

## **CHAPTER IV**

### **DATA EXERCISE**

#### **4.1. Introduction**

This study purpose is to investigate the availability of data will be used for prospective study and investigate the process of data collection to analyze data quality. Also the characteristics of active TB cases among HIV infected persons registered for 9-month IPT was investigated to applied for further data collection techniques of the prospective study.

#### **4.2 Objectives**

1. To investigate the availability of data in routine basis, to decide whether new data need to be collected for data collecting forms which will be used for prospective cohort study.
2. To investigate the process of data collection for analyzing the data quality
3. To investigate the characteristics of TB cases among HIV infected persons who have registered for 9-month IPT program in Chiang Rai province.

### **4.3. Methods of the study**

#### **4.3.1. Study design**

This study is cross sectional descriptive study

#### **4.3.2. Study population**

HIV infected persons who had active TB diagnosed during and after IPT in Chiang Rai from 1995 – 2001.

#### **4.3.3. Steps in data collection**

85 active TB cases among HIV infected persons registered for 9-month IPT were identified by using the TB and IPT registration database in TB/HIV research project in Chiang Rai.

**The data collection of objective 1;** Investigation of availability of data in routine basis was done by using the medical records, IPT registration and TB registration in each hospitals.

**The data collection of objective 2;** Investigation of data collection process was done by observation of IPT registration and TB registration and interview of research nurses.

**The data collection of objective 3;** The investigation of characteristics (Age, Gender, Ethnicity, District, Isoniazid compliance, Time from starting IPT to become active TB, TB outcome, Entering Day Care Activity) were done by using the medical records, IPT registration and TB registration during 1995 - 2001 in 6 hospitals in Chiang Rai province. (Khuntan, Chiang Kong, Phan, Wiang Papao, Mae Chan, Mae Sai Hospital)

#### **4.3.3.1. Research tools**

The data was collected using the IPT enrollment form and Active TB case investigation form attached as an Appendix II, V that will be used for prospective cohort study.

#### **4.4. Data analysis**

- The data was entered SPSS version 10.
- Quantitative analysis used frequency of characteristics of active TB case stratified by gender.
- Independent samples t test to calculate whether the mean of some scores between male and female were significantly different each other or not. The three types of scores were analyzed; age when IPT started, the months of Isoniazid pill taking, time from starting IPT to becoming active TB.

## **4.5. Findings**

### **4.5.1 Findings of Objective 1; Availability of data in routine basis**

Some information could be collected in routine basis from medical record, IPT registration and TB registration.

#### **1. Available Data**

- Demographic data (age, gender, address, nationality)
- Entering Day care activity,
- The frequency of visiting to the hospital during IPT
- The use of antiretroviral drug
- Physical exam (body weight, Tuberculin skin test reactivity)
- Blood test (Complete blood count)
- IPT and TB treatment outcome
- Dead date

#### **2. Not available or available but cannot collect systematically**

Many data couldn't be available in routine basis or systematic data collecting process were not established. So, developing data requirement forms are needed for collecting these data.

- Socio-cultural information (income, educational level, occupation, marital state)

- Life style (alcohol, cigarette, intravenous drug use, History of imprisonment)
- Contact with active TB patients
- Current and past disease history
- Physical exam (height, BCG scar, mumpus anergy skin test  
Active TB and AIDS symptom and sign)
- Laboratory test (Liver function, CD4 lymphocyte count)
- The distance from house to the hospital and the way to travel to the hospitals.

#### **4.5.2. The findings of Objective 2; The process of data collection**

At first, investigation of process of data collection was done using observation of IPT and TB registration. The second, some information was collected through interview of research nurses in TB/HIV reserch project in Chiang Rai.

##### **1. The information of IPT through observation of IPT registration book**

Only Mae Chan hospital has individual IPT information collecting forms written by TB/HIV research project staffs. There are three types of information collecting forms 1. Active TB screening form before IPT enrollment 2. IPT follow up form during Isomiazid medication 3. IPT follow up form after Isoniazid medication. But after finishing 9-month IPT, active TB was found by only passive follow up of the IPT participants. This passive follow up means that active TB was diagnosed only when patients came to the hospitals. So if patients never return to the hospital, the information of active TB was not collected.

Another hospitals have IPT registration book written by hospital staffs and these data collection formats are different in each hospital. The information included in IPT registration books is hospital number, IPT number, name, gender, age, address, the previous history of IPT, body weight, the outcome of sputum smear and chest X-ray for active TB screening before IPT enrollment, the date of hospital visit and IPT outcome. But sometimes these data did not filled completely.

## **2. The information of TB through observation of TB registration book**

Each hospital has TB registration book written by hospital nurses. The included information were name, district TB registration number, gender, age, address, the outcome of chest X-ray, the outcome of sputum smear (0, 2 or 3, 5 month after starting TB treatment and the end of TB treatment.) TB site (Pulmonary or extrapulmonary), TB status (new, relapse, transfer in, re-treatment after default, failure, others), treatment drug regime, the date of starting treatment, treatment outcome. But some informations were not filled completely.

## **3. The information collected through interviewing research nurses.**

The information of IPT target groups, methods of active TB screening before IPT enrollment and active TB diagnostic method in Phan, Mae Sai, Mae Chan, Chiang Khong Hospitals were collected through interviewing reserch nurses.

There were three main outcome identified through interview. The first, some symptomatic HIV infected persons were registered for IPT. The second, some active TB screening before IPT enrollment was done without sputum smear or chest X-ray. The third, all hospitals using sputum smear and chest X-ray for active TB diagnostic methods of IPT participants. (Table 4.1)

**Table 4.1. The IPT target groups, active TB screening method before IPT enrollment and active TB diagnostic method in four hospitals.**

	<b>Phan Hospital</b>	<b>Mae Sai Hospital</b>	<b>Mae Chan Hospital</b>	<b>Chiang Khong Hospital</b>
<b>IPT target groups</b>	Asymptomatic HIV infected person	<b>All HIV infected persons</b>	Asymptomatic HIV infected person	Asymptomatic HIV infected person
<b>Method for active TB screening before IPT enrollment</b>	Check list  <b>Some chest X-ray</b>  All Sputum smear	Check list  All chest X-ray  <b>Some sputum smear</b>	All chest X-ray and sputum smear	All chest X-ray and sputum smear
<b>Active TB diagnostic methods</b>	All chest X-ray and sputum smear	All chest X-ray and sputum smear	All chest X-ray and sputum smear	All chest X-ray and sputum smear

### **4.5.3. The findings of Objective 3; Characteristics of TB cases**

The characteristics of eighty-five active TB cases among HIV infected persons who have registered for 9-month IPT in Chiang Rai were investigated. The description of the findings were divided by six parts.

#### **4.5.3.1. Demographic data.**

(Gender, Ethnicity, district which they live, age when IPT started).

#### **4.5.3.2. The months of Isoniazid pill taking.**

#### **4.5.3.3. Time from starting IPT to becoming active TB.**

#### **4.5.3.4. TB diagnostic methods (sputum smear, chest X-ray) and TB site.**

#### **4.5.3.5. TB treatment outcome.**

#### **4.5.3.6. Entering day care activity.**

#### **4.5.3.1. Demographic data**

The findings of demographic data included 1) Gender, 2) Ethnicity, 3) District which they live 4) Age when IPT started were shown below.

##### **1) Description of the gender**

There were 53 (62.4 %) male and 32 (37.6 %) female. Gender of TB cases was male dominant. (Table 4.2 )



**Table 4.2 Description of the gender**

<b>Gender</b>	<b>Number (n =85)</b>	<b>Percentage</b>
Male	53	62.4
Female	32	37.6

**2) Distribution of the Ethnicity**

From the analysis of all TB cases, the majority of TB cases were Thai ethnicity (97.6 %).

(Table 4.3) From the analysis of each gender, two hilltribe was male. (Table 4.4.)

**Table 4.3 Description of the ethnicity in all TB cases**

<b>Ethnicity</b>	<b>Number(n =85)</b>	<b>Percentage</b>
Thai	83	97.6
Hill tribe	2	2.4

**Table 4.4 Description of the ethnicity in each gender**

<b>Ethnicity</b>	<b>Male (n =53) Number (Percentage)</b>	<b>Female(n = 32) Number (Percentage)</b>
Thai	51 (96.3 %)	32 (100 %)
Hill tribe	2 (3.7 %)	0

**3) Distribution of the District which they live**

From the analysis of all TB cases, more than half of the cases (55%) lived in Phan district, and one fifth of the cases (21.2 %) lived in Mae Chan district. (Table 4.5) From the

analysis of each gender, most dominant district was Phan in both male (56.6 %) and female (53.1 %). (Table 4.6)

**Table 4.5 Distribution of the District which they lived in all TB cases**

District	Number (n =85)	Percentage
Wiang Chai	1	1.2
Chiang Kong	4	4.7
Phan	47	55.3
Mae Chan	18	21.2
Mae Sai	3	3.5
Wiang Papao	2	2.4
Khuntan	4	4.7
Doi Luang	1	1.2
Missing	1	1.2

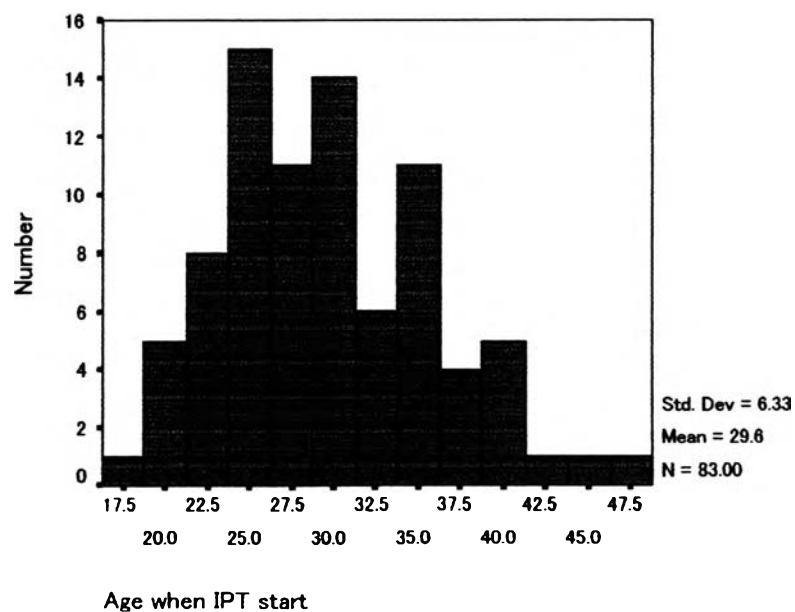
**Table 4. 6 Distribution of the District which they lived in each gender**

District	Male(n= 53) Number (Percentage)	Female(n= 32) Number (Percentage)
Wiang Chai	1 (1.8 %)	0
Chiang Kong	2 (3.6 %)	2 (6.2 %)
Phan	30 (56.6 %)	17 (53.1 %)
Mae Chan	12 (22.6 %)	6 (18.7 %)
Mae Sai	1 (1.8 %)	2 (6.2 %)
Wiang Papao	0	2 (6.2 %)
Khuntan	4 (7.2 %)	0
Doi Luang	0	1 (3.1 %)
Missing	3 (5.4 %)	2 (6.2 %)

#### 4) Distribution of the age when IPT started

From the analysis of eighty-three TB cases, the ages when IPT started ranged between 18 – 47 years old and the mean age was 29.6 years old and SD was 6.33 (Figure 4.1). From the analysis of each gender, mean ages were 29 years old in both gender. The analysis of frequency using three age groups (young, middle and elder age group), younger age group (18 to 29 years old ) were dominant in both male (55.7 %) and female (61.2 %). (Table 4.7) The differences of mean age when IPT started in male and female was analyzed using independent-samples t test. A t-test for unequal variances was used because the variances for two group were significantly unequal ( $F = 13.826$ ,  $p < .05$ ). The mean age of female ( $M = 29.23$ ,  $SD = 8.11$ ) was not significantly higher ( $t = .336$ ,  $df = 44.077$ , two-tailed  $p = .738$ ) than male. ( $M = 29.77$ ,  $SD = 5.05$ )

**Figure 4.1** Distribution of the age when IPT started in all TB cases



**Table 4.7 The age when IPT started in each gender**

<b>The group of age when IPT started</b>	<b>Male (n = 52) Number (Percentage)</b>	<b>Female (n= 31) Number (Percentage)</b>
<b>Young age group ( 18 - 29 years old)</b>	29 (55.7)	19 (61.2)
<b>Middle age group ( 30 - 39 years old)</b>	20 (38.4)	8 (25.8)
<b>Elder age group ( 40 - 49 years old)</b>	3 (5.7)	4 (12.9)

**4.5.3.2. The months of Isoniazid pill taking**

From the analysis of eighty-five TB cases, the month of Isoniazid pill taking ranged between 1 – 15 months and the median months was four. (Table 4.8 ), (Figure 4.2 ) 72 cases (84.7 %) took Isoniazid between 1 to 9 months, but 13 cases ( 15.3 %) took Isoniazid between 10 to 15 months. There were two reasons that some cases were prescribed Isoniazid more than 9 months. One reason was that, the government recommended IPT for 9 to 12 months in several years before and some cases prescribed Isoniazid for over 9 months. Another reason was that some IPT participants requested to take Isoniazid longer duration and health care providers adjusted for patient's need.

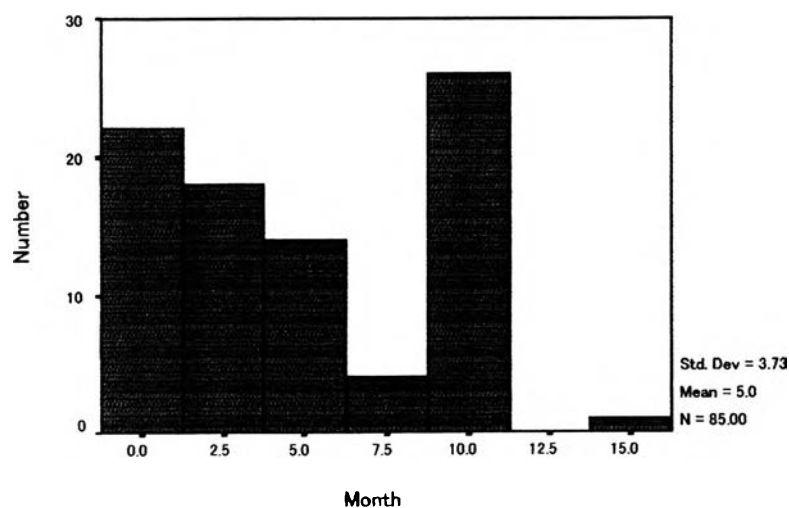
From the analysis of each gender, the number of cases took Isoniazid more than 9 months were double in female (46.8 %) compare to male (22.6 %). (Table 4.9 )

The difference of mean months of Isoniazid pill taking in male and female were analyzed using independent samples t test. The mean months of Isoniazid pill taking in female (  $M = 6.19$ ,  $S.D. = 3.93$ ) was significantly longer (  $t = - 2.389$ ,  $df = 83$ , two-tailed  $p = .019$ ) than the mean months of Isoniazid pill taking in male. ( $M = 4.25$  ,  $S.D. = 3.44$  )

**Table 4.8 The months of Isoniazid pill taking in 85 TB cases**

	Number (n = 85)	percentage
<b>IPT duration</b>		
1 month	22	25.9
2 months	13	15.3
3 months	5	5.9
4 months	5	5.9
5 months	6	7.1
6 months	3	3.5
7 months	4	4.7
9 months	14	16.5
10 months	9	10.6
11 months	3	3.5
15 months	1	1.2

**Figure 4.2 The months of Isoniazid pill taking in 85 TB cases**



**Table 4. 9 The months of Isoniazid pill taking in each gender**

<b>IPT duration</b>	<b>Male (n =53) Number (Percentage)</b>	<b>Female (n= 32) Number (Percentage)</b>
1 - 4 month	32 ( 60.3 %)	13 ( 40.6 %)
5 - 8 month	9 ( 16.9 %)	4 ( 12.4 %)
9 - 12 month	12 ( 22.6 %)	14 ( 43.7 %)
> 13 month	0	1 ( 3.1 %)

**4.5.3.3. Time from starting IPT to becoming active TB**

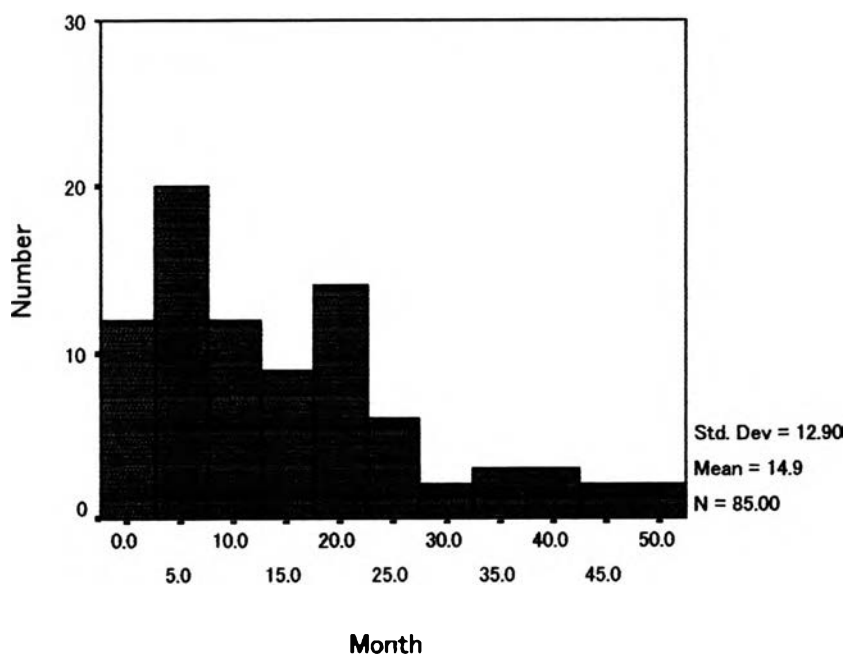
From the analysis of eighty-five TB cases, the time from starting IPT to become active TB ranged between 0 to 52 months and mean months was 14.9 months. 42.4 % of cases developed TB within 9 months from starting IPT. (Table 4. 10), (Figure 4.3)

From the analysis in each gender, the frequency of becoming active TB during 9 months was higher in male (50.9 %) compared to female (28.1 %). (Table 4.11 )

The difference of mean time from starting IPT to become active TB in male and female were analyzed using independent samples t test. The mean time from starting IPT to become active TB in female (  $M = 17.63$ ,  $S.D. = 12.83$  ) was not significantly longer (  $t = -1.522$ ,  $df = 83$ , two-tailed  $p = .132$  ) than the mean time from starting IPT to become active TB in male. ( $M = 13.26$ ,  $S.D. = 12.78$ )

**Table 4.10 Time from starting IPT to become active TB in all TB cases**

<b>Time from starting IPT to become active TB</b>	<b>Number ( N = 85)</b>	<b>Percentage</b>
1 - 9 months	36	42.4
10 - 18 months	17	20.0
19 - 27 months	20	23.5
28 - 36 months	5	5.9
> 37 months	7	8.2

**Figure 4.3 Time from starting IPT to become active TB**

**Table 4.11 Time from starting IPT to become active TB in each gender**

<b>Time from starting IPT to become active TB</b>	<b>Male (n =53) Number (Percentage)</b>	<b>Female (n= 32) Number (Percentage)</b>
1 - 9 months	27 (50.9)	9 (28.1)
10 - 18 months	9 (16.9)	8 (25)
19 - 27 months	10 (18.8)	10 (31.2)
28 - 36 months	3 (5.6)	2 (6.2)
> 37 months	4 (7.5)	3 (9.3)

**4.5.3.4. TB diagnostic methods (Sputum smear, chest X-ray) and TB site**

The outcome of sputum smear, chest X-ray, TB site and the relationship between sputum smear and TB site were described below. About the outcome of sputum smear, the frequencies of sputum smear positive and negative were the same (45.9 %). About the outcome of chest X-ray, a half of cases were missing. About the site of TB, one-fifth cases (17.6 %) were diagnosed extrapulmonary TB. (Table 4.12) About the relationship between sputum smear and pulmonary TB, the frequency of sputum smear positive cases (51.5 %) and negative cases (47.0 %) were almost equal. But about the relationship between sputum smear and extrapulmonary TB, sputum smear negative cases were dominant (46.6 %) compared to sputum smear positive cases (13.4 %) (Table 4.13)



**Table 4.12 Description of sputum smear, chest X-ray and TB site**

	<b>Number(n =85)</b>	<b>percentage</b>
<b>Sputum smear</b>		
Positive	39	45.9
Negative	39	45.9
Not done/ Unknown	7	8.2
<b>Chest X ray</b>		
Cavity	18	21.2
Non cavity	23	27.1
Effusion	1	1.2
Missing	43	50.6
<b>TB site</b>		
Pulmonary	66	77.6
Extrapulmonary	15	17.6
Pulmonary and Extrapulmonary	4	4.7

**Table 4.13 The relationship between sputum smear and TB site**

<b>Sputum outcome</b>	<b>Pulmonary TB</b>	<b>Extrapulmonary TB</b>	<b>Pulmonary and Extrapulmonary TB</b>
<b>Sputum smear Positive</b>	34 (51.5 %)	2 (13.4 %)	3 (75 %)
<b>Sputum smear Negative</b>	31 (47.0 %)	7 (46.6 %)	1 (25 %)
<b>Missing</b>	1 (1.5 %)	6 (40 %)	0
<b>Total</b>	66 (100 %)	15 (100 %)	4 (100 %)

#### 4.5.3.5. TB treatment outcome

From the analysis of TB treatment outcome in all TB cases, only one-quarter (25.9 %) completed TB treatment and more than half cases (52.9 %) were died during TB treatment. (Table 4.14) From the analysis of the outcome of TB treatment in each gender, complete rate was about one-quarter and more than half cases were died during TB treatment in both gender. (Table 4.15)

**Table 4.14 TB treatment outcome in all TB cases**

<b>TB treatment outcome</b>	<b>Number ( n = 85)</b>	<b>Percentage</b>
Complete	22	25.9
Cure	6	7.1
Died	45	52.9
Defaulted	1	1.2
Change diagnosis	2	2.4
Failure	3	3.5
Transfer out	6	7.1

**Table 4.15 TB treatment outcome in each gender**

<b>TB treatment outcome</b>	<b>Male (n =53) Number (Percentage)</b>	<b>Female (n= 32) Number (Percentage)</b>
Complete	14 (26.4%)	8 (25 %)
Cure	4 (7.5 %)	2 (6.2 %)
Died	27 (50.9 %)	18 (56.2 %)
Defaulted	1 (1.8 %)	0
Change diagnosis	2 (3.6 %)	0
Failure	1 (1.8 %)	2 (6.2 %)
Transfer out	4 (7.2 %)	2 (6.2 %)

#### 4.5.3.6. Entering Day Care Activity

From the analysis of all TB cases, about one-third of the cases (27.1 %) were entering Day Care Activity. (Table 4.16) From the analysis of each gender, the frequency of entering Day Care Activity in female (40.6 %) was double than male (18.8 %). (Table 4.17)

**Table 4.16 Entering Day care activity in all TB cases**

	<b>Number (n = 85)</b>	<b>percentage</b>
<b>Entering Day care activity</b>		
Yes	23	27.1
No	62	72.9

**Table 4.17 Entering Day care activity in each gender**

<b>Entering Day Care Activity</b>	<b>Male (n = 53) Number (Percentage)</b>	<b>Female (n = 32) Number (Percentage)</b>
Yes	10 (18.8 %)	13 (40.6 %)
No	43 (81.2 %)	19 (59.4 %)

#### 4.6. Lessons Learned

Some lessons, which were learned through the data exercise, were described below.

1. Many data that planned to be used for prospective study couldn't be available in routine basis. Because the format of IPT registration books were different in each hospitals and some data of IPT registration book was not filled completely.
2. Some symptomatic HIV infected persons were included in IPT and some active TB screening before IPT enrollment were done without sputum smear or chest X-ray.

3. Compliance of IPT was low but some patients prescribed Isoniazid more than 9 months.
4. Many cases, especially male developed active TB during 9-month IPT
  - Low number of active TB after 9 months might be due to the lack of the systematic follow-up for participants who did not come to hospitals.
5. Many extrapulmonary TB cases were observed in spite of sputum smear negative.
6. Nearly half of sputum smear were negative in all TB cases and pulmonary TB cases.

#### **4.7 Recommendations**

To apply the information which learned through the data exercise to prospective cohort study, some recommendations were described below.

1. To collect the data systematically, making the data collecting forms for prospective cohort study is needed. The developments of 5 forms described below are recommended.
  - 1) TB and AIDS symptom screening List
  - 2) IPT enrollment form
  - 3) IPT follow up form for during Isoniazid therapy.
  - 4) IPT follow up form for after Isoniazid therapy.

- 5) Active TB case investigation form
2. The criteria of symptomatic HIV and active TB screening before IPT enrollment should be informed clearly to hospital staffs, especially some hospitals using different criteria.
3. To increase IPT compliance, especially for male is important.
- 4 The development of active TB during short time after starting IPT might reflect inappropriate active TB screening. So more careful active TB screening before enrollment IPT is needed.
5. The sputum smear of many extrapulmonary TB cases was negative; so more detail extrapulmonary TB diagnostic guideline is needed for precise diagnosis.
6. Many TB cases were sputum negative, so applying more appropriate TB diagnostic method (chest X-ray and sputum culture) is needed for measuring TB incidence seriously.

## **References**

- Dennis Howitt and Duncan Creamer. (2001). A guide to computing statistics with SPSS release 10 for windows. Prentice hall.
- Wayne W. Daniel (1995). Biostatistics, John Wiley & Sons, Inc.