

CHAPTER III

METHODOLOGY

This cross-sectional, analytical study was conducted to measure the adherence of the HIV infected/AIDS patients who take ARV medicines at TAKSIN hospital and to identify the factors affecting adherence. The methodology of this study was described below:

3.1 Type of study

3.2 Target of the study

3.2.1 Inclusion criteria

3.2.2 Exclusion criteria

3.2.3 Sample size calculation

3.2.4 Sampling

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3.1 Type of study

This study is an analytical and cross-sectional study. The data collection was conducted during March to April 2010.

3.2 Target of the study

This study focused in HIV-infected/AIDS patients who take antiretroviral therapy at TAKSIN Hospital. The inclusion and exclusion criteria were described below:

3.2.1 Inclusion of criteria:

1. Take ARV medicines at TAKSIN Hospital at least 6 months.
2. Agree to participate in this study.

3.2.2 Exclusion of criteria:

1. Abnormal in memory or unconscious

3.2.3 Sample size calculation

In the multivariate analysis study [57], the sample size calculation was the 15 observations for each predictor variables or independent variables. Therefore, sample size was calculated by as follow:

$$n = 15 * (\text{number of predictor variables or number of independent variables})$$

When, n = sample size

The independent variables in this study were 13 variables; therefore the sample size was 195 samples. The researcher added 2.5% excess, so the final sample size was 200 samples.

3.2.4 Sampling [58]

There is an HIV/AIDS outpatient clinic at TAKSIN hospital on Wednesday and Thursday. The average numbers of the patients at HIV/AIDS clinic were 40 and 180, respectively. The ratio of the patients who visit HIV/AIDS clinic on Wednesday and Thursday is 40:180 or 1:4.5. The data collection period was 1 month, so, 10 cases of HIV infected/AIDS patients were selected on Wednesday and 40 cases were selected on Thursday in every week. The sampling technique in this study was a probability sampling. This method based on the concept that every unit of population has chance to be selected equally. The simple random sampling method was used to select the samples to be a representative of the population. The steps to conduct simple random sampling in this study were described below:

1. Determine numbers for every unit of population (N unit)
2. Make lottery numbers for every unit of population (N unit)
3. Bring all lotteries mix in the container
4. Pick up lottery in the container one piece until complete sample size (n)

3.3 Tools of this study and analysis

Tools in this study composed of the tools to measure patients' adherence including self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count.[15] tool to measure self-efficacy which was translated from Smith, Rublein, Marcus and others[59], tool to measure knowledge of disease and medicine which was applied from Suttinee Tunpongjaroen studied[56], tool to measure physician-patient relationship which was translated from Schneider, Kaplan, Greenfield and others [61], and MOS social support survey which was translated from Sherbourne studied[60], respectively.

3.3.1 Processes to prepare tools

1. The researcher searched the tools from literature review.
2. Tested the questionnaires with some patients and improved the contents of questionnaires.
3. The questionnaires were checked for content validity by experts before using.
4. The questionnaires were tested the reliability in the small group of patients.

3.3.2 Process of operational study

1. The samples were selected according to the inclusion criterias and exclusion criterias.
2. The samples were informed the details of the patient participant information sheet and were asked to sign in the consent form if they need to participate.
3. The data collection was conducted. The patients were asked about their demographic data and treatment data, were measured their self-efficacy, their knowledge of disease and medicine, their physician-patient relationship , their social support, and their adherence by multi method tools including self report, visual analogue scale (VAS), pill identification test (PIT) and pill count .[15]

3.3.3 Analysis

The data of all variables were analyzed by using SPSS version 13 for windows, by confidence level or confidence coefficient =95% ($\alpha=0.05$).

3.3.4 Interpreting the results of each tool

1. Patients' Adherence:

-self report is a series of question related to the patients' behaviors in taking ARV medicines. The patients were asked to answer yes or no based on their behaviors in taking ARV medicines.

-visual analogue scale (VAS), the patients were asked to rate their adherence behavior to their medication over the past four weeks. The scale of VAS ranged from 0 to 10. The meaning of scale at 10 is that he or she took all medicine doses and the meaning of scale at 0 is that he or she missed all t of ARV doses.

-pill identification test (PIT), the patients were asked about the name of ARV they take, the number of pills per dose, the time that the medicines is taken and additional instruction.

-pill count, the pharmacist checked the number of ARV that the patients took from container since the date of their last visit, then calculate the percent adherence from the following formula:

$$\% \text{ Adherence} = (\text{Dispensed} - \text{Returned}) / (\text{Expected to be taken}) * 100$$

The way to interpret the overall adherence of the patients based on multi method tools were described below: [15]

Self-report	No to all questions	Yes to 1 question	Yes to 2 or more questions
VAS	95% or more	75-94%	Less than 75 %
PIT-patient knows the...	Dose, time, and instructions	Dose and time	Dose only or confused
Pill count	95% or more	75%-94%	Less than 75%
	High	Moderate	Low
	Overall adherence		

- 1. If the results appear in the same column, e.g. self-report is all no, VAS is 95% or more, the patients knew dose, time and instructions and the pill count result is 95% or more, then the overall level of adherence is “High”.
- 2. If the results do not all line up in a single vertical column such as if the results are spread over two columns, take the adherence level of the right hand column as the estimated adherence e.g. self-report is yes to 2 or more questions, VAS is 75%-94 %, the patients knew dose and time and pill count is 95% or more, then the overall level of adherence is “Low”.
- 3. If the results are spread over three columns, then use the middle level of adherence e.g. self report is yes to 1 question, VAS is less than 75%, the patients knew dose and time and pill count is 95% or more, then the overall level of adherence is “Moderate”.



In this study, dependent variable (Y) was designed as binary variables (0, 1) as follow:

0 = non adherence

1 = adherence

The study of Paterson, Swindells, Mohr and others [13] revealed that the percentage of adherence not less than 95 percent adherence has been necessary for HIV viral suppression.

Therefore:

If overall adherence is high = Adherence (1)

If overall adherence are moderate and low = Non-adherence (0)

2. Knowledge of disease and medicine: the tool to measure the patients' knowledge was applied from the study of Suttinee Tunpongjaroen[56] which has Cronbach's alpha at 0.71. There are 15 items of questionnaires and the patients have to answer true or false or unsure.

The questionnaires item 1 to 7 are the knowledge of HIV/AIDS diseases and the questionnaire item 8-15 are the knowledge about ARV medicines.

The knowledge level was divided into 3 groups by using percentiles at 25 and 75 as follow:

Score	level
0.00-10.24	low
10.25-12.99	moderate
13.00-15.00	high

3. Self-efficacy: the questionnaire to measure self-efficacy was translated from the studied of Smith, Rublein, Marcus and others [59]. It has Cronbach's alpha at 0.76. The patients were asked to rate about their confidence to take ARV medicines in 12 difference situations. The self efficacy was ranked from 1 "least self efficacy" to 5 "highest self efficacy" as follows:

If select scale 1 (least self efficacy) = 1 score

If select scale 2 (less self efficacy) = 2 scores

If select scale 3 (moderate self efficacy) = 3 scores

If select scale 4 (high self efficacy) = 4 scores

If select scale 5 (highest self efficacy) = 5 scores

The self efficacy was divided into 3 groups by using percentiles at 25 and 75 as follow:

Score	Level
0.00-43.99	Low
44.00-57.99	moderate
58.00-60.00	high

4. Patients’social support: the tool to measure social support was translated from the survey Medical Outcomes Study (MOS) survey of the studied of Sherbourne[60]. It has Cronbach’s alpha greater than 0.91. This tool consists of 10 items which will ask the patients about their social support. The patients have to rank their social supports from “None of the time or 0” to “All of the time or 5”. The contents of this tool were divided into 5 domains as follows:

- Domain 1: Emotional/Informational support consists of four questions (1, 2, 3, 4)
- Domain 2: Tangible support consists of two questions (5, 6)
- Domain 3: Affectionate support consist of one questions (7)
- Domain 4: Positive social interaction consists of two questions (8, 9)
- Domain 5: Additional item consist of one question (10)

The questionnaire has 50 scores.

Statement	None of the time (1)	A little of the time (2)	Some of the time (3)	Most of the time (4)	All of the time (5)
Score	1	2	3	4	5

The social support was divided into 3 groups by using percentiles at 25 and 75 as follow:

Score	Level
0.00-31.99	Low
32.00-47.99	moderate
48.00-50.00	high

5. Physician-patient relationship: the tool to measure physician-patient relationship was translated from the study of Schneider, Kaplan, Greenfield and others [61]. It has Cronbach's alpha at 0.70. The patients would be asked about the relationship between health care providers and the patients. The questionnaire consisted of 15 items of likert scale and response from "poor" to "excellent" as follow in table below. There were divided into 6 domains as follows:

- Domain 1: Overall communication consisted of three questions (1, 2, 3)
- Domain 2: HIV-specific information consisted of two questions (4, 5)
- Domain 3: Adherence dialogue consisted of three questions (6, 7, 8)
- Domain 4: Participatory decision-making consisted of three questions (9, 10, 11)
- Domain 5: Overall satisfaction with Provider health care consisted of three question (12, 13, 14)
- Domain 6: Trust in Provider health care consisted of one question (15)

The total score of the physician-patients relationship was 75 scores.

Statement	poor (1)	fair (2)	good (3)	very good (4)	excellent (5)
Score	1	2	3	4	5

The physician-patient relationship was divided into 3 groups by using percentiles at 25 and 75 as follow below:

Score	level
0.00-51.99	low
52.00-70.74	moderate
70.75-75.00	high

3.4 Statistical analysis

Data was analyzed by using SPSS version 13 for windows.

1. Descriptive statistics was used to describe demographic data, Patient-related Factors, Treatment-related Factors, Healthcare term-related Factors, Social or family support and adherence to antiretroviral therapy.

2. Multivariate logistic regression analysis was used to find that factors associated with of adherence to antiretroviral therapy.