	
Cure		Failure		Transfer out			
N	%	N	%	N	%	N	%
17	85.0	1	5.0	2	10.0	20	100.0

**Frequency and percentage of study subjects according to treatment success and default by different DOT observer**

**Table 24. Frequency and percentage of study subjects according to treatment success and non-success by different types of DOT observers**

Success & Non-success	Types of DOT observers						Total	
	Family member		Health worker		Self administration			
	N	%	N	%	N	%	N	%
Success	124	68.9	146	87.4	120	70.2	<b>390</b>	<b>75.3</b>
Non-success	56	31.1	21	12.6	51	29.8	<b>128</b>	<b>24.7</b>
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 19.587$  df=2 p-value<0.001

Table 24 and 25 showed treatment success and default rates by different types of DOT observers. Health personnel supervised DOT group had higher success rate (87.4%), compared to family member supervised group (68.9 %) and self administration group (70.2%), while self administration group and family member supervised group reported relatively higher default rate (21.1% and 18.9%), compared to health personnel supervised group (6.6%). Both treatment

outcome had a significant association with different types of DOT observers (p-value<0.001 in both success and default groups).

**Table 25. Frequency and percentage of study subjects according to treatment default and non- default by different types of DOT observers**

Default & Non-default	Types of DOT observers						Total	
	Family Member		Health worker		Self administration		N	%
	N	%	N	%	N	%		
Default	34	18.9	11	6.6	36	21.1	<b>81</b>	<b>15.6</b>
Non-default	146	81.1	156	93.4	135	78.9	<b>437</b>	<b>84.4</b>
<b>Total</b>	<b>180</b>	<b>100.0</b>	<b>167</b>	<b>100.0</b>	<b>171</b>	<b>100.0</b>	<b>518</b>	<b>100.0</b>

$X^2 = 15.613$  df=2 p-value<0.001

## 4.2 Association Between Treatment Success & Default and Other Variables

### 4. 2. 1 Association between DOT related factors and, treatment success and default

This section showed the association between DOT and treatment success and default. Exploratory factors in this analysis included types of DOT observers such as a family member and health personnel, and DOT and non-DOT.

#### Types of DOT observer

As for the association between different types of DOT observers and treatment success, higher treatment success was found in health personnel supervised DOT group (87.4%) compared with the family member supervised DOT group (68.9%), and there was a statistically significant difference in treatment success between health personnel supervised DOT group and family member supervised DOT group (p-value=0.001).

Concerning the association of default with types of DOT observer, health personnel supervised DOT group had a lower default rate (6.6%) than family member supervised DOT group (18.9%) and it was statistically significant ( $p$ -value < 001).

Direct observation has a significant association with default and family member supervised DOT group reported significantly higher default rate (18.9%) than health personnel supervised DOT group (6.6%) ( $p$ -value <0.001).

**Table 26. Association between Directly observed treatment (DOT) and treatment success**

Directly observed treatment	Treatment success & non-success (%)		N	X <sup>2</sup>	df	p-value
	Succe ss	Non-succ ess				
<b>DOT &amp; non-DOT</b>				3.589*	1	0.058
DOT	77.8	22.2	347			
Non-DOT	70.2	29.8	171			
<b>Types of DOT observer</b>				19.587	2	<0.001
Family member	68.9	31.1	180			
Health personnel	87.4	12.6	167			
Self –administration	70.2	29.8	171			

\* No significance

### **Directly observed treatment (DOT)**

It was found from table 27 that the DOT group had higher percentage of treatment success (77.8%) compared to the non DOT group (70.2%). However there was only marginal association between DOT and treatment success ( $p$ -value=0.058).

As for the default rate, the non-DOT group had a higher default rate (21.1%) compared to the DOT group (13.0%) with statistical significance (p-value=0.017).

**Table 27. Association between Directly observed treatment (DOT) and treatment default**

Directly observed treatment	Treatment default & non-default (%)		N	X <sup>2</sup>	df	p-value
	Default	Non-default t				
<b>DOT &amp; non-DOT</b>				5.675	1	0.017
DOT	13.0	87.0	347			
Non-DOT	21.1	78.9	171			
<b>Types of DOT observer</b>				15.613	2	<0.001
Family member	18.9	81.1	180			
Health personnel	6.6	93.4	167			
Self – administration	21.1	78.9	171			

#### **4. 2. 2 Association between patients' socio-demographic characteristics and treatment success and default**

This section showed the association between socio-demographic characteristics of patients and treatment success. Exploratory factors in this analysis included age, gender, marital status, and occupation.

##### **Age**

It was found from table 29 that the younger age group had significantly higher percentage of treatment success compared to the older age groups.

There was significant association between age groups and treatment success (p-value = 0.046)

Regarding the default, the age group of 35 to 44, and 45 to 54 (21.7%, and 22.2%) had higher default rate compared to other age group( 15-24: 17.3%, 25-34: 12.7% and over 55: 4.2%, respectively). There was significant association between different age groups and treatment default (p-value = 0.012).

### **Gender**

Nearly equal proportion of study subjects were in both sexes with treatment success and non-success groups. There was no significant association between gender and treatment success (p-value=0. 288).

As for the defaulter, in both gender groups, defaulter cases were equally distributed (Male : Female = 16.9% : 12.7%) and there was no significant association between gender and default rate (p-value=0. 231).

### **Marital status**

Regarding the marital status in treatment success, similar proportion of each marital status (75.9 % in unmarried, 74.7% in married group, and 76.1% in other group) was found in treatment success and there was no significant association between marital status and treatment success (p-value=0. 949).

Concerning default cases, similar proportion was found in different marital status (13.9% in unmarried, 16.5% in married group, and 17.4% in other group) and there was no significant association between marital status and default (p-value=0. 708).

**Table 28. Association between patients' socio-demographic factors and treatment success**

Scio-demographic factors	Treatment success & non-success (%)		N	X <sup>2</sup>	df	p-value
	Success	Non-success				
<b>Age group</b>				11.279	5	0.046
1-14	100.0	0.0	3			
15-24	76.5	23.5	98			
25-34	78.5	21.5	158			
35-44	69.6	30.4	115			
45-54	65.3	34.7	72			
55 and above	84.4	15.3	72			
<b>Gender</b>				1.130*	1	0.288
Male	74.0	26.0	361			
Female	78.3	21.7	157			
<b>Marital status</b>				0.105*	2	0.949
Unmarried	75.9	24.1	187			
Married	74.7	25.3	285			
Widow/separate	76.1	23.9	46			
<b>Occupation</b>				12.632	5	0.027
Government-officer	87.5	12.5	8			
Employee	83.7	16.3	123			
Unemployed	67.7	32.3	124			
Housewife	76.7	23.3	43			
Farmer/labor	70.5	29.5	149			
Other	81.7	18.3	71			

\* No significance

**Table 29. Association between patients' socio-demographic data and treatment default**

Scio-demographic factors	Treatment default & non-default (%)		N	X <sup>2</sup>	df	P-value
	default	Non-default				
<b>Age group</b>				14.630	5	0.012
1-14	0	100.0	3			
15-24	17.3	82.7	98			
25-34	12.7	87.3	158			
35-44	21.7	78.3	115			
45-54	22.2	77.8	72			
55 and above	4.2	95.8	72			
<b>Gender</b>				1.434*	1	0.231
Male	16.9	83.1	361			
Female	12.7	87.3	157			
<b>Marital status</b>				0.691*	2	0.708
Unmarried	13.9	86.1	187			
Married	16.5	83.5	285			
Widow/separate	17.4	82.6	46			
<b>Occupation</b>				11.860	5	0.037
Government-officer	0.0	100.0	8			
Housewife	9.3	90.7	43			
Employee	11.4	88.6	123			
Unemployed	18.5	81.5	124			
Farmer/laborer	22.1	77.9	149			
Other	9.9	90.1	71			

\* No statistically significance.



### **Occupation**

The proportions of treatment success were higher among patients who were government official(87.5%), private enterprise employee(83.7%) and others such as student and children (81.7%) than those who were housewife (76.7%), and farmer or laborer (70.5%) and unemployed (67.7%). There was significant association between occupation and treatment success (p-value=0.027).

As for defaulter, Farmer/ Laborer group and unemployed group reported high default rate (22.1% and 18.5%, respectively). This is followed by private employee, students/children group, and housewife group (11.4%, 9.9% and 9.3% respectively) and among government officials, nobody had been defaulted (0.0%). Therefore different occupation groups and default rate had a strong association (p-value=0.037).

#### **4. 2. 3 Association between behavior of patients and treatment success and default**

This section showed the relationship between patients' behavior characteristics and treatment success and default. Exploratory factors in this analysis included compliance, alcohol, and smoking habit.

#### **Compliance with treatment**

It was found from table 33 that the good compliance group had a higher treatment success rate (76.5%), compared to those non compliance groups (69.7%). However there was no significant association between compliance and treatment success (p-value = 0.176)

**Table 30. Association between patients' behavior and treatment success**

Behavior of patients	Treatment success & non-success (%)		N	X <sup>2</sup>	df	p-value
	Success	Non-success				
<b>Compliance</b>				1.829*	1	0.176
Never missed	76.5	23.5	429			
Missed	69.7	30.3	89			
<b>Alcohol</b>				5.347*	1	0.021
No	95.2	4.8	42			
Yes	79.5	20.5	83			
<b>Smoking habit</b>				0.241	1	0.623
No	83.1	16.9	59			
Yes	79.7	20.3	79			

\* No significance

The result is the same with association between default and compliance. The non compliance group had higher default rate (18.0%) than good compliance group (15.2%), but no significance (p-value=0.504).

### **Alcohol consumption**

95.2 percent of 42 study subjects without a habit of drinking alcohol had treatment success, while among 83 study subjects with habit of drinking alcohol, only 66 cases (79.5%) had succeeded in their treatment. There was a strong association between alcohol consumption and treatment success (p-value=0.021). However alcohol consumption had no statistical association with treatment default (Fisher's Exact Test p-value =0.265).

### **Smoking**

Regarding the association between smoking and treatment success and default, the higher treatment success proportion (83.1%) and lower default rate

(8.5%) were found in non-smokers in comparison with treatment success and default of smokers (79.7% and 8.9%). However smoking was not statistically significant in association with both treatment success and default (p-value=0.623 and 0.939).

**Table 31. Association between patients' behavior and treatment default**

Behavior of patients	Treatment default & non-default (%)		N	X <sup>2</sup>	df	p-value
	Default	Non-default				
<b>Compliance</b>				0.446*	1	0.504
Never missed	15.2	84.8	429			
Missed	18.0	82.0	89			
<b>Alcohol consumption</b>				1.706*	1	0.265**
No	2.4	97.6	42			
Yes	8.4	91.6	83			
<b>Smoking habit</b>				0.006*	1	0.939
No	8.5	91.5	59			
Yes	8.9	91.1	79			

\* No statistical significance, \*\* Fisher's Exact Test p-value

#### **4. 2. 4 Association between health service related factors and treatment success and default**

This section showed the relationship between health service related factors and treatment success. Exploratory factors in this analysis included drug supply interval, drug formulation, and DOT duration.

##### **Drug supply interval**

It was found from table 36 that the daily and every two weeks drug supplied groups had significantly higher percentage of treatment success (86.8% and 79.8%, respectively) compared to the other groups (weekly group:69.0% and

Monthly group:77.8%). There was significant relationship between drug supply interval and treatment success (p-value = 0.026).

As for the default rate, drug supply interval had a statistical significance with default rate (p-value:0.006). Weekly supply group had higher default rate (22.2%) compared to other groups (daily supply group:10.1%, monthly group:11.9%, and every two week group:10.5%, respectively).

### Drug formulation

Regarding the relationship between formulation of TB drugs and treatment success, the higher treatment success proportion (82.6%) was found in combination drugs group compared to separate drugs group (71.5%). There was significant relationship between drug formulation and treatment success (p-value=0.005).

In relation to drug formulation and default, they were not associated in this study (P-value=0.082). However default rate was higher in separate drug formulation group (17.6%) than combination drug group (11.8%).

**Table 32. Correlation between side effect of tuberculosis drugs and drug formulation**

Side effect of tuberculosis Drugs	Drug formulation				Total	
	Separate Drugs		Combination of 3-4 drugs		N	%
	N	%	N	%		
No side effect	237	69.7	163	91.6	400	77.2
Side effect	103	30.3	15	8.4	118	22.8
Total	340	100.0	178	100.0	518	100.0

$X^2 = 31.75$ ,  $df = 1$ ,  $p\text{-value} = 0.001$

**Table 33. Association between health service related factors and treatment success**

Health service related factors	Treatment success & non-success (%)		N	X <sup>2</sup>	df	p-value
	Success	Non-success				
<b>Drug Supply interval</b>				9.2324	3	0.026
Daily	79.8	20.2	129			
Weekly	69.0	31.0	216			
Monthly	77.8	22.2	135			
Every two weeks	86.8	13.2	38			
<b>Drug formulation</b>				7.757	1	0.005
Separate drug	71.5	28.5	340			
Combination drug form	82.6	17.4	178			
<b>DOT duration</b>				52.076	2	<0.001
First two month	55.9	44.1	118			
6-7month	89.8	10.2	225			
Never DOT	69.7	30.3	175			
<b>Location</b>				17.449	1	<0.001
MoPH	69.1	30.9	320			
BMA	85.4	14.6	198			

### **Duration of DOT**

The proportions of treatment success were higher (89.8%) among patients who were treated under DOT for the whole course of treatment (6-8 months) than those treated under DOT for only 2 or 3 months of intensive phase (55.9%) and non DOT group (69.7%). There was a significant association between DOT duration and treatment success (p-value <0.001).

**Table 34. Association between health service-related factors and treatment default**

Health service related factors	Treatment default & non-default (%)		N	$\chi^2$	df	p-value
	Default	Non-default				
<b>Drug Supply interval</b>				12.341	3	0.006
Daily	10.1	89.9	129			
Weekly	22.2	77.8	216			
Monthly	11.9	88.1	135			
Every two weeks	10.5	89.5	38			
<b>Drug formulation</b>				3.030*	1	0.082
Separate drug	17.6	82.4	340			
Combination drug form	11.8	88.2	178			
<b>DOT duration</b>				52.076	2	<0.001
1 <sup>st</sup> two month	25.4	74.6	118			
6-7month	6.7	93.3	225			
Never DOT	20.6	79.4	175			
<b>Location</b>				13.872	1	<0.001
MoPH	20.3	79.7	320			
BMA	8.1	91.9	198			

\* No statistical significance

As for the default rate, the whole course of treatment under DOT group recorded much lower default rate(6.7%) than non-DOT group and two month DOT group (20.6% and 25.4%, respectively) and its association was statistically significant (p-value <0.001).

### **Location**

The proportions of treatment success were higher (85.4%) among patients who were treated in Bangkok Metropolitan Administration than Bangkok Chest Clinic under MoPH(69.1%). There was a significant association between two locations and treatment success (p-value <0.001).

As for the default rate, Bangkok chest clinic under MoPH reported higher default rate (20.3%) than public health centers under Bangkok Metropolitan Administration (8.1%) with statistical significance ( p-value<0.001).

### **4. 2. 5 Association between disease related factors and treatment success and default**

This section showed the relationship between disease related condition and treatment outcome. Exploratory factors in this analysis included initial AFB status, sputum status at the end of the intensive phase treatment, drug resistance, side effect of drugs, co-morbidities and, symptoms and its duration.

#### **Initial AFB status**

It was found from table 38 that the patients with more positive sputum status had significantly higher Proportion of treatment success (79.6%) compared to those patients with less positive sputum status (+:76.7% and ++: 67.1%). There was significant association between initial AFB status of patients and treatment success (p-value = 0.027). Concerning the association between initial AFB status and default, table 39 showed that less positive of sputum, more default rate., with the statistical significance ( p-value <0.001).

### **Sputum conversion status at the end of intensive phase treatment**

Sputum conversion status was significantly associated with the treatment success. It was found that patients with AFB negative result at the end of the second month of treatment had a higher treatment success rate (85.7%) than those with the AFB positive result at the end of the second month of treatment (71.1%), and there was a significant association between sputum status at the end of the 2<sup>nd</sup> month of treatment and treatment success (P-value=0.001).

Pertaining to the association between sputum status and default rate, positive sputum at the end of intensive phase treatment had higher default rate (22.8%) than the negative sputum (7.8%) with highly significant P-value<0.001.

### **Side effect**

The proportions of treatment success were higher among patients who had no side effect than those who had a side effect of drugs (79.3% and 61.9%, respectively), and there was a significant association between side effect of tuberculosis drugs and treatment success (p-value < 0.001). However default rate had no association with side effect of tuberculosis drugs.

### **Co-morbidity**

Concerning the co-morbidities such as diabetes, asthma, hypertension, chronic liver and renal diseases, the patients with and without co-morbidity had a similar rate, and there was no association between co-morbidities and treatment success (p-value:0.608). Default rate was not associated with co-morbidity as well.



### Severity of disease

No differences of treatment success and default between different degrees of severity of disease were found in this study ( p-value: 0.756, and 0.549).

**Table 35. Association between disease or physical condition related factors and treatment success**

Disease condition related factors	Treatment success & non-success (%)		N	$\chi^2$	df	p-value
	Success	Non-success				
<b>Initial AFB status</b>				7.258	2	0.027
+	76.7	23.3	172			
++	67.1	32.9	140			
+++	79.6	20.4	206			
<b>Sputum status at the 2<sup>nd</sup> month</b>				12.676	1	<0.001
Negative	85.7	14.3	357			
Positive	71.1	28.9	114			
<b>Side effect</b>				14.804	1	<0.001
No	79.3	20.8	400			
Yes	61.9	38.1	118			
<b>Other co-morbidity</b>				0.263*	1	0.608
No	74.9	25.1	442			
Yes	77.6	22.4	76			
<b>Disease severity</b>				0.559*	2	0.756
Low	74.8	25.2	408			
Moderate	75.9	24.1	79			
High	80.6	19.4	31			

\* No significance

**Table 36. Association between disease condition related factors and treatment default**

Disease condition related factors	Treatment default & non-default (%)		N	X <sup>2</sup>	df	p-value
	default	Non-default				
<b>Initial AFB status</b>				17.253	2	<0.001
+	12.8	87.2	172			
++	26.4	73.6	140			
+++	10.7	89.3	206			
<b>Sputum status at the 2<sup>nd</sup> month</b>				83.161	2	<0.001
Negative	7.8	92.2	357			
Positive	22.8	77.2	114			
No tested	57.4	42.6	47			
<b>Side effect</b>				1.047*	1	0.306
No	14.8	78.0	400			
Yes	18.6	81.4	118			
<b>Other co-morbidity</b>				0.972*	1	0.324
No	16.3	83.7	442			
Yes	11.8	88.2	76			
<b>Disease severity</b>				1.201*	2	0.549
Low	16.4	83.6	408			
Moderate	13.9	86.1	79			
High	9.7	90.3	31			

\* No significance

### **Duration of symptoms**

The association between duration of symptoms and treatment outcome was proved that longer duration of symptoms was correlated with lower success of

treatment. There was a significant association between duration of the symptoms and treatment outcome (  $p$ -value  $< 0.001$ ).

### **4.3 Logistic Regression Analysis**

As shown in Table 27 to 39, nine and seven independent variables, which  $p$ -values were less than 0.05 in bivariate test, had been found to be related treatment success and default, respectively. These factors were analyzed simultaneously by using logistic regression analysis to identify if they still remain related with patient treatment success and default after holding other variables constant. The binary logistic regression method was used to compute the OR (95%CI) and  $p$ -value. The goodness of fit test showed that no significant difference ( $p$ -value $>0.05$ ). Table 40 showed that only 6 of 9 related factors remained significant to treatment success and table 41 showed that 3 of 7 related factors remained significant to default.

#### **4. 3. 1 Relationship between treatment success and other related factors**

Among different DOT observers, health personnel supervised DOT group still remained as a significant variable influencing the treatment success. If health personnel supervised DOT group increase one unit of their total score, treatment success rate could increase 9.688 times ( $P$ -value $<0.001$ ).

Sputum negative conversion rate at the end of intensive phase treatment had a significant positive relationship with treatment success. If the score of the sputum negative conversion increase one unit, the treatment success can increase 6.411 times more than pervious model ( $P$ -value $<0.001$ ).

Among different occupations, unemployed group had more significant than farmer/laborer. If unemployed group increase one unit of their score, then, the success rate can decrease 0.374 times (P-value: 0.001). if the laborer group increase one unit of their score, the success rate can also decrease 0.577 times (P-value=0.048).

**Table 37. Factors associated to treatment success by using logistic regression**

Factors	B	OR	95% CI for OR		p-value
			Lower	Upper	
Health personnel observer	2.271	9.688	3.214	29.198	<0.001
Family member observer	0.009	1.009	0.588	1.732	0.975
Sputum negative	1.858	6.411	3.972	10.348	<0.001
Unemployed *	-0.982	0.374	0.211	0.663	0.001
Laborer / farmer*	-0.55	0.577	0.334	0.995	0.048
Drug formulation	-0.497	0.608	0.301	1.231	0.167
Side effect	-0.811	0.444	0.266	0.742	0.002
Age group	0.233	1.262	0.799	1.994	0.318
Duration for 6 month	1.881	6.563	3.184	13.527	<0.001
Constant	0.396	1.486			0.168

\* Their reference group are government official, private company employee, students/children and house wives.

As for the side effect, it remained significant after controlling other variables. If the side effect increases one unit of its score, success rate can decrease 0.444 times than the previous model (P-value=0.002).

#### 4. 3. 2 Relationship between treatment default and other factors

Regarding the DOT observer, health personnel DOT observer still remained as a significant factor with default. If the score of health personnel DOT observer increase one unit, the default rate will decrease 0.073 times more than previous model (P-value < 0.001).

As for the relationship between combination drug formulation and default, there was a significant relationship in the logistic regression.(P-value=0.025). if the score of separate drug form increase one unit, then the default rate can increase 2.531 times more than previous model.

**Table 38. Factors associated to treatment default by using logistic regression**

Factors	B	OR	95% CI	p- value
Health personnel DOT observer	-2.621	0.073	0.020-0.266	<0.001
Family member DOT observer	-0.251	0.778	0.422-1.435	0.422
Occupation of patients as laborer	0.832	2.297	1.236-4.269	0.009
Occupation of unemployed	0.741	2.098	1.070-4.113	0.031
Side effect	0.102	1.107	.606-2.024	0.741
Age group between young and old	-0.132	0.877	0.518 -1.482	0.623
Drug supply interval	0.842	2.320	0.889 - 6.057	0.085
Constant	-0.888	0.411		0.006

Sputum negative conversion at the end of intensive phase treatment still remained significant after controlling other confounding factors (P-value<0.001). If the score of sputum negative status increase one unit, then the treatment default rate can decrease 0.174 times more than previous model.

Among different occupation groups, unemployed and laborer groups remained significant relationship with treatment default. If the score of laborer group increase one unit, default rate will increase 2.297 times more than previous model (p-value: 0.009). In case of unemployed, it will increase 2.098 times more (p-value=0.031).