การวัดความร่วมมือและปัจจัยที่มีผลต่อความร่วมมือในการใช้ยาต้านไวรัสเอดส์ในผู้ป่วย
ที่ติดเชื้อเอชไอวีและผู้ป่วยเอดส์ ณ โรงพยาบาลตากสิน

นางสาวธิดารัตน์ สุจิพิธธรรม

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต

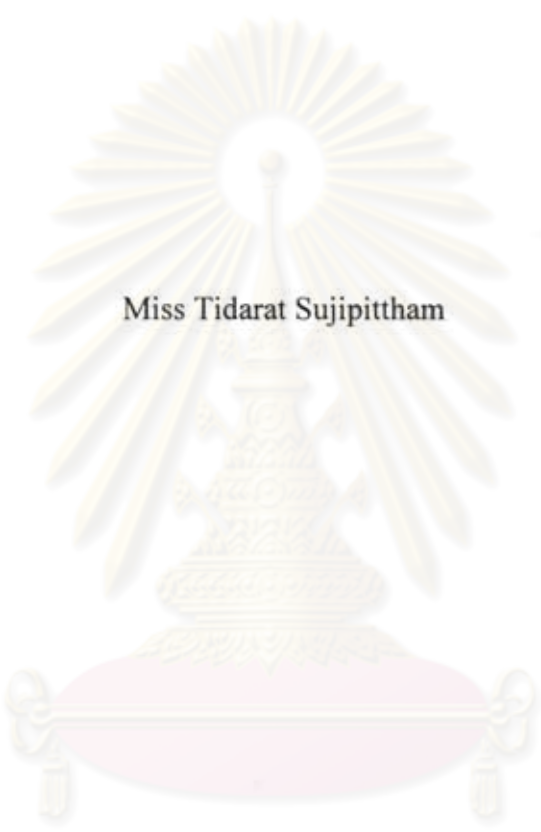สาขาวิชาเภสัชศาสตร์สังคมและบริหาร ภาควิชาเภสัชศาสตร์สังคมและบริหาร

คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

ปีการศึกษา 2553

530058

ADHERENCE ASSESSMENT AND FACTORS AFFECTING ADHERENCE TO
ART AMONG HIV-INFECTED/AIDS AT TAKSIN HOSPITAL

Miss Tidarat Sujipittham

A Thesis Submitted in Partial Fulfillment of the Requirements

for the Degree of Master of Science Program in Social and Administrative Pharmacy

Department of Social and Administrative Pharmacy

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Thesis Title   ADHERENCE ASSESSMENT AND FACTORS AFFECTING
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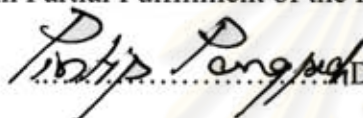By   Miss Tidarat Sujipittham

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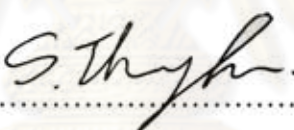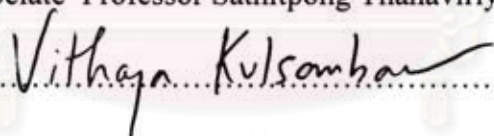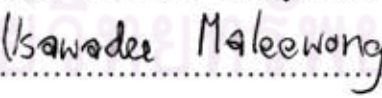
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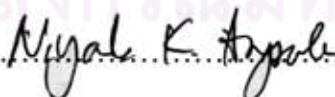
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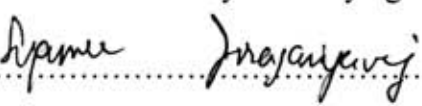
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ธิคารัตน์ สุจิพิธธรรม : การวัดความร่วมมือและปัจจัยที่มีผลต่อความร่วมมือในการใช้ยาต้านไวรัสเอดส์
ในผู้ป่วยที่ติดเชื้อเอชไอวีและผู้ป่วยเอดส์ ณ โรงพยาบาลตากสิน (ADHERENCE
ASSESSMENT AND FACTORS AFFECTING ADHERENCE TO ART
AMONG HIV-INFECTED/AIDS AT TAKSIN HOSPITAL) อ. ที่ปรึกษา
วิทยานิพนธ์หลัก: รศ.ดร.วิทยา กุลสมบูรณ์, อ. ที่ปรึกษาวิทยานิพนธ์ร่วม: ดร.อุษาวดี มาลีวงศ์, 85
หน้า

การวิจัยนี้เป็นการศึกษาแบบภาคตัดขวางเชิงวิเคราะห์ โดยมีวัตถุประสงค์เพื่อ (1) ประเมินความ
ร่วมมือในการใช้ยาต้านไวรัสเอชไอวี ณ โรงพยาบาลตากสิน โดยใช้การประเมินความร่วมมือในการใช้ยาแบบ
หลายวิธีร่วมกัน (2) เพื่อวิเคราะห์หาความสัมพันธ์ระหว่างปัจจัยต่างๆ ต่อความร่วมมือในการใช้ยาต้านไวรัสเอช
ไอวี ทำการเก็บข้อมูลในช่วงเดือน มีนาคม ปี พ.ศ. 2553 ถึงเดือนเมษายน ปี พ.ศ. 2553 ในกลุ่มผู้ป่วยที่ติดเชื้อ
เอชไอวีและผู้ป่วยเอดส์ที่ได้รับการรักษาด้วยยาต้านไวรัสเอดส์ ณ โรงพยาบาลตากสิน ผู้ป่วยเข้าร่วมการวิจัย
จำนวน 200 คนผู้วิจัยเก็บข้อมูลโดยการสัมภาษณ์ ผู้ป่วย และทำการประเมินความร่วมมือในการใช้ยา
ผลการวิจัยพบว่า ผู้ป่วยเป็นเพศชาย ร้อยละ 53 อายุเฉลี่ยที่ 38.20 ปี มีสถานภาพสมรสแล้ว ร้อยละ 43.5 มี
ระดับการศึกษาสูงสุดในระดับประถมศึกษา ร้อยละ 35.5 ประกอบอาชีพรับจ้าง/ลูกจ้าง ร้อยละ 58.5 มีรายได้
น้อยกว่า 5,000 บาทต่อเดือน ร้อยละ 42 ใช้สิทธิการรักษาประกันสุขภาพถ้วนหน้า ร้อยละ 70.5 ส่วนใหญ่
ได้รับการติดเชื้อทางเพศสัมพันธ์จากเพศตรงข้าม ร้อยละ 65.5 ระยะเวลาเฉลี่ยในการใช้ยาต้านไวรัสตั้งแต่เริ่ม
รักษาถึงปัจจุบันประมาณ 3 ปี ส่วนใหญ่พบว่า ไม่เกิดอาการไม่พึงประสงค์จากการใช้ยา ร้อยละ 81.5
รับประทานยาต้านไวรัสเอชไอวี วันละ สองเวลา ร้อยละ 70.5 ในการวัดความร่วมมือในการใช้ยาโดยใช้หลาย
วิธีการวัดอันประกอบด้วย 1.self-report 2.visual analogue scale (VAS) 3.pill identification
test (PIT) และ 4. pill count พบว่าผู้ป่วยส่วนใหญ่มีความร่วมมือในการใช้ยาต้านไวรัสเอชไอวี (ความ
ร่วมมือในการใช้ยา มากกว่าหรือเท่ากับ 95 %) คิดเป็นร้อยละ 70 และจากการวิเคราะห์ความสัมพันธ์ระหว่าง
ความร่วมมือในการใช้ยากับปัจจัยต่างๆที่ส่งผลต่อความร่วมมือในการรับประทานยาต้านไวรัสเอชไอวี โดยใช้
สถิติ ถดถอยแบบโลจิสติกส์ พบว่าเพศหญิง ความมั่นใจในการรับประทานยา และ ความสัมพันธ์ระหว่างผู้ป่วย
กับบุคลากรทางการแพทย์นั้นมีความสัมพันธ์ต่อความร่วมมือในการใช้ยาอย่างมีนัยสำคัญทางสถิติ สรุปว่าจาก
การใช้หลายเครื่องมือในการวัดร่วมกัน พบว่า ผู้ป่วยส่วนใหญ่มีความร่วมมือในการใช้ยา และพบว่าเพศหญิง
ความมั่นใจในการรับประทานยา และความสัมพันธ์ที่ดีระหว่างบุคลากรทางการแพทย์กับผู้ป่วยนั้นจะมีส่วน
เสริมสร้างความร่วมมือในการใช้ยาต้านไวรัสเอชไอวีที่เพิ่มขึ้น ดังนั้นบุคลากรทางการแพทย์ควรมีกิจกรรมที่
ส่งเสริมให้ผู้ป่วยมีความมั่นใจในการใช้ยาเพิ่มขึ้น และสร้างความสัมพันธ์ที่ดีกับผู้ป่วยเพื่อให้ผู้ป่วยมีความร่วมมือ
ในการใช้ยา อันจะส่งผลดีต่อประสิทธิภาพในการรักษาต่อไป

ภาควิชา.....เภสัชศาสตร์สังคมและบริหาร....ลายมือชื่อนิสิต.......ธิคารัตน์ สุจิพิธธรรม........

สาขาวิชา...เภสัชศาสตร์สังคมและบริหาร....ลายมือชื่อ อ. ที่ปรึกษาวิทยานิพนธ์หลัก..............

ปีการศึกษา..............2553..............ลายมือชื่อ อ. ที่ปรึกษาวิทยานิพนธ์ร่วม..............

###5176851833: MAJOR SOCIAL AND ADMINISTRATIVE PHARMACY

KEYWORDS: ADHERENCE / FACTORS AFFECTING ADHERENCE / HIV-INFECTED/AIDS

TIDARAT SUJIPITTHAM: ADHERENCE ASSESSMENT AND FACTORS AFFECTING ADHERENCE TO ART AMONG HIV-INFECTED/AIDS AT TAKSIN HOSPITAL. THESIS ADVISOR: ASSOC.PROF. VITHAYA KULSOMBOON, Ph.D., THESIS CO-ADVISOR: USAWADEE MALEEWONG, Ph.D. 85 pp.

This study was an analytical, cross–sectional study. The objectives of this study were to (1) assess the adherence to ARV medication among HIV/AIDS patients at TAKSIN hospital by using multiple adherence measurement. (2) Analyze the relationship between the factors affecting patient adherence to ARV medication. In data collection was conducted by using interviewing and assessment tools during March to April 2010 in HIV/AIDS outpatient clinic at TAKSIN Hospital. The samples were 200 HIV/AIDS patients who take antiretroviral medicines. The results showed that majority of the samples were male (53%), the average of age was 38.20 years-old, were married (43.5%), were completed primary school (35.5%), were employee (58.5%), had an income less than 5,000 baht per month (42%), were in universal health care coverage program (70.5%), contacted infection due to heterosexual transmission (65.5%), took ARV medicine for 3 years, no adverse event from antiretroviral (81.5%), at present the patients took ARV medicines two times/day (70.5%). Using multi-method consisted of self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count in order to assess the adherence of HIV/AIDS patients, the results revealed that majority of patients (70%) had adherence to ARV medication (adherence level more than 95%). The relationship between adherence and the factors affecting patient adherence to ARV medication by using multivariate logistic regression analysis showed that female, self-efficacy and patient-health care provider relationship had positive relationship with adherence to ARV medicine ($p < 0.05$). In conclusion, the health care provider should provide the programs to enhance the self-efficacy of the HIV/AIDS patients and also establish the good relationship between patients-providers in order to increase the adherence level to improve the effectiveness of treatment in HIV/AIDS patients.

Department: ..Social and Administrative Pharmacy...Student's Signature...Tidarat Sujipittham

Field of Study: Social and Administrative Pharmacy.Advisor's Signature...Vithaya Kl...

Academic Year:.......2010.............Co-advisor's Signature.Usawadee Maleewo.

ACKNOWLEDGEMENTS

CONTENTS

LIST OF TABLES

LIST OF ABBREVIATIONS

ABC	=	abacavir
ART	=	antiretroviral therapy
ARV	=	antiretroviral
ATV	=	atazanavir
AZT	=	zidovudine
ddI	=	didanosine
DLV	=	delavirdine
DOT	=	directly observed treatment
DRV	=	darunavir
d4t	=	stavudine
EFV	=	efavirenz
ETV	=	etravirine
FPV	=	forsamprenavir
FTC	=	emtricitabine
HAART	=	highly active antiretroviral therapy
IDV	=	indinavir
LPV/r	=	lopinavir/ritonavir
MAL	=	maraviroc
MEMS	=	medication event monitoring system
NFV	=	nelfinavir

NNRTIs	=	non- nucleoside reverse transcriptase inhibitors
NRTIs	=	nucleoside reverse transcriptase inhibitors
NVP	=	nevirapine
OIs	=	opportunistic infections
PC	=	pill count
PIs	=	protease inhibitors
PIT	=	pill identification test
RAL	=	raltegravir
RTV	=	ritonavir
SQV-Sgc	=	saquinavir soft gel caps
TDF	=	tenofovir-disoproxil-fumarate
TDM	=	therapeutic drug monitoring
TPV	=	tipranavir
VAS	=	visual analogue scale
3TC	=	lamivudine

CHAPTER I

INTRODUCTION

Rationale and Statement of the Problem

Acquired Immunodeficiency Syndrome (AIDS) is an infectious disease caused by Human Immunodeficiency Virus (HIV). HIV is one of the viral in the retrovirus family, which has two types of the disease identified HIV-1 and HIV-2. The Type 1 (HIV-1) is the major form of infection in HIV/AIDS throughout the world, while the Type 2 (HIV-2) is found mostly in West Africa.[1,2] Transmission of HIV occurs through three primary modes as follows: sexual intercourse, parenteral and perinatal. In sexual intercourse, the receptive anal and vaginal of intercourse are the most common modes of transmission. The probability of HIV transmission from receptive anorectal intercourse was 0.1% to 3% per sexual contact and was 0.1% to 0.2% per sexual contact for receptive vaginal intercourse. Using of contaminated needles or other devices by drug abusers has been the main cause of parenteral transmission of HIV, while, healthcare workers have a small occupational risk of getting HIV. Perinatal infection is the most common cause of pediatric HIV infection. The risk of mother-to-child transmission is approximately 25% in the absence of breast-feeding. Breast-feeding can also transmission HIV.[3] HIV/AIDS patients who have lower immune system or immune deficiency (CD4) would have a high risk to have opportunistic infections (OIs) and also increased morbidity and mortality.[1]

In 2007, there have been 33 million people living with HIV/AIDS (PLWHA) around the world, two million people died from HIV/AIDS worldwide and during this year here were 2.7 million newly infected patients worldwide, The reported from World Health Organization (WHO) showed that only 4 million HIV-positive people in low -income and middle-income countries can access to ARV medicines in 2008.. [4] The Bureau of Epidemiology and the Department of Disease Control reported that there were 358,260 cases of PLWHA and 95,983 deaths in Thailand. [5] AIDS is the important problem of Public Health, because majority of the PLWHA in Thailand were 15-59 years old.[5]

Presently, standard regimen in the HIV-infected/AIDS treatment is a combination of 3 or more antiretroviral drugs which is called "highly active

antiretroviral therapy" (HAART).[1,6] HAART has a high efficacy in improving immune function (CD4), reducing HIV viral in plasma, reducing opportunity drug resistance in treatment, improving quality of life and also reducing HIV-related morbidity and mortality.[1,7-10] HAART standard regimen which was used in Thailand, was GPO-vir, the combination of Stavudine (d4T), lamivudine (3TC), and Nevirapine (NVP). In case of the patients who cannot use GPO-vir, physician will shift to other regimens such as Efavirenz (EFV) instead of NVP.[5]

HIV infected/AIDS patients have to take ARV medicines continuously to extend their lifelong treatment.[1] Several studies found that adherence to antiretroviral regimens is an essential factor in providing adequate suppression of viral replication, increasing CD4 and reducing drug resistance. In contrast, non-adherence to the prescribed antiretroviral regimen is associated with a rapid infection of resistant HIV strains resulting in treatment failure.[6,7-10] Adherence is very important in terms of reducing the occurred emergence and spread of drug resistance with cross-resistance. HIV virus can resist to the other class of ARV medicine resulting in ineffectiveness of ARV treatment. Not just for an individual but also for the society. Little, Holte, Routy and others found that one in five newly infected patients infected the resistance virus.[11] Alteri explored a cohort of 255 newly diagnosed HIV-1 infected individuals and analyze the prevalence of HIV-1 strains with at least one major drug resistance, the finding showed that 10 was NRTI-resistance, 9 was NNRTI and 1 was PI-resistance.[12] Patients who acquired HIV from homosexual intercourses were mode of a virus with resistance mutation.[12] Paterson, Swindells, Mohr and others found that the adherence level more than 95 percent was necessary for HIV viral suppression.[13] The finding showed that if adherence decreases, viral load (VL) will increase in a dose–response effect. In addition, Hogg, Yip, Chan and others reported that every 10 percent of the decrease in adherence will increase 16 percent of HIV-related mortality.[14]

At present, there were 1,080 new HIV-infected/AIDS patients at TAKSIN Hospital. Seventy-four patients died during January to November 2009. The result of using interviewing to measure adherence of HIV infected/AIDS patients at Taksin Hospital showed that 99.3% of the patients had adherence $\geq$ 95%> However, when using SMAQ questionnaire which was developed by Knobel, Alonso, Casado and others[8], it was found that only 54% of patients (26 cases of 48 cases) had adherence $\geq$ 95%. Up to now, there is no gold standard in the measurement of adherence.[1]

WHO recommended to use multi-method for measurement patient adherence in order to increase the accuracy of the results.[4] WHO suggested that only one tool may not be valid and may not have high accuracy. The tools to measure the adherence in this study were multi-method tools which were recommended from Steel, Nwokike, Joshi and others [15] study including Self-report assessment, Visual analogue scale (VAS), Pill Identification Test (PIT), and Pill count. The study also explored factors affecting adherence to antiretroviral therapy (ART) among HIV-infected/AIDS patients at TAKSIN Hospital. This study will be useful for provider worker for applying the result in their practice of clinic HIV/AIDS at TAKSIN Hospital. It will increase the understanding of patient's behavior and will be used to support the adherence to antiretroviral therapy. This will improve the immune function, reduce HIV viral in plasma, reduce opportunity of drug resistance in treatment, improve quality of life, reduce HIV-related morbidity and mortality, and reduce failure to treatment in the future.

Research question

1. What is the adherence level of HIV/AIDS patients at TAKSIN Hospital measured by multi-method tools?
2. What are the factors affecting adherence to ARV medication of HIV/AIDS patients at TAKSIN Hospital?

Objectives of the study

1. To assess the adherence to ARV medication among HIV-infected/AIDS patients at TAKSIN hospital by using multi-method tools.
2. To analyze the relationship between factors affecting patient adherence to ARV medication and the adherence level.

Scope of the study

The samples in this study were HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital. The time period for data collection was during March 2010- April 2010.

Expected benefits

1. The multi-method assessment could be applied for patient adherence in routine practice.

2. Physician-patient relationship may be improved based on the results from this study.

3. Health care providers could increase the level of patient adherence by using the results related to factors influencing on patient adherence.

Definition used in the study

ART is antiretroviral therapy.

HAART is antiretroviral therapy more than or equal to 3 drugs in combination which is called "highly active antiretroviral therapy.(HAART)

Adherence is defined as taking medicine with correct type, correct dose and correct time , taking medicine on time (not to exceed half an hour) , taking medicine always (everyday), taking medicine continuously (continually forever) by patients who participate with the plan and willingly decide in taking medicine according to the prescribed medicine.[16]

Poor adherence is the level of adherence that a patient had which was <95% of adherence.

Good adherence is the level of adherence that a patient had which was ≥ 95% of adherence.

Multi-method tool is adherence assessment by using four tools [15] that consist of Self-report, Visual analogue scale (VAS), Pill Identification Test (PIT), Pill count.

Patient-related factors are the factors including knowledge of disease and medication, gender, age, status, education, occupation, income, self-efficacy.[17,18, 19]

Health care team-related factors are the factors including patient-healthcare provider relationship.[17, 18, 19]

Treatment-related factors are the factors including dose frequency, adverse effects, duration of treatment.[17, 18, 19]

Social or Family Support factors are the factors including friend, family, cousin, and AIDS patients who support patient.[17, 18]

Conceptual framework

Patient –related Factors

- Self efficacy

- Knowledge of disease and medication

- Gender

- Age

- Status

- Education

- Occupation

- Income

Treatment-related Factors

- Adverse effect

- Duration of treatment

- Dose frequency

Adherence to ART

Health care team-related Factors

- Patient-health care Provider relationship

Social or Family Support

- Social support
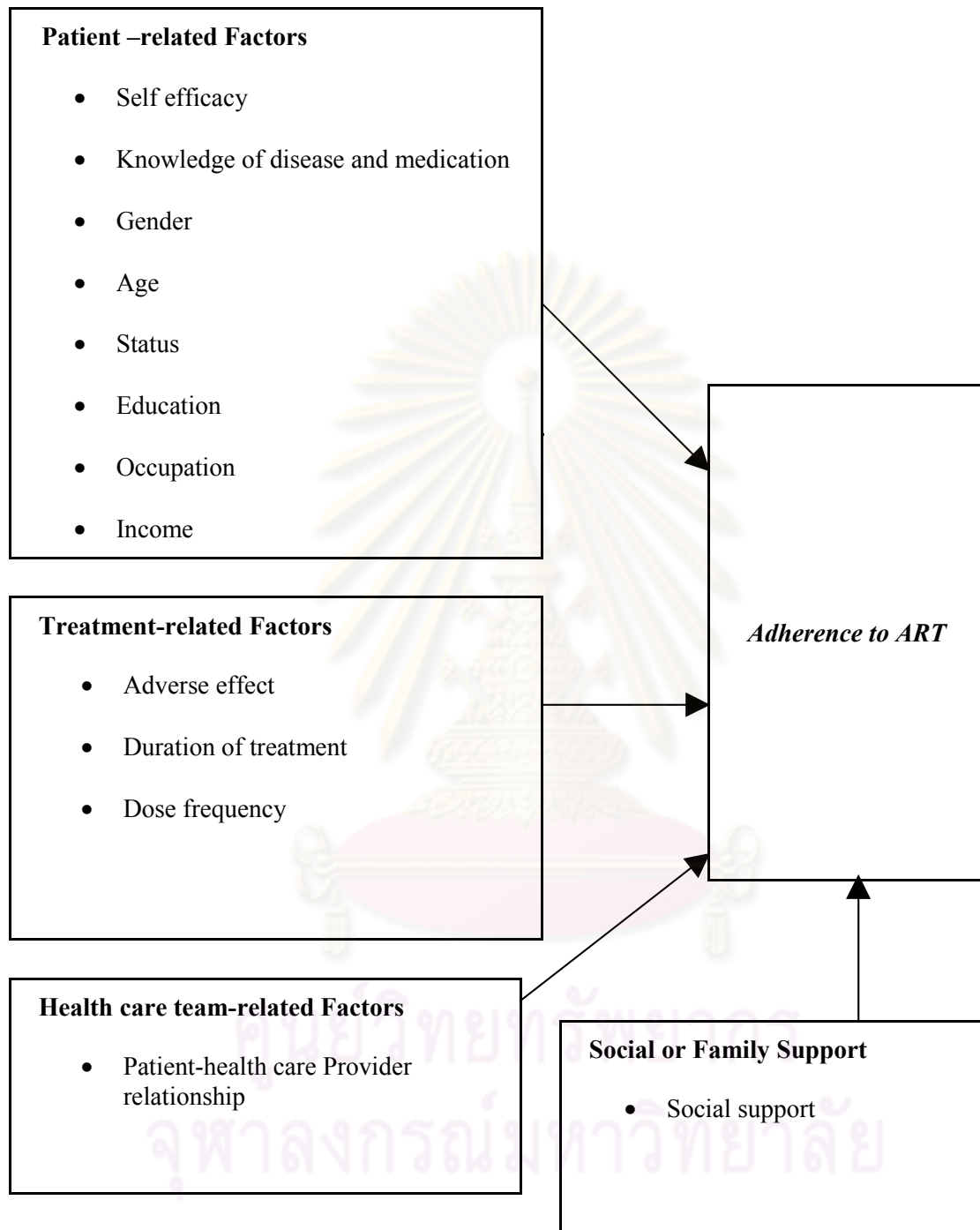
CHAPTER II
LITERATURE REVIEW

This study was aimed to assess the adherence to ARV medication among HIV-infected/AIDS patients at TAKSIN hospital by using multi-method tool to measure adherence and to analyze the factors affecting patient adherence to ARV medication. The literature review focused on AIDS disease, ARV treatment, adherence to ART, method of assessment adherence and the factors affecting patient adherence to ARV medication.

2.1 Acquired Immunodeficiency Syndrome (AIDS)

2.2 Treatment HIV-infected/AIDS patients

2.3 Adherence to ARV

2.4 Tools of assessing adherence

2.5 The factors affecting patient adherence to ARV medication

2.1 Acquired Immunodeficiency Syndrome (AIDS)

Acquired Immunodeficiency Syndrome (AIDS) is an infectious disease caused by Human Immunodeficiency Virus (HIV). HIV is one of the viral in the retrovirus family, which has two types of the disease identified HIV-1 and HIV-2. The Type 1 (HIV-1) is the major form of infection in HIV/AIDS throughout the world, while the Type 2 (HIV-2) is found mostly in West Africa.[1,2] Transmission of HIV occurs through three primary modes as follows: sexual intercourse, parenteral and perinatal. In sexual intercourse, the receptive anal and vaginal of intercourse are the most common modes of transmission. The probability of HIV transmission from receptive anorectal intercourse was 0.1% to 3% per sexual contact and was 0.1% to 0.2% per sexual contact for receptive vaginal intercourse. Using of contaminated needles or other devices by drug abusers has been the main cause of parenteral transmission of HIV, while, healthcare workers have a small occupational risk of getting HIV. Perinatal infection is the most common cause of pediatric HIV infection. The risk of mother-to-child transmission is approximately 25% in the absence of breast-feeding. Breast-feeding can also transmission HIV.[3] HIV/AIDS patients who have lower immune system or immune deficiency (CD4) would have a high risk to have opportunistic infections (OIs) and also increased morbidity and mortality.[1]

There have been 33 million people living with HIV/AIDS (PLWHA) around the world, 2 million people died from HIV/AIDS worldwide in 2007. Around 2.7 million were newly infected with HIV worldwide in 2007 and WHO reported that only 4 million HIV-positive people had access to ARV medication in low -income and middle-income countries in 2008.[4] The situation of AIDS disease in Thailand that is reported by the Bureau of Epidemiology, the Department of Disease Control[5] showed that there have been 358,260 cases of PLWHA and 95,983 deaths. In Thailand, AIDS is a major health problem, because most of the people living with HIV/AIDS (PLWHA) were 15-59 years old who can yield the productivity to the social.[5]

The HIV life cycle [20]

There are six stages in the HIV life cycle:

1. Binding and Fusion: HIV begins its life cycle when it binds to a CD4 receptor and one of two co-receptors on the surface of a CD4 T-lymphocyte. The virus will fuses with the host cell. After fusion, the virus release RNA and its genetic material, into the host cell.

2. Reverse Transcription: An HIV enzyme called reverse transcriptase converts the single-stranded HIV RNA to double-stranded HIV DNA.

3. Integration: The newly formed HIV DNA enters the host cell's nucleus, an HIV enzyme called integrase "hides" the HIV DNA within the host cell's own DNA. The integrated HIV DNA is called provirus. The provirus may remain inactive for several years, producing few or no new copies of HIV.

4. Transcription: When the host cell receives a signal to become active, the provirus uses a host enzyme called RNA polymerase to create copies of the HIV genomic material, as well as shorter strands of RNA called messenger RNA (mRNA). The mRNA is used as a blueprint to make long chains of HIV proteins.

5. Assembly: An HIV enzyme called protease cuts the long chains of HIV proteins into smaller individual proteins. As the smaller HIV proteins come together with copies of HIV's RNA genetic material, a new virus particle is assembled.

6. Budding: The newly assembled virus pushes out ("buds") from the host cell. During budding, the new virus steals part of the cell's outer envelope. This envelope, which acts as a covering, is studded with protein/sugar combinations called HIV glycoproteins. These HIV glycoproteins are necessary for the virus to bind CD4 and co-receptors. The new copies of HIV can now move on to infect other cells.

Disease classification systems [21]

The U.S Centers for Disease Control and Prevention (CDC) classified HIV/AIDS states based on CD4 cell count and clinical categories which was shown in Table 2.1.

Table 2.1 CDC Classification System for HIV-Infected Adults and Adolescents [21]

CD4 Cell Categories	Clinical Categories		
	(A) Asymptomatic	(B) Symptomatic	(C) AIDS
(1) ≥500 cells/μL	A1	B1	C1
(2) 200-499 cells/μL	A2	B2	C2
(3) <200 cells/μL	A3	B3	C3

CDC Classification System: Category B Symptomatic Conditions [21]

Category B symptomatic conditions refer to symptomatic conditions occurring in an HIV-infected adolescent or adult that meets at least 1 of the following criteria:

a) They are attributed to HIV infection or indicate a defect in cell-mediated immunity.

b) They are considered to have a clinical that is complicated by HIV infection. Examples include, but are not limited to, the following:

1. Bacillary angiomatosis

2. Oropharyngeal candidiasis (thrush)

3. Vulvovaginal candidiasis

4. Pelvic inflammatory disease (PID)

5. Cervical dysplasia (moderate or severe)/cervical carcinoma in situ

6. Hairy leukoplakia

7. Idiopathic thrombocytopenic purpura

8. Constitutional symptoms, such as fever (>38.5°C) or diarrhea lasting >1 month

9.Peripheral neuropathy

10. Herpes zoster (shingles) involving ≥2 episodes or ≥1 dermatome.

CDC Classification System: Category C AIDS-Indicator Conditions [21]

1. There are clinical conditions as follow:

2. Bacterial pneumonia

3. Candidiasis of the bronchi, trachea, or lungs Candidiasis

4. Esophageal

5. Cervical carcinoma

6. Coccidioidomycosis

7. Extrapulmonary

8. Cryptococcosis

9. Extrapulmonary

10. Cryptosporidiosis

11. Chronic intestinal (>1-month duration)

12. Cytomegalovirus disease (other than liver, spleen, or nodes)

13. Encephalopathy

14. Herpes simplex

15. Bronchitis, pneumonitis

16. Esophagitis

17. Histoplasmosis

18. Disseminated or extrapulmonary

19. Isosporiasis

20. Chronic intestinal (>1-month duration)

21. Kaposi sarcoma

22. Lymphoma

23. Burkitt

24. Immunoblastic, or primary central nervous system

25. Mycobacterium avium complex (MAC)

26. Mycobacterium tuberculosis

27. Pulmonary or extrapulmonary

28. Mycobacterium

29. Pneumocystis jiroveci (formerly carinii) pneumonia (PCP)

30. Progressive multifocal leukoencephalopathy (PML)

31. Salmonella septicemia, recurrent (nontyphoid)

32. Toxoplasmosis of brain

33. Wasting syndrome due to HIV (involuntary weight loss >10% of baseline body weight)

34. Chronic diarrhea (≥2 loose stools per day ≥1 month) or chronic weakness and documented fever ≥1 month.

2.2 HIV-infected/AIDS treatment

At present, the standard regimen in the treatment of HIV-infected/AIDS patients is 3 or more combination of antiretroviral drugs which is called "highly active antiretroviral therapy (HAART).[1,6] The combination of antiretroviral therapies for HIV infection have demonstrated efficacy in improving immune function (CD4), reducing HIV viral in plasma (undetectable level), reducing opportunity drug resistance in treatment, improving quality of life and reducing HIV-related morbidity and mortality.[1,7-10]

Antiretroviral therapy (ART) are divided into five class according to [1, 6, 22, 23]

1. Nucleoside reverse transcriptase inhibitors (NRTIs): composes of

Zidovudine (AZT), Stavudine(d4T), Lamivudine(3TC), Didanosine(ddI), Abacavir(ABC), Tenofovir-disoproxil-fumarate(TDF), Emtricitabine(FTC)*   and fixed–dose combination: AZT/3TC 300/150 mg, 3TC/ABC, TDF/FTC*, AZT/3TC/ABC*

Mechanism of action: the principle mode of action is inhibition of HIV reverse transcriptase via viral DNA chain termination; inhibits RNA-dependent and DNA-dependent DNA polymerase activities of reverse transcriptase.

2. Non-nucleoside reverse transcriptase inhibitors (NNRTIs): composes of

Nevirapine(NVP), Efavirenz(EFV), Delavirdine(DLV)*, Etravirine(ETV)*and fixed-dose combination of NRTIs and NNRTIs: d4T 30 or 40 mg/3TC 150 mg/NVP 200 mg and AZT 250 mg/3TC 150 mg/NVP 200 mg.

Mechanism of action: activity against HIV-1 by binding to reverse transcriptase. It consequently blocks the RNA-dependent and DNA-dependent DNA polymerase activities including HIV-1 replication .It does not require intracellular phosphorylation for antiviral activity.

3. Protease inhibitors(PIs): composes of

Indinavir(IDV), Ritonavir(RTV), Nelfinavir(NFV), Saquinavir soft gel caps (SQV.Sgc), Lopinavir/ritonavir(LPV/r), Atazanavir(ATV), Forsamprenavir (FPV)*, Darunavir(DRV), Tipranavir(TPV)*.

Mechanism of action: inhibits HIV protease and renders the enzyme incapable of processing polyprotein precursor which leads to production of non-infectious immature HIV particles.

4. Entry inhibitors:

Fusion inhibitor: Enfuvirtide(T-20) (subcutaneously) is the drug that inhibit HIV viral to go in cell.

CCR5 antagonist: maraviroc(MAL)*

5. Integrase inhibitors: Raltegravir(RAL)*

(* not available in Thailand)

The primary goals driving the decision to initiate antiretroviral therapy [1, 6, 23] are to

1.) Reduce HIV-related morbidity and prolong survival.

2.) Improve quality of life (QOL).

3.) Restore and preserve immunologic function, increase CD4.

4.) Maximally and durably suppress viral load (reduce HIV viral in plasma undetectable level).

5.) Prevent vertical HIV transmission.

Adoption of treatment strategies recommended in these guidelines has resulted in substantial reductions in HIV-related morbidity and mortality and has reduced vertical transmission. Higher plasma HIV RNA levels (viral load) are associated with more rapid disease progression, although other factors likely contribute as well to the rate of CD4 T-cell decline. Maximal suppression of plasma viremia for as long as possible to delay the selection of drug resistance mutations, to preserve CD4 T-cell numbers, and to confer substantial clinical benefits are the most important goals of antiretroviral therapy.[1, 6, 23]

Recommendation for initiation of ART

The details in table 2.2, table 2.3 and table 2.4 are the recommendation for initiation of antiretroviral therapy (ART) of THAILAND Guideline, WHO Guideline and Department of Health and Human Services (DHHS) Guideline, respectively.

Table 2.2 THAILAND Guideline as follow: [23]

Clinical symptom	CD4 (cell/mm^3)	Recommendation
AIDS-defining illness	Value anything	Treatment with ARV
Symptomatic HIV disease	Value anything	Treatment with ARV
Asymptomatic HIV disease	<200	Treatment with ARV
Asymptomatic HIV disease	200-350	Follow clinical symptom, CD4 every 3 month , move treatment
Asymptomatic HIV disease	>350	Follow clinical symptom, CD4 every 6 month , move treatment

Table 2.3 WHO Guideline for start antiretroviral therapy in HIV-Infected Adults and Adolescents [1]

CD4(cells/mm^3)	Recommendation in Treatment
< 200	Treatment with ARV
200-350	Treatment with ARV prior CD4 will reduce to < 200 cells/ mm^3
> 350	No treatment

Table 2.4 Department of Health and Human Services (DHHS) Guideline for start antiretroviral therapy in HIV-Infected Adults and Adolescents in United States [1]

Clinical Category	CD4(cells/μL)	Plasma HIV RNA (copies/ml)	Recomendation in Treatment
AIDS defining illness	Any value	Any value	Treat with ARV
Asymptomatic HIV disease	CD4< 200	Any value	Treat with ARV
Asymptomatic HIV disease	CD4>200 but≤350	Any value	Should treat with ARV and should explain advantage and disadvantage of ARV treatment
Asymptomatic HIV disease	CD4>350	>100,000	Some physician recommend to treat with ARV
Asymptomatic HIV disease	CD4>350	<100,000	May start ARV

Guideline for selection regimen for the patients who are naive for antiretroviral therapy in THAILAND Guideline [1,23]

1. **First regimen**: The standard regimen for Thai HIV/AIDS patients is stavudine+lamivudine+nevirapine(GPOvir)
2. **Second regimen**: There are three alternative regimens:
2.1 stavudine+lamivudine+efavirenz is recommended when patients experience to NVP side effects such as allergic.
2.2 zidovudine+lamivudine+nevirapine is recommended when patients have an adverse drug reaction related to stavudine.
2.3 zidovudine+lamivudine+efavirenz is recommended when patients have an adverse drug reaction or allergy related to stavudine and nevirapine.

3. **Third regimen:** There are two alternative regimens:

3.1   Stavudine+lamivudine+indinavir/ritonavir or

3.2   Zidovudine+lamivudine+indinavir/ritonavir

WHO Guidelines [1]

WHO Guidelines recommended that the **first regimen** should be 2NRTIs+NNRTIs and **second regimen** should be 2NRTIs+PIs.

1.   NRTIs group type 1: should select between lamivudine and emtricitabine

2.   NRTIs group type 2: should select between zidovudine and stavudine or tenofovir and abacavir

3.   NNRTIs group: should select between efavirenz and nevirapine

(For the PIs group WHO recommends the second regimen)

DHHS Guideline [1]

Table 2.5 Antiretroviral therapy regimen that is recommended as the preferred component in naive antiretroviral therapy by the Department of Health and Human Services (DHHS), United States

	Column A (NNRTI or PI)		Column B (NRTI 2 type)
Preferred component	NNRTI or PI Efavirenz ATZ+RTV Fosamprenavir+RTV (2 times/day) LPV+RTV (2 times/day)	+	Tenofovir + Emtricitabine or Zidovudine + Lamivudine
Alternative to Preferred component	NNRTI or PI Nevirapine ATZ Fosamprenavir Fosamprenavir+RTV (1 time/day) LPV+RTV (1time/day)	+	Abacavir + Lamivudine or Didanosine+(Emtricitabine or Lamivudine)

Significant drug interactions can occur with many antiretroviral agents:
[3]

1. **Ritonavir** is a potent inhibitor of cytochrome P450 enzyme 3A and is used to reduce clearance of other PIs.
2. Two NRTIs, **zidovudine** and **stavudine**, antagonize each other's metabolism and should not be given together.
3. Rifampin may reduce the concentrations of PIs and is contraindicated with use of most PIs.
4. Saint John's wart is a potent inducer of metabolism and is contraindicated with PIs and NNRTIs.

Causes of Antiretroviral Treatment Failure [1, 6, 23]

Antiretroviral Treatment Failure refers to suboptimal response to therapy. Treatment Failure is often associated with Virologic Failure, Immunologic Failure, and/or Clinical progression. Many factors are associated with increasing risk of Treatment Failure, as follow:

1. Baseline of the patients , such as:
    a. Previous initial introduction to therapy, which less potent regimens
    b. Higher pre-treatment of baseline HIV RNA level
    c. Lower pre-treatment CD4 T-cell count
    d. Prior AIDS diagnosis
    e. Co-morbidities (e.g., depression, active substance use)
    f. Presence of a drug-resistant virus
    g. Prior treatment failure with the development of drug resistance or cross resistance
2. Incomplete medication adherence (non-adherence) and missed clinic appointments
3. Drug side effects and toxicity
4. Suboptimal pharmacokinetics (absorption, metabolism and food/fasting requirements, adverse drug-drug interactions)
5. Suboptimal potency of the antiretroviral regimen
6. Other, unknown reasons

2.3 Adherence to ARV

The Ministry of Public Health in Thailand defines adherence as taking medicine correctly (correct type, correct dose, correct course, correct time) taking medicine on time (variance should not exceed than half an hour) taking medicine always (take medicine on time everyday) and taking medicine continuously (continually forever) by the patients who can participate and decide for their treatment.[16]

Bosworth, Steffens, Flint and others defines adherence as the patient's participation and engagement in maintaining regimen as follows: she or he believes treatment will be beneficial, strongly implying a therapeutic partnership between provider and patient that is essential for the patient's success in following the prescribed regimen.[24]

The U.S. DHHS defines adherence as closely monitoring or adhering to a prescribed treatment regimen. This includes taking the correct dose at the correct time, exactly as prescribed.[2]

Adherence to ARV medication is a factor for treatment successful. A level of adherence more than or equal to 95% of prescribed doses is need for a maximal response to ARV medication (undetectable viral load). Conversely; suboptimal intake of antiretroviral therapy will decrease the probability of viral suppression and it may increase of drug-resistant HIV-1 strains.[1, 6, 13, 25]

The results of the studied of Wagels by using MEMS (medication event monitoring system) to assess the adherence during the first month to six month of treatment showed that good adherence (>95% doses took) associated with viral suppression and adherence level > 95% from first month of ART will significantly higher suppression when compared to patients with lower adherence rates.[27]

The results of the studied of Abaasa, Kalyango, Levin and others by using self-report and pill count found that 78.2% of patients had mean adherence > 95% and had 42.5 deaths per 100 patient-years for non-adherence patients and 6.1 deaths per 100 patient-years for adherence patients. Non-adherence to ART was significantly associated with mortality. Patients that had a CD4 count < 50 cells/mm3 will have a higher mortality when compared to patients with a CD4 count equal to or more than 50 cells/mm3 and good adherence will improve survival.[28]

The results of the study of Paterson, Swindells, Mohr and others that explored the effects of different levels of adherence of therapy to virologic outcome,

immunologic outcome and a clinical outcome showed that adherence was significantly associated with a successful virologic outcome and will increase CD4 and virologic failure. The samples in this study was 22% of patients with an adherence of 95% or greater, 61% of patients with (80% - 94.9% adherence), and 80% of patients with less than 80% adherence. Patients with adherence of 95% or greater had fewer days in the hospital (2.6 days per 1000 days of follow-up) than patients with less than 95% adherence (12.9 days per 1000 days of follow-up). No opportunistic infections or deaths happen in patients with 95% or greater adherence.[13]

Those related studies of adherence to antiretroviral found that good adherence (more than or equal 95 percent) will affect to the suppression of RNA, increase CD4 and prolong survival and reduce morbidity as showed in Table 2.6

Table 2.6 Related studies of adherence

Authors/year	Objective	Results	Conclusion
Wagels,2004	to evaluated adherence by using MEMS during the first 25 days of treatment and week 24 of program	Adherence level >95% in the first 4 weeks can improve viral suppression (77% of patients was suppression viral load at adherence >95%)	higher suppression RNA during the first month are associated with good adherence or >95%
Abaasa,et al 2008	to assess adherence by self-report, pill count	78.2% of patients >95% adherence, 6.1 deaths per 100 patient-years for adherence, CD4 count of less than 50 cells/mm3 will have a higher mortality	good adherence will improve survival

Paterson,et al 2000	to explored effects of different levels of adherence of therapy on virologic outcome, immunologic outcome and a clinical outcome	Adherence associated with increase CD4, Virologic failure was 22% of pts (95% adherence) , 61% of pts.(80% - 94.9% adherence), 80% of pts.(< 80% adherence). 95% adherence had fewer days in the hospital (2.6 days per 1000 days), < 95% adherence (12.9 days per 1000 days). No OIs or deaths happen in patients with 95% adherence	adherence was associated with a successful virologic outcome, immunologic outcome and a clinical outcome

2.4 Tools of assessing adherence

Tools for adherence assessment [1, 15, 30] can be divided into two categories as follow:

1. Direct and objective measures as follow:

-Directly observed treatment (DOT)

-Therapeutic drug monitoring (TDM)

-Biomarkers

-Medication event monitoring system (MEMS)

2. Indirect measures as follow:

-Pharmacy records

-Self-report

-Pill count (PC)

-Visual analogue scale (VAS)

-Pill identification test (PIT)

Directly observed treatment (DOT): the technique of this method is that the healthcare provider will direct administer medication to patient and observe the patient in taking medicine at the moment.[31] However, Farmer, Leandre, Mukherjee and others recommended that DOT was more expensive.[32]

Therapeutic drug monitoring (TDM): the technique of this method is to monitor the therapeutic drug levels in blood, however, TDM have some limitations. First, TDM can only monitor the adherence to the dose prior the clinic visit. Second,

the pharmacokinetics of many antiretroviral, especially protease inhibitors, may be affected from drug–drug interactions, drug interactions with foods and nutritional supplements that can affect to the potential poor absorption, for example, Ritonavir has drug interactions and auto induces its own metabolism. Third,[33] this method is more expensive.

Biomarkers: this method can be used to monitor adherence by adding the second non-toxic medicine in order to indicate that patient took medication such as add Vitamin B2 to check the level of vitamin B2 in the urine.

Medication Event monitoring System (MEMS): MEMS is an Electronic pill bottle, it is a new method to measure adherence. This device composes of special pill bottle caps equipped with have an electronic chip and hardware that record each time that patient opens a pill bottle. Patients who use pillboxes may open their electronic bottles only daily or weekly (to fill their pillboxes). However, electronically measured adherence may not be accurately measured because opening the cover of drug bottle but not taking a pill that it cannot confirm that medicine be took. Finally, the cost of MEMS is more expensive.[33] However MEMS are correlate with virological outcome.

Pharmacy records: this method is a convenient measurement of adherence in the situation that the patients get ART from only one source. However, when a patient receives drug from pharmacy, it is not sure that ARV pills have been taken or not.

Self-report: this method is the most common tool to measure the adherence. This method use face-to-face interviewing and ask the patient to complete the questionnaires. In face-to-face interviewing, the patients were asked about the number of dose that they miss during the past 7 day.[30] The part of patient-completed questionnaire is designed to evaluate a patient's treatment adherence behavior. There is many versions of self-report such as Patient Medication Adherence Questionnaire (PMAQ) that contains 31 items [34], Simplified Medication Adherence Questionnaire (SMAQ) that contains 6 items [8]. Self-report is the simplest tools to measure adherence with speedy and viability to use. However, the adherence data from this method may be overestimated and patients may give data that are not really true. However, several studies highlighted the usefulness of the self-report as an adherence measurement tool, and showed that it correlate with the virological outcome. It shows adequate levels of sensitivity and specificity when it was compared with other measures. It is reliable, showing sufficient internal consistency

and reproducibility. It is easy to apply and inexpensive. Self report is an instrument that may be used in the majority of clinical settings.[8]

Pill count (PC): the technique of this method is to count the amount of drug remaining. This method is very easy, convenient but data is unreliable because patients may leave the pills without taking them.[30]

Visual analogue scale (VAS): the technique of this method is to ask the patients to rate about their behavior of adherence to the prescribed ART from 0 (non adhere) to 10 (adhere). The meaning of 10 score is that he or she took all medicine doses and the 0 score is that he or she missed all doses. VAS is a simple tool.[15]

Pill identification test (PIT): this method is a new tool to measure adherence, the healthcare provider will ask the patients about the name of medicine, number of pills per dose, time to take pill and other instructions. PIT is reliable and correlate with validated self-report adherence measure.[15]

Even though, some adherence tools are valid, majority of tools cannot meet all the features of ideal tool. At present, there is no gold standard in measurement of adherence. WHO recommended multi-method adherence tool to be used in measuring adherence. Multi-method adherence tool is an accurate assessment adherence which is necessary for effective and efficient treatment planning.[35]

In this study, multi-method tools were used including self-report, VAS, PIT, and pill count based on the studied of Steel, Nwokike, Joshi and others.[15] Multi-method tool to measure ART adherence in resource-constrained settings was developed by Rational Pharmaceutical Management Plus Program, Management Sciences for Health, supported by U.S.Agency for International Development (USAID).

2.5 The factors affecting patient adherence to ARV medication

For HIV-infected/AIDS patients, a good adherence (equal or more than 95% of the prescribed dose) is associated with HIV viral suppression.[13] The results of Hogg, Yip, Chan and others study revealed that every 10 percent decrease in adherence will increase 16 percent of HIV-related mortality.[14] this finding was confirmed by the results of Chesney study [17] and the American Pharmacists Association study.[18]

Golin, Liu, Hays and others [41] explored 140 HIV-infected patients at a county hospital HIV clinic during the year follow the initiation of a new highly active

ARV regimen. The purpose of this study was to access the predictors of long-term (up to 1 year) adherence to newly initiated combination ARV. Measurement for adherence was done every 4 weeks by calculation score from medication event monitoring system (MEMS), pill counts and self-reports and evaluated demographic. The result showed that by average, patients took 71% of their prescribed dose. African-American ethnicity, lower income, lower education, higher alcohol use, higher dosage frequency, and fewer adherence aids (e.g. pillbox, timer) were associated with poorer adherence level.

Pinheiro, Carvalho-Leite, Drachler and others [48] conducted a cross-sectional study in HIV-infected adults treated with ARV in Southern Brazil. Adherence to treatment was assessed by a self-report. The results showed that of the 195 patients, 56.9% reported ≥95% adherence on the previous two days. An adherence increased with the self-efficacy in taking medicine and decreased with perceptive of negative effects and physical concerns. An adherence was lower for taking ARV >4 times per day and was higher for the patient with at least 8 years of schooling. Taking medicine >4 times a day were independently associated with non adherence. Self-efficacy was the most important factor to predict the adherence. The number of years of schooling was positively associated with adherence.

Glass, De Geest, Weber and others [49] conducted a cohort study and used 2-item self-reported adherence questionnaire to measure adherence. The definitions of non-adherence in this study are missing 1≥ dose, or missing ≥ 2 doses and taking medicine <95% of dose in the previous 4 weeks. The results showed that > 30% of patients reported missing ≥ 1 dose, 14.9% missed ≥ 2 doses, and 7.1% took < 95% of doses in the previous 4 weeks and the patients who are young, living alone, the number of regimens, were the factors associated with non-adherence. In conclusion, this studied found that the younger patients, lacked of social support and the perception of the complexity of treatment were important factors that related to non-adherence with ARV.

Maggiolo, Ripamonti, Arici and others [50] conducted cross-sectional study on HIV patients that receive HAART from January to May 2001 to assess the adherence by using a self-administered questionnaire. The purpose of this studied was to assess the factors associated with lower compliance and causes of non-adherence. The results showed that 50.9% of patients were adherence and the results of multiple logistic regressions showed that older, lower numbers of pills, fewer daily

doses were factors associated with adherence behavior and forgetful, being away from home and problem with ARV schedule were the most frequent causes of non-adherence.

Murri, Marconi, Wu AW, and others [51] conducted a study to assess variables that can predict the non-adherence. The method of this studied was a prospective study of HIV-infected patients who were prescribed Ritonavir-or Indinavir-containing regimen by using a questionnaire and assessed the patients' knowledge of the treatment regimen, adherence behavior, and reason of missing ARV. Non-adherence was measured by self-report. The results showed that age less than 35 years old, and having adverse effect "a lot" of vomiting or pruritus was significantly correlated to non-adherence. In conclusion, it was found that younger age and self-reported vomiting or pruritus was associated with non-adherence.

Duran, Spire, Raffi and others [9] conducted a study to assess self-reported symptoms in the patients who started to take two nucleoside reverse transcriptase inhibitors and one PIs and assessed the influence of these symptoms on adherence. The adherence and the patient reported symptoms were measured at 1 and 4 months after initiation to HAART through self-administered questionnaires. Results showed that the patients had at least one symptom of fatigue or diarrhea (94.0% at Month 1; 88.0% at Month 4). These symptoms were the most common side effects that were reported. About 81.3% and 75.0% of patient adhered to HAART during the 4 days prior to M1 and M4, respectively. Younger, history of antiretroviral treatment, unstable housing, poor social support, alcohol consumption, and the patients who reported a higher number of symptoms at M1 were more likely to be non adherent at M4. In conclusion, it was found that patients with a high number of symptoms after HAART initiation were high risk of non-adherence.

Murphy, Belzer, Durako and others [38] conducted a study to find the barriers to HAART adherence among HIV-infected adolescents and to explore the association of barrier and non-adherence. The findings showed that viral load was significantly associated with self-reported adherence, only 28.3% of adolescents reported taking all of their prescribed ARV. The barriers to adherence were medication-related ADR and complications in daily routine.

Schneider, Kaplan, Greenfield and others [53] conducted a study to assess the association of physician-patient relationship and adherence. The adherence was measured by using a 4-item self-report scale. The physician-patient relationship was

measured in the area of general communication, HIV-specific information, participatory decision making, overall satisfaction, willingness to recommend physician, and physician trust. The results showed that the patients were 42 years old, 15% were female, 73% were white, and 57% were gay, physician-patient relationship was significantly associated with adherence.   In conclusion, this studied showed that the physician-patient relationship was associated with medication adherence and the researchers suggested that physician-patient relationship is an important point of intervention to improve patients' medication adherence.

In Thailand, Kamolrat Inthisak [54] conducted a study to assessed adherence to ARV and explored the factors affecting an adherence to ARV at Chiangmai Hospital, Nongkai. Samples were 21 patients who received ARV during April to June 2007. Adherence was assessed using a visual analog scale, pill counts and medication logbook. The result from the visual analog scale showed that there was 81.6% adherence and 61.9% adherence during 7 day and 1 month respectively, and confirmed by pill count and log book indicated that over 90% of patients had >95% adherence. Factors affecting adherence were age, marriage status, occupation, communication skills of health care professionals, numbers of drugs prescribed.

Kanitta Punsreniramon [40] explored cross-sectional and studied to medical adherence by using tools as follow: pill count, GEEMA questionnaire and medication taking diary and studied factors influence patients adherence and studied relationship between medication adherence. The results found that adherence level were 91%, 95.5% and 97% assessment by GEEMA, medication-taking diary, pill count respective. Correlation analysis using score from GEEMA in order to seek factor affect medical adherence and found that age, alcohol, knowledge of disease and medicine, self efficacy, income, social support and healthcare team-patient.

Thidaporn Jirawattanapisal, Opart Karnkawingpong, Ponlasin Narkwichienet and others [55] explored accuracy and compare four different tools consist of pill count, interview, VAS, medical reminder card in monitor adherence among HIV-infected patient in Thailand. The results found that from four tools, there was 90.7% of patient adherence ≥ 95% adherence. Combine of result from four tools had better correlation with HIV viral load than using only one tool.

Those related studies are following Table 2.7

Table 2.7 Related studies of factor affecting adherence

Authors/ year	Objective	Studied sample	Adherence measurement	adherence	Factor associated with adherence
Golin, et al 2002	to access predictor of long-term adherence to new initiated ARV	140 cases	MEMS, pill counts, self-report	71% that adherence >95%	ethnicity, lower income, lower education, higher alcohol use, higher dose frequency, fewer adherence aids were poor adherence
Pinheiro, et al 2002	to access HIV-infected being treat with ARV and factors of adherence	195 cases	self-report	56.9% that adherence >95%	self-efficacy, low dose frequency, number of years of school > 8 yrs were adherence
Glass, et al 2006	to explored HIV –infected by cohort study and factor influence to adherence	3,607 cases	self-report	93% that adherence>95%	younger, lacked social support were non adherence
Maggiolo, et al 2002	to assess the factors associated with non adherence and cause of non adherence	623 cases	self-report	50.9% that adherence >95%	older, lower number of pills, fewer daily doses were adherence
Murri, et al 2001	to assess variables that predictive of non adherence	140 cases	self-report	69% that adherence >95%	younger, vomit and pruritus were non adherence
Duran, et al 2001	to assess the influence of these symptom to adherence	336 cases	self-report	75% that adherence >95%	high number of adverse symptom was non adherence

Authors/ year	Objective	Studied sample	Adherence measurement	adherence	Factor associated with adherence
Murphy, et al 2003	to assess the barriers to ARV in adolescent	231 cases	self-report	28.3% that adherence >95%	ADR, complication in daily routine were non adherence
Schneider, et al 2004	to assess of a better physician-patient relationship to adherence	554 cases	self-report	87% that adherence >95%	better physician-patient associated to adherence
Inthisak, 2008	to assess adherence to ARV and explore the factor affect adherence	21 cases	VAS, pill counts, medication logbook	61.9% that adherence >95%	age, marriage, occupation, communication skill of health care professional, clarify data, sufficient drug supply, number of drug item and ease of oral administration
Punsreniramon, 2006	to assess adherence by using many tools and factors influence adherence and relationship between medication adherence and stage of change	276 cases	pill count, self-report and medication taking diary	91.7% ,95.5%, 97.3% respective	age, alcohol, knowledge of disease and medicine, self-efficacy, income, social support, healthcare term-patient

Authors/ year	Objective	Studied sample	Adherence measurement	adherence	Factor associated with adherence
Turner BJ,2003	to evaluate the factor relationship with adherence	3,249 cases	self-report	82% that adherence> 95%	women have fewer adherence
Howard A.A, 2002	to determine the predict of adherence over time take ARV	161 cases	MEMS	88% that adherence >95%	more than 2 years were adherence

The results in Table 2.7 showed that from thirteen studies, there were eight studies used only self-report for measure adherence, there was one study used MEMS for measure adherence, there were three studies used three tools for measure adherence such as 1) MEMS (medication event monitoring system), pill counts, self-report. 2) VAS, pill counts, medication logbook. 3) Pill counts, self-report, medication taking diary. There was one study used four tools for measure adherence such as pill counts, interview, VAS, medical reminder card. This study used multi-method for measurement the patients' adherence. WHO recommended that it should be an accurate assessment, because adherence tool is necessary for effective and efficient treatment planning. Only one tool may not be valid and may not have high accuracy. This study used the measurement about adherence assessment by tools from the study of Steel, Nwokike, Joshi and others [15] in measurement adherence including Self-report, Visual analogue scale (VAS), Pill Identification Test (PIT), Pill count.

The results from table 2.7 showed that factors associated with adherence were:

1. Patient –related Factors

Gender

The result of Turner [36] studied found that women have fewer adherences than men. The Studied of Littlewood, Vanable, Carey and others [37] found that women have scored higher adherences than men.

Age

The study of Murphy, Belzer, Durako and others [38] found that only 28.3% of adolescents taking all of their prescribed antiretroviral medications in the previous month. Kamolrat Inthisak studied found that younger effect to more than 95% adherence.[19] Glass, De Geest, Weber and others[49] Murri, Marconi, Wu and others[51] found that younger were non adherence.

Knowledge of disease and medication

Kanitta Punsreniramon studied[40] found that Knowledge regarding the disease and antiretroviral therapy on the part of patients knowledge in disease and antiretroviral therapy were associated with adherence in antiretroviral therapy.

Self-efficacy

Golin, Liu, Hays and others [41] found that the patient's good faith and self-efficacy in took antiretroviral medication will increase adherence. Kanitta Punsreniramon studied found that self-efficacy effect to adherence.[40]

Income

Golin, Liu, Hays and others [41] Kanitta Punsreniramon[40] found that lower income were poor adherence.

Education

Golin, Liu, Hays and others[41] Pinheiro, Carvalho-Leite, Drachler and others[48] Thidaporn Jirawattanapisal, Opart Karnkawingpong, Ponlasin Narkwichienet and others[55] found that lower education were poor adherence.

Status

Kamolrat Inthisak[54] found that married were high adherence.

Occupation

Thidaporn Jirawattanapisal, Opart Karnkawingpong, Ponlasin Narkwichienet and others [55] found that had occupation were high adherence.

2. Treatment-related Factors

Adverse effects

Murri, Marconi, Wu and others found that vomit and pruritus were associated with non adherence.[51] Duran, Spire, Raffi and others found that high number of adverse symptom was associated with non adherence.[9] Murhy, Belzer, Durako and others[38] found that ADR were associated with non adherence.

Dose frequency

Golin, Liu, Hays and others [41] Murphy, Belzer, Durako and others [38] Pinheiro, Carvalho-Leite, Drachler and others [48] found that a greater dose frequency was associated with a lower adherence level (p=0.006). However, the total number of pills and the number of antiretroviral medications were not significantly associated with adherence.

Duration of treatment

Howard studied found that the length of time on the prescribed medication that patients on antiretroviral therapy for more than 2 years will have an adherence level more than patients on antiretroviral therapy of 2 years or less than 2 years (p=0.005).[44]

3. Health care team-related Factors

Patient-healthcare provider relationship

A good patient-healthcare provider relationship may be important motivate for took pill and adherence to complex combination drug therapy.[40] Schneider, Kaplan, Greenfield and others[53] found that best physician-patient relationship to adherence.

4. Social or family support

Several studied found that satisfaction with one's social support improved good adherence and non-adherence reported that will less satisfaction with their social support therefore low social support are associated with poor adherence to ART.[40, 49]

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

3.3 Tools of this study and analysis

    3.3.1 Processes to prepare tools

    3.3.2 Process of operational study

    3.3.3 Analysis

    3.3.4 Interpreting results of each tool

3.4 Statistical analysis

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 * (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% (α=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 at0.71. 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.

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CHAPTER IV
RESULTS

This chapter provides the results of the study according to the research methodology which was presented in chapter III. It consists of 8 parts of the results as follow:

4.1 Demographic data

4.2 Treatment data

4.3 Knowledge of disease and medical data

4.4 Self-efficacy in taking antiretroviral data

4.5 Social support data

4.6 Physician-patient relationship data

4.7 Adherence data

4.8 Analyzing the relationship between adherence and the factors affecting patient adherence to ARV medication

4.1 Demographic data

The samples in this study were 200 HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital.

Demographic data in this study such as gender, age, status, educational level, occupation and income were described in tables 4.1 and 4.2

Table 4.1 Demographic data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Demographic Data	No. of Pts.	Percent (%)
Gender		
Male	106	53.0
Female	94	47.0
Status		
Single	82	41.0
Married	87	43.5
Widowed/ divorce / separate	31	15.5
Education		
No study	4	2.0
Primary school	71	35.5
Secondary school	57	28.5
High school	34	17.0
Diploma	8	4.0
Bachelor degree	24	12.0
Master degree or Ph.D. degree	2	1.0
Occupation		
Un-employed	16	8.0
Agriculture	1	0.5
Employee	117	58.5
Housewife	19	9.5
Government official/ state enterprise	2	1.0
Business Owner	36	18.0
Others	9	4.5

Income

< 5,000 Baht/month	84	42.0
5,000-10,000 Baht/month	75	37.5
10,001-15,000 Baht/month	20	10.0
15,001-20,000 Baht/month	13	6.5
>20,000 Baht/month	8	4.0

Table 4.2 Demographic data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Demographic Data	Minimum	Maximum	Average
age	23	61	38.20

Of 200 HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital, majority of the samples were male, 106 cases (53 percent), were married, 87 cases (43.5 percent), were completed primary school, 71 cases (35.5 percent), were employee, 117 cases (58.5 percent), had an income less than 5,000 baht per month, 84 cases (42 percent). The average of age of HIV infected/AIDS patients was 38.20 years-old, minimum of age was 23 years-old and maximum of age was 61 years-old.

4.2 Treatment data

Treatment data in this study including the right of treatment, cause of infection, duration of treatment, adverse event, dose frequency and regimen were described in tables 4.3, table 4.4 and table 4.5

Table 4.3 Treatment data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Treatment Data	No.of Pts.	Percent (%)
Right of treatment		
Out of pocket	2	1.0
CSMBS(Civil servant medical benefit scheme)	2	1.0
SSS (Social security scheme)	54	27.0
UC (Universal coverage)	141	70.5
Other (na.)	1	0.5
Cause of infection		
Homosexual transmission	22	11.0
Heterosexual transmission	131	65.5
Needle	19	9.5
Other	28	14.0
Adverse event		
Adverse event	37	18.5
No adverse event	163	81.5
Dose frequency		
One time/day	53	26.5
Two times/day	141	70.5
Three times/day	6	3.0

Table 4.4 Treatment data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Treatment Data	Minimum	Maximum	Average
Duration of treatment	6 month	204 month	36.84 month

From table 4.3: Treatment data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital showed that majority of the samples were in universal health care coverage program, 141 cases (70.5 percent), contacted infection by heterosexual transmission, 131 cases (65.5 percent), no adverse event from antiretroviral during last 1 month, 163 cases (81.5 percent), at present the patients took ARV medicines two times/day, 141 cases (70.5 percent). Table 4.4 shows minimum, maximum and average of duration of ARV treatment. The results showed that HIV-infected/AIDS patients had an average of duration of treatment of 36.84 months or about 3 years. Minimum duration of treatment was 6 months and maximum duration of treatment was 204 months or about 17 years.

Table 4.5 Regimen of HIV-infected/AIDS

Regimen	No.of Pts.	Percent (%)
d4T+3TC+NVP	17	8.5
3TC+TDF+NVP	4	2.0
3TC+AZT+NVP	77	38.5
3TC+TDF+EFV	49	24.5
3TC+d4T+EFV	19	9.5
LPV+RTV	2	1.0
3TC+AZT+EFV	19	9.5
TDF+3TC+RTV+ATV	8	4.0
3TC+DDI+ LPV+RTV	1	0.5
3TC+TDF+d4T	1	0.5
ABC+3TC+EFV	1	0.5

AZT+3TC+ LPV+RTV	1	0.5
TDF+3TC+LPV+RTV	1	0.5
Total	200	100.0

d4T = stavudine, 3TC = lamivudine, NVP = nevirapine, TDF = tenofovir, AZT = zidovudine, EFV = efavirenz, LPV= lopinavir, RTV = ritonavir, ATV =atazanavir , DDI =didanosine, ABC=abacavir

During the data collection period, 77 patients (38.5%) used 3TC+AZT+NVP or (GPOvirZ).

4.3 Knowledge of disease and medical data

To assess the knowledge of the disease and the medical data of HIV-infected/AIDS patients, the patients were asked to answer the questions related to the knowledge of the disease and the medical which was applied from study of Suttinee Tunpongjaroen [56]. There were 15 questions, so the total scores were 15 scores. The results of the knowledge of disease and medical treatment of HIV-infected/AIDS patients were described in tables 4.6 and 4.7.

Table 4.6 Knowledge of disease and medical data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Knowledge of disease and medicine data (total scores = 15)	Minimum	Maximum	Average
scores	6	15	11.89

Table 4.7 Knowledge of disease and medical data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Question "Knowledge of disease and medicine data"	Answer correct (No.of Pts.)	Answer correct (Percent :%)
1. "AIDS was caused by Human Immunodeficiency Virus (HIV) "	193	96.5
2. "AIDS can contact by sexual transmission only "	127	63.5
3. "AIDS can contact from blood "	182	91.0
4. "AIDS cannot contact from mother transmission to children "	147	73.5
5. "AIDS can cure "	168	84.0
6. "CD4 is the predictor of immune status "	166	83.0
7. "If CD4 increase OIs will decrease "	173	86.5
8. "While you take medicine and you have mild nausea or/and vomiting , you should stop taking medicine "	127	63.5
9. "GPOvir S30 can cause atrophy "	116	58.0
10. "While you take medicine and you have mild rash and itching , you should stop taking medicine "	101	50.5
11. "You can stop medicine if you feel better "	180	90.0
12. "You have to take medicine on time according to physicians' instruction "	198	99.0
13. "You are not required to take medicine completely according to physicians' instruction "	191	95.5
14. "If you take medicine irregularly you may be have drug resistance "	191	95.5
15. "If you have drug resistance in first regimen, you can have drug resistance in the second regimen "	126	63.0

From table 4.6, the evaluation of the knowledge of the disease and medical data of HIV-infected/AIDS patient showed that patients had an average of the knowledge score at 11.89 scores. The maximum score was 15, the minimum score was 6. From table 4.7 we found that HIV-infected/AIDS patients had the most correctly answered in item 12, which asked "you have to take medicine on time depending on physician instruction" 198 cases (99 percent). The second most correctly answered item is item 1 "AIDS was caused by Human Immunodeficiency Virus (HIV)", 193 cases (96.5 percent). The correct scores of other questions were, item 13 "you are not required to take medicine completely according to physicians' instruction ", 191 cases (95.5 percent), item 14 "if you take medicine irregularly you may be have drug resistance ", 191 cases (95.5 percent), item 3 "AIDS can contact from blood ", 182 cases (91 percent), item 11 "you can stop medicine if you feel better ", 180 cases (90 percent), item 7 "if CD4 increase, OIs will decrease", 173 cases (86.5 percent), item 5 "AIDS can cure ", 168 cases (84 percent), item 6 "CD4 is the predictor of immune status ", 166 cases (83 percent), item 4 "AIDS cannot contact from mother transmission to children ", 147 cases (73.5 percent), item 2 "AIDS can contact by sexual transmission only ", 127 cases (63.5 percent), item 8 "while you take medicine and you have mild nausea or/and vomiting, you should stop taking medicine ", 127 cases (63.5 percent), item 15 "if you have drug resistance in first regimen, you can have drug resistance in the second regimen ", 126 cases (63 percent), item 9 " GPOvir S30 can cause atrophy ", 116 cases (58 percent), item 10 "while you take medicine and you have mild rash and itching, you should stop taking medicine ", 101 cases (50.5 percent), respectively.

The 25 and 75 percentile of the score were used to classify the level of knowledge of the disease and medical data. The results showed that there were 50 cases, (25 percent) who were classified into low knowledge level. There were 65 cases, (32.5 percent) who were classified into moderate knowledge level. There were 85 cases, (42.5 percent) who were classified into high knowledge level as follow table 4.8

Table 4.8 Knowledge level

Knowledge level	No.of Pts.	Percent (%)
low	50	25.0
moderate	65	32.5
high	85	42.5

4.4 Self-efficacy in taking antiretroviral data

      To assess the self-efficacy in taking antiretroviral the HIV-infected /AIDS patients were asked about their confidence in difference situation. The self-efficacy evaluation tools was tested to check the reliability, the cronbach's alpha was 0.896. The patients were asked to rate their confidence to take ARV medications in 12 different situations. The questionnaire was applied from study of Smith, Rublein, Marcus and others [59]. Patients were asked to rank their confidence to take medicine on time and regularly in each specific situation from least confidence (1) to highest confidence (5) based on Likert scale concept. The results of evaluation with self–efficacy to take antiretroviral of HIV-infected/AIDS were described in table 4.9 and table 4.10.

Table 4.9 Self-efficacy in taking antiretroviral drugs of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Self-efficacy in take antiretroviral data (total scores = 60)	Minimum	Maximum	Average
scores	16	60	49.47

Table 4.10 Self-efficacy in taking antiretroviral data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

item	Question of Self-efficacy in took antiretroviral data "You had self-efficacy to take ARV, when you in each specific situation"	Average (scores) (total scores=5)
1	"When you are at home"	4.58
2	"Even though the pills may be big and difficult to swallow"	4.32
3	"When nobody reminds you about the time that you should take the medicine"	3.97
4	"During the weekend"	4.31
5	"When the medicine can cause mild side effects"	3.68
6	"When you feel healthy"	4.41
7	"When you are very sick"	3.77
8	"When you are in sorrow"	3.81
9	"While you have long trip"	4.00
10	"When you have to take ARV medicine in front of the people who do not know that you are infected"	3.74
11	"You can strict to your medicine schedule for the next 7 days"	4.36
12	"You can strict to your medicine schedule for the next 14 days"	4.39

From table 4.9, the evaluation of self-efficacy in taking antiretroviral of HIV-infected/AIDS patient showed that the average of the self-efficacy score was 49.47. The maximum self-efficacy score was 60, the minimum self-efficacy score was 16. From table 4.10, it was found that the self-efficacy score in each situation were, item 1 "when you are at home", 4.58 scores, item 6 " when you feel healthy ", 4.41 scores, item 12 " you can strict to your medicine schedule for the next 14 days ", 4.39 scores, item 11 "you can strict to your medicine schedule for the next 7 days " 4.36 scores, item 2 "even though the pills may be big and difficult to swallow", 4.32 scores, item 4 "during the weekend", 4.31 scores, item 9 "while you have a long trip", 4.00 scores, item 3 "when nobody reminds you about the time you should take the medicine", 3.97 scores, item 8 "when you are in sorrow", 3.81 scores, item 7 "when you are very sick", 3.77 scores, item 10 "When you have to take ARV medicine in front of the people who do not know that you are infected", 3.74 scores and to get mean minimum point is item 5 "when the medicine can cause mild side effects", 3.68 scores, respectively.

Using the 25 and 75 percentile to classify the level of self-efficacy in taking antiretroviral, the results showed that there were 46 cases, (23 percent) who were classified into low self-efficacy level. There were 103 cases, (51.5 percent) who were classified into moderate self-efficacy level. There were 51 cases, (25.5 percent) who were classified into high self-efficacy level as described in table 4.11

Table 4.11 Self-efficacy level

Self-efficacy level	No. of Pts.	Percent (%)
low	46	23.0
moderate	103	51.5
high	51	25.5

4.5 Social support data

The social support evaluation tool was tested to check the reliability; the cronbach's alpha was 0.957. The questionnaire was applied from study of Sherbourne

[60] and there was 10 items. Patients were asked to rank about weather there were someone who can support them in each situation or not, from none of the time (1) to all of the time (5) based on Likert scale concept. The results of evaluation with social support of HIV-infected/AIDS were described in table 4.12 and table 4.13.

Table 4.12 Social support data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Social support data (total scores = 50)	Minimum	Maximum	Average
scores	10	50	38.49

Table 4.13 Social support data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

item	Question of social support data	Average (scores) (total scores=5)
1	"You have someone to listen to you when you need to talk with"	3.74
2	"You have someone to give you good advice when you have a problem"	3.74
3	"You have someone to cheer you up when you are worried"	3.87
4	"You have someone who understands your health problem"	3.91
5	"You have someone to help you if you were confined to bed"	3.81

6	"You have someone to accompany you to visit the doctor if you needed"	3.59
7	"You have someone who love you "	4.05
8	"You have someone who make you feel relax"	3.99
9	"You have someone who can do something together with you enjoyable"	3.79
10	"You have someone to help you without expectation to get something from you "	4.03

From table 4.12, the evaluation of social support of HIV-infected/AIDS patient showed that patients had an average of the social support score at 38.49 scores. The maximum social support score was 50, the minimum social support score was 10. From table 4.13, it was found that HIV-infected/AIDS patients had the highest mean score in item 7 "you have someone who love you " 4.05 scores, item 10 "you have someone to help you without expectation to get something from you", 4.03 scores, item 8 "you have someone who make you feel relax ", 3.99 scores, item 4 "you have someone who understands your health problem", 3.91 scores, item 3 "you have someone to cheer you up when you are worried ", 3.87 scores, item 5 "you have someone to help you if you were confined to bed", 3.81 scores, item 9 "You have someone who can do something together with you enjoyable", 3.79 scores, item 2 "you have someone to give you good advice when you have a problem", 3.74 scores, item 1 "you have someone to listen to you when you needed", 3.74 scores and item 6 "you have someone to accompany you to visit the doctor if you needed", 3.59 scores respectively.

Using the 25 and 75 percentile to classify the level of social support, the results showed that there were 48 cases, (24 percent) who were classified into low social support level. There were 92 cases, (46.0 percent) who were classified into moderate social support level. There were 60 cases, (30.0 percent) who were classified into high social support level as was described in table 4.14.

Table 4.14 Social support level

Social support level	No.of Pts.	Percent (%)
Low	48	24.0
moderate	92	46.0
high	60	30.0

4.6 Physician-patient relationship data

The cronbach's alpha of the physician-patient relationship evaluation tool was 0.945. There were 15 questions, so the total scores were 75 scores. The questionnaire was applied from study of Schneider, Kaplan, Greenfield and others [61]. Patients were asked to rank about their relationship with healthcare provider, from poor (1) to excellent (5) based on Likert scale concept. The results of evaluation with physician-patient relationship of HIV-infected/AIDS were described in table 4.15 and table 4.16.

Table 4.15 Physician-patient relationship data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Physician-patient relationship data (total scores = 75)	Minimum	Maximum	Average
scores	18	75	60.25

Table 4.16 Physician-patient relationship data of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital

Item	Question of Physician-patient relationship data	Average (scores) (total scores=5)
1	"Healthcare providers suggest you what to do when there is an adverse event "	3.87
2	"Healthcare providers take care of you "	3.99
3	"Healthcare providers understand your worry about your health"	3.91
4	"Healthcare providers explain to you about the sexual activities"	4.01
5	"Healthcare providers ask you about stress in your life that may affect your health "	3.77
6	"Healthcare providers explain about ARV medication usage "	4.32
7	"Healthcare providers understand your problems in taking ARV medicine "	4.05
8	"Healthcare providers help you to solve your problems in taking ARV medicine "	3.90
9	"Healthcare providers get you to participate in selection of the medicine that you would prefer "	3.60
10	"Healthcare providers offer choices to your medicine and tell about the categories of medicines"	3.87
11	"Healthcare providers discuss the pros and cons of each choice with you "	3.99

12	"Healthcare providers are friendly "	4.20
13	"Healthcare providers answer clearly in your medicine and AIDS "	4.25
14	"Healthcare providers have knowledge and competency in treatment"	4.27
15	"You trust for health care providers' treatment"	4.38

From table 4.15, the evaluation of physician-patient relationship of HIV-infected/AIDS patient showed that patients had an average score of physician-patient relationship at 60.25. The maximum physician-patient relationship score was 75, the minimum physician-patient relationship score was 18. From table 4.16, it was found that the highest score of the patient provider relationship was in item 15 "You trust for health care providers' treatment ", 4.38 scores, item 6 "Healthcare providers explain about ARV medication usage ", 4.32 scores, item 14 "Healthcare providers have knowledge and competency in treatment ", 4.27 scores, item 13 "Healthcare providers answer clearly in your medicine and AIDS ", 4.25 scores, item 12 "Healthcare providers are friendly ", 4.20 scores, item 7 " Healthcare providers understand your problems in taking ARV medicine", 4.05 scores, item 4 "Healthcare providers explain to you about the sexual activities", 4.01 scores, item 2 "Healthcare providers take care of you ", 3.99 scores, item 11 "Healthcare providers discuss the pros and cons of each choice with you ", 3.99 scores, item 3 "Healthcare providers understand your worry about your health", 3.91 scores, item 8 "Healthcare providers help you to solve your problems in taking ARV medicine ", 3.90 scores, item 1 "Healthcare providers suggest you what to do when there is an adverse event ", 3.87 scores, item 10 "Healthcare providers offer choices in your medicine and tell about the categories of medicine ", 3.87 scores, item 5 "Healthcare providers ask you about stress in your life that may affect your health ", 3.77 scores and item 9 "Healthcare providers get you to participate in selection of the medicine that you would prefer ", 3.60 scores, respectively.

Using the 25 and 75 percentile to classify the level of physician-patient relationship, the results showed that there were 49 cases, (24.5 percent) who were classified into low physician-patient relationship level. There were 101 cases, (50.5 percent) who were classified into moderate physician-patient relationship level. There were 50 cases, (25.0 percent) who were classified into high physician-patient relationship level as follow in table 4.17

Table 4.17 Physician-patient relationship level

physician-patient relationship	No. of Pts.	Percent (%)
low	49	24.5
moderate	101	50.5
high	50	25.0

4.7 Adherence level of HIV-infected/AIDS patient

The evaluation tools about the adherence of HIV-infected/AIDS consists of self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count which was applied from STEEL G studied[15].

1. Self-report was a series of questions where the patient's response was yes or no. Each question consisted of four items and asked about the patients' behaviors in taking ARV medicines.

2. Visual analogue scale (VAS) was a tool where patients were asked to rate their adherence behavior to their medication over the past four weeks. A line started from 0 to 10. The scale at 10 mean he or she took all medicine dosage and scale at 0 mean he or she missed all of the dosage.

3. Pill Identification Test (PIT) was a tool where the patients were asked to specify the number of pills per dose, time that the medications were taken and the additional information.

4. Pill count was a tool that the patients were asked about the remaining of medicine since the date of their last visit, then calculate percent adherence from the following formula:

% Adherence = (Dispensed – Returned) / (Expected to be taken) * 100

Example

The physician prescribed GPOvirZ 250 in the dosage regimen 2 times a day, for example, take 1 tab (8.00) 1 tab (20.00). The amount of ARV prescribed was 180 pills and the patient returned in the container was 14 pills:

% Adherence = (Dispensed – Returned) / (Expected to be taken) * 100
= (180-14)/ (180)*100
% Adherence = 92%

The details of each result from each tool (self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count) were presented in table 4.18.

Table 4.18 The compliance results of each tool (self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count)

Tools	No. of Pts.	Percent (%)
Self-report		
Self-report was No in all questions	161	80.5
Self-report was Yes in 1 question	33	16.5
Self-report was Yes in 2 or more questions	6	3.0
VAS		
VAS was 95% or more	142	71.0
VAS was 75-94%	48	24.0
VAS was Less than 75%	10	5.0
PIT		
patient knows dose, time and instructions	163	81.5
patient knows dose, time	33	16.5
patient knows dose only or confused	4	2.0
Pill count		
Pill count was 95% or more	176	88.0
Pill count was 75%-94%	17	8.5
Pill count was Less than 75%	7	3.5

From table 4.18, the results of each tool such as self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count showed that number of the patients who answered No in all questions in self report tool was 161 cases (80.5 percent), the patients who had VAS at 95% or more was 142 cases (71.0 percent), the patient known dose, time and instructions was 163 cases (81.5 percent) and the pill count at 95% or more was 176 cases (88.0 percent).

The results of overall adherence were interpreted based on the concepts 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%
Overall adherence	High	Moderate	Low

1. If all results appeared in the same column, e.g. self-report was All No, VAS was 95% or more, PIT was Dose, Time and instructions and pill count was 95% or more, then the overall level of adherence was "High".

2. If the results do not all line up in a single vertical column such as if the results were spread over two columns, took the adherence level of the right hand column as the estimated adherence e.g. self-report was yes to 2 or more questions, VAS was 75%-94 %, PIT was dose and time and pill count was 95% or more, then the overall level of adherence was "Low".

3. If the results were spread over three columns, then use the middle level of adherence e.g. self report was yes to 1 question, VAS was less than 75%, PIT was dose and time and pill count was 95% or more, then the overall level of adherence was "Moderate".

The results of the adherence level of HIV-infected/AIDS patients were described in table 4.19.

Table 4.19 The adherence level of HIV-infected/AIDS patients

Adherence level	No. of Pts.	Percent (%)
High	140	70.0
Moderate	42	21.0
Low	18	9.0
Total	200	100.0

Table 4.19 showed number of patients, percent, and adherence level of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN hospital. It was found that 140 cases (70 percent) of HIV-infected/AIDS had an adherence of a high level, 42 cases (21 percent) in had moderate level, and 18 cases (9 percent) had low adherence level

To classify the adherence of the HIV infected/AIDS patients, 2 conditions were used as described below.

1. If the patients had overall adherence at high level then the patient is adherence to ARV treatment.
2. If the patients had overall adherence at moderate or low then the patient is non-adherence to ARV treatment.

The adherence to ARV treatment of HIV-infected/AIDS patients in this study was presented in table 4.20

Table 4.20 The adherence to ARV treatment of HIV-infected/AIDS patients

Result of adherence	No. of Pts.	Percent (%)
non adherence	60	30.0
Adherence	140	70.0
Total	200	100.0

Table 4.20 shows number of patients, percent and adherence of HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN hospital. It was found that 140 cases (70 percent) of HIV-infected/AIDS patients adhered to ARV treatment, and 60 cases (30 percent) of HIV-infected/AIDS not adhered to ARV treatment.

4.8 Analytical the relationship between adherence and the factors affecting patient adherence to ARV medication

The multivariate logistic regression analysis was used to analyze the relationship between the factors affecting patient adherence to ARV medication. Based on the conceptual framework, there were 13 factors that were analyzed to find the relationship to adherence to ARV treatment included self-efficacy, knowledge of disease and medicine, gender, age, status, education, occupation, income, adverse effect, duration of treatment, dose frequency, patient-health care provider relationship and social support . The results were presented in table 4.21.

Table 4.21 Variables in the Equation

	B	S.E.	df	P-value	Exp(B)	95.0% C.I. for EXP(B)	
						Lower	Upper
female	0.917	0.356	1	0.010	2.501	1.244	5.031
low self-efficacy point			2	0.024			
moderate self-efficacy point	0.977	0.616	1	0.113	2.656	0.794	8.884
high self-efficacy point	1.417	0.536	1	0.008	4.126	1.444	11.789
low patient-provider relationship point			2	0.012			
moderate patient-provider relationship point	1.474	0.550	1	0.007	4.367	1.485	12.846
high patient-provider relationship point	0.530	0.488	1	0.278	1.699	0.652	4.425
constant	-3.095	0.607	1	0.000	0.045		

Table 4.21 showed the odd ratio (OR) or Exp (B) of the relationship between the factors affecting patient adherence to ARV medication. The factors consisted of self-efficacy, knowledge of disease and medicine, gender, age, status, education, occupation, income, adverse effect, duration of treatment, dose frequency, patient-health care provider relationship and social support with adherence to ARV medicine. There were factors associated with adherence to ARV treatment included female, self-efficacy and patient-health care provider relationship. The odds of relationship of 3 three factors were described below:

1. Female had a higher adherence level for 2.501 times compared to male (OR: 2.501: 95%CI: 1.244-5.031).

2. The moderate level of self-efficacy had a higher adherence level for 2.656 times compared to low level of self-efficacy.(OR: 2.656: 95%CI: 0.794-8.884) and the high level of self-efficacy had a higher adherence level for 4.126 times compared to low level of self-efficacy.(OR: 4.126: 95%CI: 1.444-11.789).

3. The moderate level of patient-health care provider relationship had a higher adherence level for 4.367 times compared to with low level of patient-health care provider relationship (OR: 4.367: 95%CI: 1.485-12.846) and the high level of patient-health care provider relationship had a higher adherence level for 1.699 times compared to low level of patient-health care provider relationship (OR: 1.699: 95%CI: 0.652-4.425). This study had not found any relationship between status, education, occupation, income, knowledge of disease and medicine, age, adverse effect, duration of treatment, dose frequency, social support and adherence to ARV medicine.

Prediction equation of adherence to ARV medicine

The prediction equation of adherence to ARV medicine was presented as follows:

Prediction equation = Z = -3.095 + 2.501(female) +2.656(moderate self-efficacy point) +4.126(high self-efficacy point) +4.367(moderate patient provider point) +1.699(high patient provider point)

This equation had rate of predicting correctly or overall hit rate for at 74.5 percent of 200 HIV-infected/AIDS patients as were presented in table 4.22:

Table 4.22 Overall hit rate equal

		Predicted		
		Adherence		Percentage Correct
Observed		Adherence	non adherence	
adherence	adherence	133	7	95.0
	non adherence	44	16	26.7
	Overall Percentage			74.5

CHAPTER V
CONCLUSION AND DISCUSSION

Conclusion and discussion

The study of "Adherence assessment and factors affecting adherence to ART among HIV-infected/AIDS at TAKSIN hospital" was an analytical, cross–sectional study. The objectives of this study were to assess the adherence to ARV medication among HIV-infected/AIDS patients at TAKSIN hospital by using multiple adherence measurement and to analyze the relationship between the factors affecting patient adherence to ARV medication. The data collection was conducted by using interviewing and assessment tools during March to April 2010 in HIV-infected/AIDS outpatient clinic at TAKSIN Hospital. The samples were 200 HIV/AIDS patients who took antiretroviral therapy.

5.1 Demographic data

The sample in this study is 200 HIV-infected/AIDS patients who took antiretroviral therapy at TAKSIN Hospital, it was found that majority of the samples were male, 106 cases (53 percent), were married, 87 cases (43.5 percent), were completed primary school, 71 cases (35.5 percent), were employee, 117 cases (58.5 percent), had an income less than 5,000 baht per month, 84 cases (42 percent). The average age of the patients was 38.2 years-old.

5.2 Treatment data

It was found that majority of the samples were in universal health care coverage program, 141 cases (70.5 percent), contacted infection due to heterosexual transmission, 131 cases (65.5 percent), no adverse event from antiretroviral within 1 month, 163 cases (81.5 percent), during the data collection period the patients took ARV medicines two times/day, 141 cases (70.5 percent), had an average of duration of treatment of 3 years.

5.3 Knowledge of disease and medicine data

It was found that the patients had average of the score knowledge at 11.89 scores. The most correctly answered question was item 12, which asked "you have to take medicine on time depending to physician s' instruction " 198 cases (99 percent) and least correctly answered question was item 10, "while you take medicine and you have mild rash and itching ,you should stop taking medicine " 101 cases (50.5 percent). Using the 25 and 75 percentile to classify the level of knowledge of the disease and medical data, the results showed that there were 50 cases, (25 percent) who were classified into low knowledge level. There were 65 cases, (32.5 percent) who were classified into moderate knowledge level. There were 85 cases, (42.5 percent) who were classified into high knowledge level. These results showed that majority of HIV-infected/AIDS patients did not know what to do when they had mild adverse event due to ARV medicine. They usually stopped to take medicine when they had mild adverse event. This situation can increase drug resistance and treatment failure in the future. Therefore healthcare provider should provide the important information that when they faced with mild adverse event they should go back to see the doctor.

5.4 Self-efficacy in take antiretroviral data

It was found that patients had an average of the score self-efficacy at 49.47 scores. The most confidence to take ARV medication was item 1 "when you are at home", 4.58 scores and the least confidence to take ARV medication was item 5 "when the medicine can cause mild side effects", 3.68 scores. Using the 25 and 75 percentile to classify the level of self-efficacy in taking antiretroviral, the results showed that there were 46 cases, (23 percent) who were classified into low self-efficacy level. There were 103 cases, (51.5 percent) who were classified into moderate self-efficacy level. There were 51 cases, (25.5 percent) who were classified into high self-efficacy level. These results showed that majority of HIV-infected/AIDS patients had least self-efficacy to take ARV medicine when the medicine caused mild side effects. This situation can increase drug resistance and treatment failure in the future. Therefore, healthcare provider should provide suggestion to patients when they faced an adverse event from antiretroviral treatment in order to increase self-efficacy in taking antiretroviral therapy on time and regularly.

5.5 Social support data

It was found that patients had average of the score social support was 38.49 scores. The highest average score of social support was item 7 "you have someone who love you", 4.05 scores, and least average score was item 6 "you have someone accompany you to see the doctor if you needed it", 3.59 scores. Using the 25 and 75 percentile to classify the level of social support, the results showed that there were 48 cases, (24 percent) who were classified into low social support level. There were 92 cases, (46.0 percent) who were classified into moderate social support level. There were 60 cases, (30.0 percent) who were classified into high social support level. The majority of HIV-infected/AIDS patient were not have someone to accompany them to visit the doctor. Therefore, health care providers had to give consultation and care with patients regarding to the social support of patients such as parents, siblings relative, friends and girlfriend in order to increase effective treatment of patients.

5.6 Physician-patient relationship data

It was found that patients had average of the score physician-patient relationship at 60.25 scores. The highest average score of the patient provider relationship was item 15 "You trust to health care providers' treatment", 4.38 scores and the least average score was item 9 "Healthcare provider get you participate in selection ARV medicine that you would prefer", 3.60 scores. Using the 25 and 75 percentile to classify the level of physician-patient relationship, the results showed that there were 49 cases, (24.5 percent) who were classified into low physician-patient relationship level. There were 101 cases, (50.5 percent) who were classified into moderate physician-patient relationship level. There were 50 cases, (25.0 percent) who were classified into high physician-patient relationship level. Therefore, healthcare provider should provide the best relationship to the patients in order to improve the relationship with the patients then it would affect to the quality of treatment.

5.7 Adherence data

The evaluation of adherence to ARV medicine of HIV-infected/AIDS patient by using multi-method such as self-report, visual analogue scale (VAS), pill identification test (PIT) and pill count based on the recommendation of WHO

recommendation [35] was used in this study. WHO recommended that accurate assessment adherence was necessary for effective and efficient treatment. Using many tools to assess adherence was found in the studied of Steel, Nwokike, Joshi and others [15] and studied of Thidaporn Jirawattanapisal, Opart Karnkawingpong, Ponlasin Narkwichienet and others [55]. The majority of HIV-infected/AIDS patients in this study adhered to ARV medication, 140 cases (70 percent).

The results from Paterson, Swindells, Mohr and others[13] studies found that percentage adherence of more than 95 percent adherence had been necessary for HIV viral suppression and the relation between adherence and viral load (VL) was proved that if adherence decreases then viral load (VL) will be increase as a counter dose–response effect. Good adherence to antiretroviral will be increase efficacy of treatment such as preserve immunologic function, increase CD4 and decrease opportunistic infections, decrease HIV-related morbidity and prolong survival, suppress viral load, prevent vertical HIV transmission.[1,6,23] Therefore healthcare providers should aware to the importance of adherence and tried to improve the adherence in every process of the treatment, regularly.

5.8 Analytical the relationship between adherence and the factors affecting patient adherence to ARV medication

It was found that female, self-efficacy and patient-health care provider relationship had high associate with adherence to ARV medicine, significantly, ($p < 0.05$).

1. Female had a higher adherence level for 2.501 times compared to male (OR: 2.501: 95%CI: 1.244-5.031).

2. The moderate level of self-efficacy had a higher adherence level for 2.656 times compared to low level of self-efficacy (OR: 2.656: 95%CI: 0.794-8.884) and high level of self-efficacy had a higher adherence level for 4.126 times compared to with low level of self-efficacy (OR: 4.126: 95%CI: 1.444-11.789).

3. The moderate level of patient-health care provider relationship had a higher adherence level for 4.367 times compared to with low level of patient-health care provider relationship (OR: 4.367: 95%CI: 1.485-12.846) and high level of patient-health care provider relationship had a higher adherence level for 1.699 times

compared to low level of patient-health care provider relationship (OR: 1.699: 95%CI: 0.652-4.425).

However, this study had not found the association between status, education, occupation, income, knowledge of disease and medicine, age, adverse effect, duration of treatment, dose frequency, social support and adherence to ARV medicine.

It was found that the female, self-efficacy and patient-health care provider relationship had an association with adherence to ARV medicine, significantly ($p < 0.05$).

Female associated to adherence to ARV medicine was similar to the study of Littlewood, Vanable, Carey and others [37] which was found that women associated to the increasing of adherences.

Self-efficacy associated to adherence to ARV medicine was similar to the study of Golin, Liu, Hays and others [41] and Kanitta Punsreniramon studied [40] which were found that self-efficacy affect to adherence.

Patient-healthcare provider relationship associated to adherence to ARV medicine was similar to the study of Schneider, Kaplan, Greenfield and others [61] and the study of Kanitta Punsreniramon.[40]

This study had not found any association between status, education, occupation, income, knowledge of disease and medicine, age, adverse effect, duration of treatment, dose frequency, social support and adherence to ARV medicine.

Marital status not associated to adherence was not similar to the study of Kamolrat Inthisak[54] which was found that married affect to adherence.

Education not associated to adherence was not similar to the study of Thidaporn Jirawattanapisal, Opart Karnkawingpong, Ponlasin Narkwichienet and others [55] which were found that lower education affect to non adherence.

Occupation not associated to adherence was different to the study of Thidaporn Jirawattanapisal, Opart Karnkawingpong, Ponlasin Narkwichienet and others [55] which were found that occupation affect to adherence.

Income were not associate to adherence that difference from study of Golin, Liu, Hays and others[41] that found that low income to affect non adherence.

Knowledge of disease and medicine were not associate to adherence that difference from study of Kanitta Punsreniramon studied [40] that found that knowledge regarding the disease and antiretroviral therapy on the part of patients

knowledge in disease and antiretroviral therapy were associated with adherence in antiretroviral therapy.

Age were not associate to adherence that difference from study of Kamolrat Inthisak[19] studied that found that younger affect to more than 95% adherence.

Adverse effect were not associate to adherence that difference from study of Duran, Spire, Raffi and others[9] found that high number of adverse symptom was affect to non adherence.

Duration of treatment were not associate to adherence that difference from study of Howard[44] that found that the length of time on the prescribed medication that patients on antiretroviral therapy for more than 2 years will had an adherence level more than patients on antiretroviral therapy of 2 years or less than 2 years (p=0.005).

Dose frequency were not associate to adherence that difference from study of Golin, Liu, Hays and others[41] Murphy, Belzer, Durako and others[38] Pinheiro, Carvalho-Leite, Drachler and others[48] that found that a greater dose frequency was associated with a lower adherence level (p=0.006).

Social support were not associate to adherence that difference from study of Kanitta Punsreniramon[40] that found that social support had affect to adherence.

This study show that the female, self-efficacy and patient-health care provider relationship that had associate with adherence to ARV medicine, significance (p<0.05).

Therefore, health care providers should provide the programs to enhance the self-efficacy of the HIV/AIDS patients and also establish the good relationship between patients-providers in order to increase the adherence level to improve the effectiveness of treatment in HIV/AIDS patients.

Limitation of this study

1. This study was an analytical and a cross-sectional study then it may not be appropriate to measure adherence to ARV medicine only one time, in order to confirm the results, we should have a repeated measurement to adherence more than one time.

2. The majority of questionnaires were Likert scale and close questionnaire. Some additional details such as the reason why they do or do not were not being included in the questionnaire. It may limit the response in patients' answering.

3. Data collection was done by interviewing in the hall which may not have privacy.

Recommendations based on the results

1. Multi-method was more effectiveness in classifying adherence than only one method.

2. Health care providers should pay more attention to male HIV-infected/AIDS patients than female because male patients usually have lower level of adherence than female patients.

3. Health care providers should provide the programs to enhance self-efficacy, good relationship between patient-providers in order to increase adherence level such as providing the privacy room for HIV-infected/AIDS patients consultation and also for the activities with their friends.

4. The pharmacists should be one of the health care team to take care of HIV-infected/AIDS patients and give information about ARV medications that they take, and consult them for the antiretroviral therapy side effects, in order to increase good relationship and good perception that affected to patients' adherence.

Policy Recommendations

1. It was found that female, self-efficacy in taking medicine and good relationship between patient-providers affected to good adherence therefore health care providers in hospital should pay more attention to male HIV-infected/AIDS patients than generally in order to increase adherence and health care providers should provide the programs to enhance self-efficacy, good relationship between patient-providers in order to increase adherence level.

2. In the future the multi-method for assessment adherence to antiretroviral therapy should be applied in clinical practice.

Recommendations for further study

1. Further study should be designed to measure adherence every 3 months and 6 months to monitor the adherence level.

2. Further study should use the opened questionnaire to ask patients about their opinion and reasons of the patients concerning the factors affected adherence in order to find their causes of miss dose.

References

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APPENDIX

ลำดับที่................

แบบสอบถามเพื่อการวิจัย

**เรื่อง การวัดความร่วมมือและปัจจัยที่มีผลต่อความร่วมมือในการใช้ยาต้านไวรัสเอดส์ใน
ผู้ป่วยที่ติดเชื้อเอชไอวีและผู้ป่วยเอดส์ ณ โรงพยาบาลตากสิน**

<u>หมายเหตุ</u>:   ข้อมูลของท่านจะถูกเก็บเป็นความลับ และถูกนำเสนอในแบบภาพรวม
เท่านั้น และ ข้อมูลที่ท่านตอบต่อไปนี้จะไม่มีผลกระทบใดๆต่อการรักษาที่ท่านกำลัง
ได้รับอยู่และไม่สามารถระบุหรือบ่งชี้ถึงตัวท่านได้

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ตอนที่ 1 ข้อมูลทั่วไปของผู้ป่วยและประวัติการรักษาของผู้ป่วย

คำชี้แจง กรุณาทำเครื่องหมาย /   ลงในช่อง ( ) ที่ต้องการ หรือเติมข้อความในที่ว่างที่
กำหนด

1. เพศ

( ) 1. ชาย   ( ) 2. หญิง

2. อายุ...............ปี

3.สถานภาพ

( ) 1. โสด   ( ) 2. สมรส   ( ) 3. หม้าย/หย่า/แยกกันอยู่

4.ระดับการศึกษาสูงสุด

( ) 1. ไม่ได้เรียนหนังสือ   ( ) 2. ประถมศึกษา   ( ) 3. มัธยมศึกษา

( ) 4. มัธยมปลาย / ปวช. หรือเทียบเท่า   ( ) 5. ปวส. /อนุปริญญา หรือเทียบเท่า

( ) 6. ปริญญาตรี   ( ) 7. สูงกว่าปริญญาตรี

5. อาชีพ

( ) 1. ไม่ได้ประกอบอาชีพ ( ) 2. เกษตรกร   ( ) 3. รับจ้าง/ลูกจ้าง

( ) 4. เกษียณอายุ   ( ) 5. แม่บ้าน/พ่อบ้าน ( ) 6. ข้าราชการ/พนักงานรัฐวิสาหกิจ

( ) 7. ค้าขาย/เจ้าของกิจการ ( ) 8. นักเรียน/นักศึกษา ( ) 9.อื่นๆ(โปรดระบุ.....................)

6.รายได้

( ) 1. ต่ำกว่า 5,000 บาท   ( ) 2. 5,000 – 10,000 บาท

( ) 3. 10,001 – 15,000 บาท   ( ) 4. 15,001 – 20,000 บาท

( ) 5. มากกว่า 20,000 บาท

7.ปัจจุบันเข้ารับการรักษาที่คลินิกยาเสพติดด้วยหรือไม่

( ) 1. ใช่ (โปรดระบุ.....................)

( ) 2. ไม่ใช่

8. สิทธิในการรักษาพยาบาล

( ) 1.ชำระเงินสด   ( ) 2. สวัสดิการข้าราชการ

( ) 3. ประกันสังคม   ( ) 4. บัตรทอง

( ) 5. อื่นๆ (โปรดระบุ.............................)

9. สาเหตุที่ได้รับการติดเชื้อ

( ) 1.ทางเพศสัมพันธ์(ชายกับชาย)   ( ) 2. ทางเพศสัมพันธ์(ชายกับหญิง)

( ) 3. ทางเข็มฉีดยา   ( ) 4. อื่นๆ(โปรดระบุ..................................)

10. ระยะเวลาในการใช้ยาต้านไวรัสเอดส์ตั้งแต่เริ่มรักษาที่นี่จนถึงปัจจุบัน...........เดือน/ปี

11. ในระยะ 1 เดือนที่ผ่านมา ท่านรับประทานยาต้านไวรัสแล้วเกิดอาการไม่พึงประสงค์ จากยา เช่น คลื่นไส้อาเจียน มึนหัวเวียนหัว ผื่นคันตามตัว ผื่นแดงนูนขึ้นรุนแรงมาก หรือ อื่นๆที่แพทย์วินิจฉัย หรือไม่

( ) 1. เกิดอาการไม่พึงประสงค์ (โปรดระบุ....................................)

( ) 2. ไม่เกิดอาการไม่พึงประสงค์

ตอนที่ 2 ความรู้เรื่องโรคและยา

คำชี้แจง กรุณาทำเครื่องหมาย / ลงในช่อง ที่ตรงกับความคิดเห็นของท่านมากที่สุด

คำถามต่อไปนี้เป็นคำถามเพื่อประเมินความรู้เกี่ยวกับโรคเอดส์และเข้าใจเรื่องยา

คำถาม	ถูก	ผิด	ไม่แน่ใจ
1.โรคเอดส์เป็นโรคที่เกิดจากการติดเชื้อไวรัสเอชไอวี			
2.โรคเอดส์สามารถติดต่อได้ทางเพศสัมพันธ์เท่านั้น			
3.โรคเอดส์ติดต่อกันได้ทางเลือด			
4.โรคเอดส์ไม่สามารถติดต่อ จากแม่ไปสู่ลูก			
5.โรคเอดส์สามารถรักษาให้หายขาดได้			
6.ค่าซีดีโฟร์(CD4) เป็นค่าที่บอกถึงภูมิคุ้มกันของร่างกายต่อโรคติดเชื้ออื่นๆ			
7.ถ้าค่าซีดีโฟร์สูงขึ้นจะลดการเกิดโรคติดเชื้อฉวยโอกาสหรืออาการแทรกซ้อนอื่นๆ			
8.หากกินยาต้านไวรัสเอดส์แล้วมี อาการคลื่นไส้อาเจียนแม้เล็กน้อย ควรหยุดยาทันที			
9.ยาจีพีโอเวียร์(GPOvir S30) สามารถทำให้เกิดอาการแก้มตอบได้			
10.หากกินยาต้านไวรัสเอดส์แล้วมี อาการผื่นแดงนูนและมีอาการคันเล็กน้อย ควรหยุดยาทันที			
11.คุณสามารถหยุดใช้ยาต้านไวรัสเอดส์ได้หากมีอาการดีขึ้น			
12.คุณต้องกินยาต้านไวรัสเอดส์ให้ ตรงเวลา ตามที่แพทย์สั่ง			
13.คุณไม่จำเป็นต้องกินยาต้านไวรัสเอดส์ให้ ครบตามจำนวนที่แพทย์สั่ง			
14.การกินยารักษาโรคเอดส์ไม่สม่ำเสมอ อาจทำให้เกิดการดื้อยาได้			
15.หากเกิดการดื้อยาต้านไวรัสเอดส์สูตรแรก คุณมีโอกาสที่จะเกิดการดื้อยาต้านไวรัสเอดส์สูตรที่เปลี่ยนใหม่เพิ่มมากขึ้น			

ตอนที่ 3 ความมั่นใจในการกินยาต้านไวรัส

คำชี้แจง กรุณาทำเครื่องหมาย / ลงในช่อง ที่ตรงกับความคิดเห็นของท่านมากที่สุด

       1 หมายถึง มั่นใจในการกินยาต้านไวรัสน้อยที่สุด

       2 หมายถึง มั่นใจในการกินยาต้านไวรัสน้อย

       3 หมายถึง มั่นใจในการกินยาต้านไวรัสปานกลาง

       4 หมายถึง มั่นใจในการกินยาต้านไวรัสมาก

       5 หมายถึง มั่นใจในการกินยาต้านไวรัสมากที่สุด

ประเด็นข้อคำถาม	1	2	3	4	5
คุณมั่นใจว่าสามารถกินยาได้<u>ตรงเวลาและครบทุก</u>มื้อในระดับใด เมื่ออยู่ในสถานการณ์ดังต่อไปนี้					
1.เมื่อคุณอยู่ที่บ้าน					
2.ถึงแม้ว่ายาอาจจะเม็ดใหญ่และกลืนยาก					
3.เมื่อไม่มีใครคอยเตือนคุณเมื่อถึงเวลากินยา					
4.ระหว่างวันหยุดสุดสัปดาห์					
5.เมื่อกินยาแล้วเกิดอาการข้างเคียงเพียงเล็กน้อย					
6.เมื่อรู้สึกว่าคุณมีสุขภาพแข็งแรงดี					
7.เมื่อคุณรู้สึกป่วยมากๆ					
8.เมื่อคุณรู้สึกเศร้ามากๆ					
9.ขณะที่ต้องเดินทางไกล					
10.ถ้าต้องกินยาต่อหน้าคนอื่นที่ไม่รู้ว่าคุณติดเชื้อ					
11.อีก 7 วันข้างหน้าสามารถกินยาได้ตรงเวลาและครบทุกมื้อ					
12.อีก 14 วันข้างหน้าสามารถกินยาได้ตรงเวลาและครบทุกมื้อ					

ตอนที่ 4 แรงสนับสนุนของคนรอบตัว เช่น พ่อแม่ พี่น้อง ญาติ เพื่อน แฟน

คำชี้แจง กรุณาทำเครื่องหมาย / ลงในช่อง ที่ตรงกับความคิดเห็นของท่านมากที่สุด

    1 หมายถึง ไม่มีเลยสักครั้ง

    2 หมายถึง มีน้อยครั้ง

    3 หมายถึง มีปานกลาง

    4 หมายถึง มีบ่อยครั้ง

    5 หมายถึง มีทุกครั้งที่ต้องการ

ประเด็นข้อคำถาม	1	2	3	4	5
คนใกล้ตัวของคุณที่สามารถปฏิบัติตัวดังต่อไปนี้ได้มากน้อยแค่ไหน					
1.รับฟังปัญหาของคุณ					
2.ให้คำแนะนำที่ดีในเวลาคุณมีปัญหา					
3.ให้กำลังใจเมื่อคุณมีเรื่องกังวลหรือไม่สบายใจ					
4.เข้าใจในปัญหาด้านสุขภาพของคุณ					
5.ช่วยคุณได้ถ้าคุณจะต้องนอนป่วยนานๆ					
6.พาคุณไปพบหมอได้เมื่อคุณต้องการ					
7.รักคุณ					
8.คุณอยู่ด้วยแล้วสบายใจ					
9.ทำกิจกรรมสนุกสนานร่วมกัน					
10.ช่วยคุณโดยไม่หวังสิ่งตอบแทนใดๆ					

ตอนที่ 5 ความสัมพันธ์ระหว่างคุณและบุคลากรทางการแพทย์ ได้แก่ หมอ พยาบาล เภสัชกร

คำชี้แจง กรุณาทำเครื่องหมาย / ลงในช่อง ที่ตรงกับความคิดเห็นของท่านมากที่สุด

       1 หมายถึง น้อย

       2 หมายถึง ปานกลาง

       3 หมายถึง ดี

       4 หมายถึง ดีมาก

       5 หมายถึง ดีเยี่ยม

ประเด็นข้อคำถาม	1	2	3	4	5
คุณคิดว่าบุคลากรทางการแพทย์ปฏิบัติตนต่อคุณอย่างไรในสถานการณ์ดังต่อไปนี้					
1.อธิบายข้อปฏิบัติตัวเวลาเกิดอาการ ไม่พึงประสงค์จากการใช้ยา					
2.ใส่ใจดูแลคุณ					
3.เข้าใจในความกังวลใจของคุณเกี่ยวกับสุขภาพ					
4.อธิบายการปฏิบัติตนเมื่อมีเพศสัมพันธ์					
5.ซักถามเกี่ยวกับความเครียด ที่จะส่งผลต่อสุขภาพของคุณ					
6.ให้ข้อมูลเกี่ยวกับการกินยาอย่างครบถ้วน					
7.เข้าใจถึงปัญหาในการกินยาของคุณ					
8.ช่วยแก้ปัญหาในการกินยาของคุณ					
9.ให้คุณมีส่วนร่วมในการตัดสินใจ ในการเลือกการรักษาด้วยยา					
10.เสนอทางเลือกของยาที่ใช้รักษา และบอกประเภทของยา					
11.อธิบายข้อดี – ข้อเสีย ของแต่ละทางเลือกในการรักษา					
12.มีความเป็นมิตร					
13.ตอบคำถามเรื่องโรคและยาได้ชัดเจน					
14.มีความรู้ความสามารถในการรักษา					
15.ทำให้คุณเชื่อมั่นและไว้วางใจในการรักษา					

ตอนที่ 6 แบบวัดความร่วมมือในการใช้ยาของผู้ป่วย

หมายเหตุ ก่อนประเมินความร่วมมือในการใช้ยาให้บอกผู้ป่วยว่า "ผู้ติดเชื้อส่วนใหญ่กิน ยาหลายเม็ด หลายเวลาในระหว่างวัน ผู้ติดเชื้อส่วนใหญ่พบว่ากินยาไม่ตรงเวลา แล้วมัน เป็นสิ่งสำคัญสำหรับผู้วิจัย ที่จะเข้าใจเกี่ยวกับการกินยาของคุณจริงๆ ไม่ต้องกังวล เกี่ยวกับสิ่งที่จะบอกผู้วิจัย เช่น ถ้าคุณไม่กินยาสม่ำเสมอ ผู้วิจัยต้องการจะทราบว่า อะไร ที่เกิดขึ้นจริง ไม่ว่าอะไรที่คุณคิดผู้วิจัยอยากทราบ"

_____

1. Self-Report

คำชี้แจง กรุณาทำเครื่องหมาย / ลงในช่อง ที่ตรงกับความจริงของท่านมากที่สุด

ประเด็นข้อคำถาม	ใช่	ไม่ใช่
1. บางครั้งพบว่าเป็นเรื่องยากที่จะจดจำเรื่องการกินยาใช่หรือไม่		
2. เมื่อคุณรู้สึกอาการดีขึ้น บางครั้งคุณหยุดกินยาใช่หรือไม่		
3. เมื่อหนึ่งเดือนที่ผ่านมา คุณกินยาไม่ตรงเวลาและไม่สม่ำเสมอทุก มื้อ ใช่หรือไม่		
4. บางครั้งถ้าคุณรู้สึกอาการแย่ลง คุณจะหยุดกินยา		

2. Visual Analogue Scale (VAS)

คำชี้แจง ให้ผู้ป่วยคิดกลับไปย้อนหลังเกี่ยวกับพฤติกรรมการกินยา เมื่อ 1 เดือนที่ผ่านมา ว่าผู้ป่วยกินยาไม่สม่ำเสมอหรือกินยาไม่ตรงเวลา โดยทำเครื่องหมาย X บนเส้นสเกล ข้างล่าง

หมายเหตุ

สเกลที่ 0 หมายถึง กินยาไม่สม่ำเสมอทุกมื้อและไม่ตรงเวลาทุกวันเมื่อ 1 เดือนที่ผ่านมา
สเกลที่ 10 หมายถึง กินยาสม่ำเสมอทุกมื้อและตรงเวลาทุกวันเมื่อ1 เดือนที่ผ่านมา

```
0    1    2    3    4    5    6    7    8    9    10

I-----I-----I-----I-----I-----I-----I-----I-----I-----I-----I
```

คะแนน..............%

3. Pill Identification Test (PIT)

ชื่อยา	รู้ชื่อยา (Y/N)	รู้จำนวนเม็ดยาต่อมื้อ (Y/N)	เวลากินยาตอนเช้า	เวลากินยาตอนเย็น	รู้เวลากินยา (Y/N)	รู้คำแนะนำในการกินยา

4. Pill Count

คำชี้แจง นับจำนวนเม็ดยาที่เหลือหลังจากที่คนไข้ได้รับยาไปเมื่อครั้งล่าสุดที่มาพบหมอ เพื่อมาคำนวณหาเปอร์เซ็นต์ความร่วมมือในการใช้ยา (% Adherence) จากสูตรข้างล่างนี้

% Adherence = (จำนวนเม็ดยาที่หมอสั่ง – จำนวนเม็ดยาที่เหลือ) / จำนวนเม็ดยาที่ควรจะต้องกินจริง * (100)

% Adherence = (………-- ………) / ………* (100) = …………..%

% Adherence = (………-- ………) / ………* (100) = …………..%

% Adherence = (………-- ………) / ………* (100) = …………..%

ค่าเฉลี่ย % Adherence = ... %

BIOGRAPHY

NAME	**MISS TIDARAT SUJIPITTHAM**
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