

คุณภาพชีวิตของผู้ติดเชื้อเอชไอวี/เอดส์ใน 3 โรงพยาบาลในประเทศไทย



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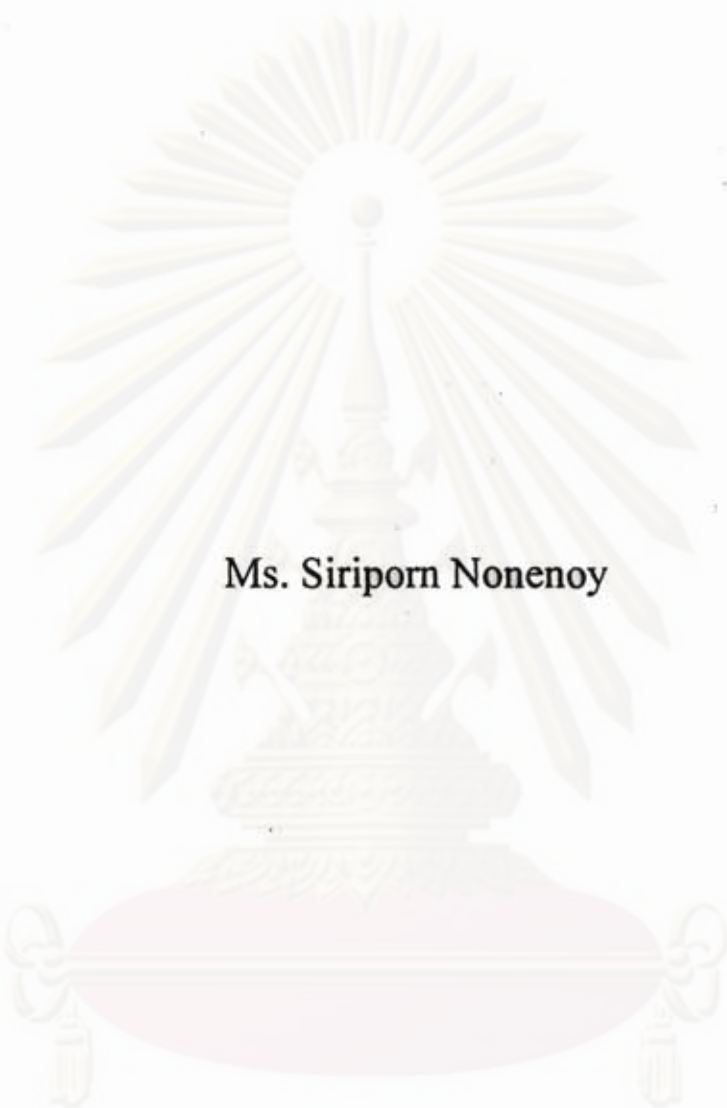
วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาสาธารณสุขศาสตรมหาบัณฑิต
สาขาวิชาการพัฒนาระบบสาธารณสุข
วิทยาลัยวิทยาศาสตร์สาธารณสุข จุฬาลงกรณ์มหาวิทยาลัย

ปีการศึกษา 2552

ลิขสิทธิ์ของจุฬาลงกรณ์มหาวิทยาลัย

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**HEALTH RELATED QUALITY OF LIFE
AMONG PERSONS LIVING WITH HIV/AIDS IN
3 HOSPITAL IN THAILAND**



Ms. Siriporn Nonenoy

**A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Public Health Program in Health Systems Development
College of Public Health Sciences
Chulalongkorn University
Academic Year 2009
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Thesis Title HEALTH RELATED QUALITY OF LIFE AMONG
PERSONS LIVING WITH HIV/AIDS IN 3 HOSPITALS IN
THAILAND

By Ms. Siriporn Nonenoy

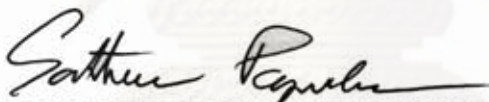
Field of Study Health Systems Development

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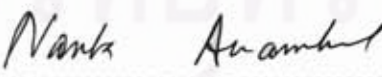
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ศิริพร โนน้อย : คุณภาพชีวิตของผู้ติดเชื้อเอชไอวี/เอดส์ใน 3 โรงพยาบาลในประเทศไทย (HEALTH RELATED QUALITY OF LIFE AMONG PERSONS LIVING WITH HIV/AIDS IN 3 HOSPITALS IN THAILAND) อ.ที่ปรึกษา
วิทยานิพนธ์หลัก : ALESSIO PANZA, M.D., M.P.H. , 70 หน้า

การศึกษานี้เป็นการศึกษาแบบภาคตัดขวางวัตถุประสงค์หลักเพื่อประเมินความสัมพันธ์ของคุณภาพชีวิตของผู้ติดเชื้อเอชไอวี/เอดส์โดยศึกษาความสัมพันธ์ทางด้านปัจจัยพื้นฐานที่เกี่ยวข้องทางด้านประชากร เศรษฐกิจ สังคม และ ประวัติความเจ็บป่วยรวมถึงปัจจัยที่เกี่ยวข้องกับการได้รับเชื้อเอชไอวี/เอดส์ในผู้ป่วยนอกของสถาบันบำราศนราดูร นนทบุรี โรงพยาบาลสันป่าดอง เชียงใหม่ และโรงพยาบาลลพบุรี จังหวัดลพบุรี เครื่องมือที่ใช้ในการเก็บข้อมูลเพื่อศึกษาคุณภาพชีวิตคือ แบบประเมินคุณภาพชีวิตฉบับย่อขององค์การอนามัยโลกฉบับภาษาไทย ซึ่งเป็นครั้งแรกที่ทำการศึกษาในผู้ป่วย HIV/AIDS จำนวนมากคือ 3,596 คนในประเทศไทย การวิเคราะห์ข้อมูลใช้สถิติเชิงบรรยายและสถิติเชิงอ้างอิง (one-way ANOVA, Kruskal-Wallis Test, Pearson Correlation and independent t-test) ในการศึกษาความสัมพันธ์ระหว่างตัวแปรอิสระต่างๆกับคุณภาพชีวิต

ผลการศึกษาพบความสัมพันธ์อย่างมีนัยสำคัญทางสถิติ ดังต่อไปนี้คือ เพศชายมีระดับคะแนนคุณภาพชีวิตสูงกว่าเพศหญิงในด้านร่างกาย จิตใจ และคุณภาพชีวิตโดยรวม กลุ่มอายุอายุน้อยมีคะแนนคุณภาพชีวิตที่สูงกว่ากลุ่มตัวอย่างที่มีอายุมากกว่าในด้านร่างกายและสังคม ในขณะที่กลุ่มตัวอย่างที่มีอายุมากพบมีระดับคะแนนคุณภาพชีวิตที่ต่ำกว่ากลุ่มอายุน้อยในด้านจิตใจและสิ่งแวดล้อม กลุ่มที่มีสถานภาพสมรสมีคะแนนคุณภาพชีวิตสูงในด้านจิตใจมากกว่ากลุ่มโสดและหย่าร้าง กลุ่มที่มีการรับประทานยาอย่างถูกต้อง กลุ่มที่ติดเชื้อเอชไอวี/เอดส์มากกว่า 3 ปี และกลุ่มที่ไม่มีมีของอาการของโรคเอดส์ มีคะแนนคุณภาพชีวิตที่สูงในด้านสังคม กลุ่มที่มีจำนวนเชื้อไวรัสตัว (VL <50 copies/ml) มีคะแนนคุณภาพชีวิตสูงทุกด้าน ยกเว้นด้านสังคม กลุ่มที่มีระดับการศึกษาสูง รายได้สูง และมีระดับซีดี 4 มากกว่า 200 มีคะแนนคุณภาพชีวิตที่สูง ดังสรุปได้ว่า ผู้ติดเชื้อเอชไอวี/เอดส์ มีระดับคุณภาพชีวิตในระดับปานกลางถึงสูง ซึ่งใกล้เคียงกับหลายประเทศที่พัฒนาแล้ว ซึ่งอาจเป็นเพราะ ปัจจัยพื้นฐานที่เกี่ยวข้องทางด้านประชากร เศรษฐกิจ สังคม และ ประวัติความเจ็บป่วย บางประการ การเข้าถึงยาได้อย่างทั่วถึง การรับประทานยาที่ถูกต้อง การเข้าถึงการดูแลทางด้านสุขภาพของผู้ติดเชื้อเอชไอวี/เอดส์ เครื่องมือวัดคุณภาพชีวิตขององค์การอนามัยโลกชุดย่อ ฉบับภาษาไทย เป็นเครื่องมือที่เหมาะสมในการวัดระดับคะแนนคุณภาพชีวิตในผู้ติดเชื้อเอชไอวี/เอดส์ได้เป็นอย่างดี

สาขาวิชา : การพัฒนาระบบสาธารณสุข

ปีการศึกษา : 2552

ลายมือชื่อนิติ

ลายมือ อ.ที่ปรึกษาวิทยานิพนธ์หลัก




5179158153 : MAJOR HEALTH SYSTEMS DEVELOPMENT
 KEYWORDS : HEALTH-RELATED QUALITY OF LIFE / WHO-BREF-THAI
 / THAILAND / HIV/AIDS / CLINICAL HIV/AIDS

SIRIPORN NONENOY : HEALTH RELATED QUALITY OF LIFE
 AMONG PERSONS LIVING WITH HIV/AIDS IN 3 HOSPITALS IN
 THAILAND.

THESIS ADVISOR : ALESSIO PANZA, M.D., M.P.H. , 70 pp.

A cross sectional study looked at the association between socio-demographic factors, HIV/AIDS clinical history and health-related quality of life (QOL) in HIV/AIDS persons. It used the WHOQOL-BREF-THAI questionnaire completed by 3,596 patients during 2008 in three Thai hospitals. The questionnaire explored five QOL domains: Physical, Psychological, Social, Environment and Overall and it was for the first time administered to many HIV/AIDS patients in Thailand. Descriptive statistics and inferential statics (bivariate and multivariate : one-way ANOVA, Kruskal-Wallis Test, Pearson Correlation and independent t-test)) were used to test association between independent factors and QOL. **Results:** The following associations were all statistically significant. Males had higher QOL than females in Physical, Psychological and Overall domains. Younger age was associated with higher QOL in Physical and Social domains, older age in Psychological and Environment domains. Married had higher psychological QOL than single and separated. Good adherence to, more than 3 year duration of ARV treatment and not suffering AIDS related events were associated with higher QOL in all except social domains. VL <50 copies/ml had higher QOL in all domains except social and environment domain. Higher education, high income and more than 200 CD4+ cell per mm³ had higher QOL in all domains. **Conclusion:** Thai HIV/AIDS persons have health-related moderate to high QOL comparable similar person from high income countries. This is mainly due to similarities in some socio-demographic characteristics, free availability of and adherence to ARV, accessibility to other of HIV/AIDS care components. The WHOQOL-BREF-THAI questionnaire is an appropriate instrument to measure QOL in Thai HIV/AIDS persons.

Field of Study : Health System Development

Student's Signature 

Academic Year : 2009

Advisor's Signature 

ACKNOWLEDGEMENT

I would like to express my sincere gratitude and appreciation to my thesis advisor, Alessio Panza, M.D. for his kindness, valuable guidance and encouragement throughout the period of my study.

I thank the faculty of the Collage of Public Health Science for their teaching and administrative team for their organization and coordination.

I additional, I acknowledge and sincerely thank the all The Progress Study Team, and, more especially the patient who participate in The Progress study. It is my sincere hope that continuing research will lead to the improved management of HIV disease, to the benefit of those infections today and those who may be infected in the future.

In particular, I would like to thank Dr.Wadchara Pumpradit for his tireless support, inspiration, helpful advice and encouragement.

Finally, I wish to express my deepest unconditional gratitude to my beloved parent, who brought me up and made me everything I am, to my husband and my daughter for their affection, support, assistance.



ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย

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CHAPTER I

INTRODUCTION

1.1 Background and significance of the problem

The origin of AIDS and HIV has puzzled scientists ever since the illness first came to light in the early 1980s. For over twenty years it has been the subject of fierce debate and the cause of countless arguments, with everything from a promiscuous flight attendant to a suspect vaccine programme being blamed. The first recognized cases of AIDS occurred in the USA in the early 1980s. A number of gay men in New York and California suddenly began to develop rare opportunistic infections and cancers that seemed stubbornly resistant to any treatment. At this time, AIDS did not yet have a name, but it quickly became obvious that all the men were suffering from a common syndrome. The discovery of HIV, the Human Immunodeficiency Virus, was made soon after. While some were initially resistant to acknowledge the connection (and indeed some remain so today), there is now clear evidence to prove that HIV causes AIDS (Peter Kanabus, 2008).

The history of AIDS is a short one, no one was aware of this deadly illness. Since then the global AIDS epidemic has become one of the greatest threats to human health and development. UNAIDS/WHO (2007) report more than two and a half million adults and children became infected with HIV (Human Immunodeficiency Virus), the virus that causes AIDS. By the end of the year, an estimated 33 million people worldwide were living with HIV/AIDS. AIDS stigma and discrimination have been seen all over the world, refers to the prejudice and discrimination directed at people living with HIV/AIDS (PLWHA), and the groups and communities that they are associated with. It can result in people living with HIV and AIDS being rejected from their community, shunned, discriminated against or even physically hurt, stigma directed at PLWHA not only makes it more difficult for people trying to come to terms with and manage their illness on a personal level, but it also interferes with attempts to fight the AIDS epidemic as a whole (Peter Kanabus, 2008).

With an alarming increase of Human Immunodeficiency Virus (HIV) /Acquired Immunodeficiency Syndrome (AIDS) in developing countries, estimated number of people living with HIV in Thailand, end 2007 is 610,000 people estimated prevalence 1.4% in adult (Peter Kanabus, 2008). Today, there are no cure and no effective vaccine for the prevention or treatment of HIV infection. However, developments in ARV therapy have resulted in prolong life and reducing the frequency of opportunistic infection, also inability to afford highly active anti-retroviral therapy, key issues like the quality of life (QOL) has come to the fore. Determining the impact on the quality of life in HIV/AIDS patients is important for estimating the burden of the disease. This is true because AIDS has a chronic debilitating course and the long-term adverse side effects of current treatments

modalities are uncertain. The social stigma attached with the proclamation of HIV sero-positivity may at times force the individual to change the job or the place of living, putting further stress on the already weak economic situation. This further leads to progressive deterioration of health, low morale, repeated consultation, abstinence from work and low productivity. The vicious cycle thus goes on, economic deprivation and social isolation takes its toll on the quality of life in HIV/AIDS patients.

Quality of life is a multi-dimensional concept whose definition and assessment remains controversial (Naveet Wig et al., 2008). Quality of life is conceptualized in terms of "an absence of pain or an ability to function in day to day life". Several researchers described Quality of life as a "fighting spirit" associated with longer survival time for individuals. "Quality of life relates both to adequacy of material circumstances and to personal feelings about these circumstances (Naveet Wig et al, 2008). It includes "overall subjective feelings of well being that are closely related to morale, happiness and satisfaction". Further as health is generally cited as one of the most important determinants of overall quality of life, it has been suggested that quality of life may be uniquely affected by specific disease process such as AIDS. Health-related quality of life measures are increasingly being used for understanding the impact of diseases and treatments from a patient perspective HIV/AIDS.

World health Organization (WHO) developed WHOQOL generic cross-100 in 15 country including Thailand. WHOQOL-100 is based on clear definition of quality of life also; the WHOQOL-BREF-THAI is the 26 items abbreviated version of the WHOQOL-100(Phantipa Sakthong and et al, 2007). In Thailand the Thai version of brief measure (WHOQOL-BREF-THAI) has been tested for its psychometric properties in a large population against the WHOQOL-100 and found to be a shorter and more convenient to use, and also has better comprehensibility .The study in Bamrasnaradura Hospital (Phantipa a Sakthong nd et al.,2007), the WHOQOL-BREF-THAI consists of 26 items has been tested for its Psychometric Properties in 120 out Thai patients living with HIV/AIDS, the study show that WHOQOL-BREF-THAI can be a good generic health –related quality of life instrument in HIV/AIDS.

The present study aimed to determine the Socio- demographic factors and impact associations between of Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) with health-related quality in a specific group of large patients living with HIV/AIDS in Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital by WHOQOL-BREF-THAI.

จุฬาลงกรณ์มหาวิทยาลัย

1.2 Research questions

1.2.1 What is the impact of Human Deficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) on the quality of life (WHOQOL-BREF-THAI) on such patients in Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital?

1.2.2 What are the associations between Socio- demographic factors of Persons Living with HIV/AIDS in Bamrasnaradura Hospital, Sanpatong Hospital, Lopburi Hospital and quality of life (WHOQOL-BREF-THAI)?

1.3 Objectives of study

1.3.1 To determine the association between Socio- demographic factors of Persons Living with HIV/AIDS in Bamrasnaradura Hospital, Sanpatong Hospital , Lopburi Hospita and quality of life

1.3.2 To determine the Human Immunodeficiency Virus (HIV)/ Acquired Immunodeficiency Syndrome (AIDS) impact on health-related quality of life in persons living with HIV/AIDS (PHA)

1.4 Operational Definitions :

Person living with HIV/AIDS is a person, who has HIV positive status. In this study, there are both independent and dependent variables.

1.4.1 Independent Variables

1.4.1.1 Socio- demographic factors are composed as following,

- (1) Age : refers to how old the interviewee is at the time of the interview
- (2) Gender : refers to Gender at birth (Male, Female)
- (3) Education achievement: refers to the highest year or education of the interviewee. It was devided in to7 levels ; No certificate, Primary certificate, Secondary certificate, High School certificate, Associates/ Technical/ Vocational certificate, Bachelor of Science or Arts and More than BS/ BA
- (4) Occupation : The specify in current occupation; this study lists are Unemployed, Wage earner, Self-employed, Government Official, Working for Government Enterprise, Working for Private or Individual company, Others: Specify;
- (5) Monthly Income: refer to the amount of money that the interviewees receive per month in Thai Baht.
- (6) Current marital status : Specify as Widowed ,Single, Married, Divorced, Not married, in a committed relationship, Separate

1.4.1.2 HIV/AIDS clinical history Factors

HIV/AIDS Clinical impact factors in this study were including details below;

- (1) CDC clinical category: Used U.S. Centers for Disease Control and Prevention (CDC) classification system and the World Health Organization (WHO) Clinical Staging and Disease Classification System (1993), The CDC categorization of HIV/AIDS is based on the lowest documented CD4+ cell count (Table E 1 in appendix A) and on previously diagnosed HIV-related conditions (Tables E 2 and E3 in appendix A).
- (2) CD4+ count : absolute CD4+ count at baseline data
- (3) Plasma VL : HIV-1 RNA copies/ml at baseline data
- (4) Duration of HIV/AIDS infection : as indicate on date of first HIV positive status until to interview date
- (5) Duration of ARV initiation : as indicate on date of start ARV until to interview date
- (6) Adherences to ARV: Use Case Adherence Index questionnaire (S. B. Mannheimer et al, 2006). Data have been collected by study coordinators or doctors at 3 Hospitals as details in Appendix B

1.4.2 Dependent Variables

Health-related quality of life (HRQoL) is defined as individuals' perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns (World health Organization, 1993).

In this study, HRQoL was measured by WHOQOL-BREF-THAI , which contained five domains:

- Physical health
- Psychological Health
- Social relationship
- Environment and
- Overall quality of life

1.5 Conceptual Framework

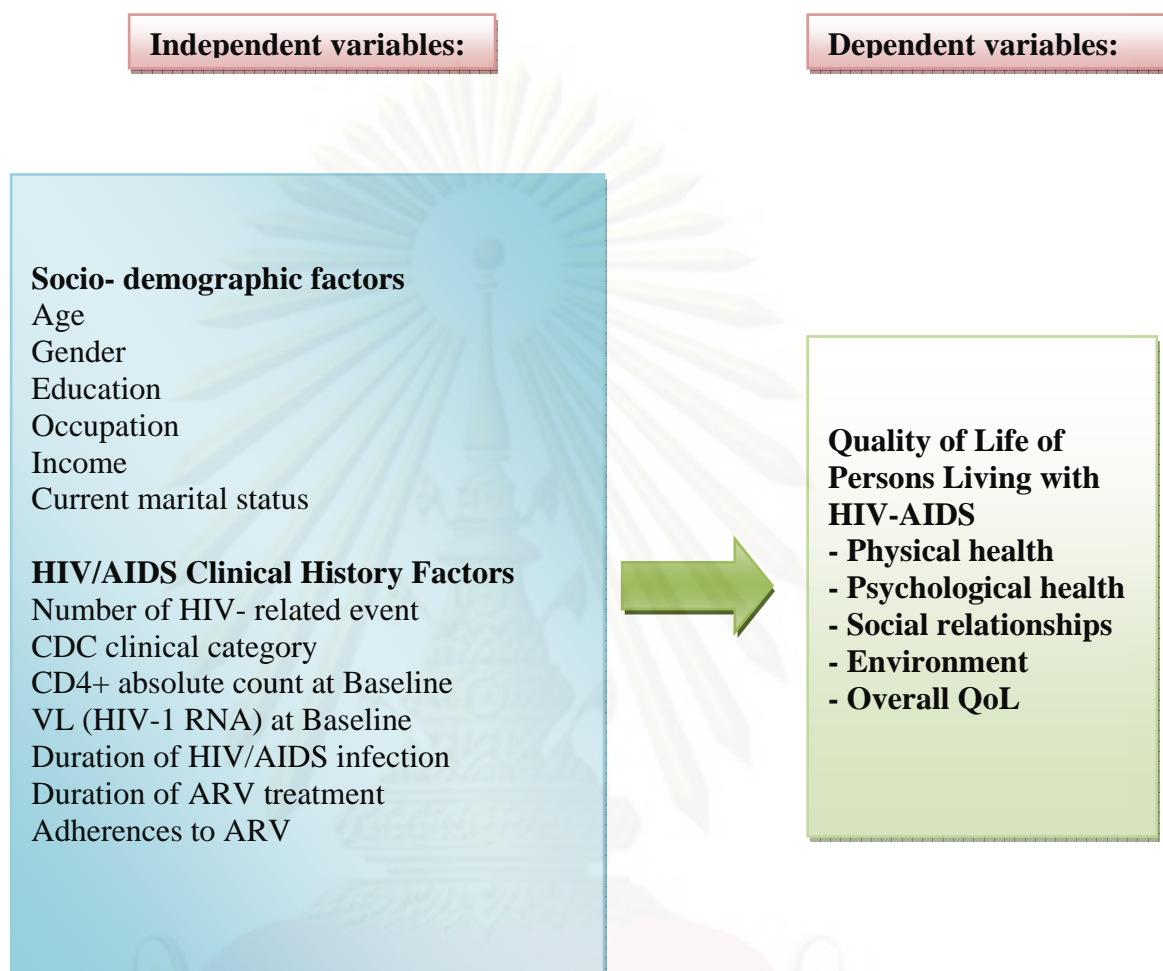


Figure.1: Conceptual framework

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CHAPTER II

LITERATURE REVIEW

2.1 Definition of Health

Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity (World health Organization, 1948).

2.2 Concept of Quality of life

QoL refer to the adequacy of people's material circumstances and to their feeling about these circumstances. Indicators include personal wealth and possession, feel of safety, level of freedom, and opportunity; health status also forms one of many components in this broad concept (McDowell, 2006).

They are variously termed Quality of life (QoL) or Health –Related Quality of life (HRQoL). Quality of life is a broad concept, including the dimension covered by general health measurement and extending to other topics.

An expert group meeting convened by Economic and social Commission for Asia and Pacific (United Nations, 1995) developed a model for a survey of the QoL including six components as following:

(1) Health: health is a key aspect of QoL not only in its own right but in its implications for all other QoL components. People need a minimum standard of health in order to be able to work, support themselves and their families, contribute to society and take advantage of the recreational and cultural opportunities in their environment. Disease illness and disability greatly affect labor productivity, resource saving, and population growth.

(2) Education: like health, education is not only a key component of the QoL, but has pervasive implications for others as well. In this regard, education must be viewed in all its dimension: the acquisition of formal education, as represented by literacy, numeracy and other skills, as well as non-formal education, relating to the wider world, such as socialization and culturalization process, with are both essential contributors to the QoL.

(3) Working life: in addition to its income-generating function, working life has important implications for the overall QoL by way of its provision of opportunities for self-fulfillment through personal development as well as social mobility. The quality of work and the working environment undoubtedly have a fundamental impact on people's lives, since a substantial part most adults' time is spent at work.

(4) Physical environment: the physical environment is defined here as comprising the built environment infrastructure created to support human activity as well as the

natural environment. Safe drinking water and adequate sanitary facilities have a tremendous impact in diminishing the risk of endemic disease and improving general health conditions,

(5) Family life: the conditions of family life have an immediate impact on the QoL of every individual and are also critical determinants of the QoL. At the same time, the family, as the basic social and economic institution, is greatly affected by the social problems associated with economic change. Both family function and restructure are for adapting to the changing socio-economic environment. As part that process, the roles of family members are also undergoing a transition.

(6) Poverty: poverty is defined as the inability to meet the individual's basic needs. It must thus be seen within the context of human need. However, human needs vary from one country to another as well as among social groups within countries. Furthermore, they include a perceptual element which also varies among social groups and individuals overtime.

2.3 International development WHOQOL

The World Health Organization Quality of Life (WHOQOL) project was initiated in 1991. The aim was to develop an international cross-culturally comparable quality of life assessment instrument. It assesses the individual's perceptions in the context of their culture and value systems, and their personal goals, standards and concerns. The WHOQOL instruments were developed collaboratively in a number of centers worldwide, and have been widely field-tested. WHO's initiative to develop a quality of life assessment arose for a number of reasons. WHO's initiative to develop a quality of life assessment arises, therefore, both from a need for a genuinely international measure of quality of life, and restates its commitment to the continued promotion of an holistic approach to health and health care, as emphasised in the WHO definition of health as "A state of physical, mental and social well-being, not merely the absence of disease and infirmity (Division of Mental Health and Prevention of substance abuse,1998).

Whilst the WHOQOL-100 allows a detailed assessment of individual facets relating to quality of life, it may be too lengthy for some uses, for example, in large epidemiological studies where quality of life is only one amongst many variables of interest. In these instances, assessments will be more willingly incorporated into studies if they are brief, convenient and accurate. The WHOQOL-BREF Field Trial Version has therefore been developed to look at domain level profiles which assess quality of life. Two datasets were used to select items for inclusion in the WHOQOL-BREF. The first included all data from the fifteen field centers who participated in the WHOQOL pilot study. Also, 300 participated from Thailand were enrolled. The second dataset included data from the thirteen centers who field-tested the WHOQOL-100 (345 participated were including). The WHOQOL-BREF is currently being validated in field studies involving 30 languages (including Thailand), the appropriate language version, and permission for using it, can be obtained from the National field centre or for new versions from WHO Under no circumstances should

the WHOQOL-BREF be used without permission. (Division of Mental Health and Prevention of substance abuse,1998).

2.4 Proposed used of the WHOQOL-BREF

It is anticipated that the WHOQOL assessments will be used in broad-ranging ways. They will be of considerable use in clinical trials, in establishing baseline scores in a range of areas, and looking at changes in quality of life over the course of interventions. It is expected that the WHOQOL assessments will also be of value where disease prognosis is likely to involve only partial recovery or remission, and in which treatment may be more palliative than curative. For epidemiological research, the WHOQOL assessments will allow detailed quality of life data to be gathered on a particular population, facilitating the understanding of diseases, and the development of treatment methods. The international epidemiological studies that would be enabled by instruments such as the WHOQOL-100 and the WHOQOL-BREF will make it possible to carry out multi-centre quality of life research, and to compare results obtained in different centres. Such research has important benefits, permitting questions to be addressed which would not be possible in single site studies. Multi-centre collaborative studies can also provide simultaneous multiple replications of a finding, adding considerably to the confidence with which findings can be accepted. In clinical practice the WHOQOL assessments will assist clinicians in making judgements about the areas in which a patient is most affected by disease, and in making treatment decisions. In some developing countries, where resources for health care may be limited, treatments aimed at improving quality of life through palliation. Together with other measures, the WHOQOL-BREF will enable health professionals to assess changes in quality of life over the course of treatment. It is anticipated that in the future the WHOQOL-100 and the WHOQOL-BREF will prove useful in health policy research and will make up an important aspect of the routine auditing of health and social services. Because the instrument was developed cross-culturally, health care providers, administrators and legislators in countries where no validated quality of life measures currently exist can be confident that data yielded by work involving the WHOQOL assessments will be genuinely sensitive to their setting. (Division of Mental Health and Prevention of substance abuse,1998).

2.5 HIV/AIDS Clinical history Factors and Socio-demographic Data

S.A. Call and et al. (2000) state that, clinical trial and intervention studies in human immunodeficiency virus (HIV) infections have focused on traditional clinical measures as outcomes. Primary outcome measures have including mortality, occurrence of opportunistic infection, progression to clinical definition infections, and progression to a clinical definition of acquired immunodeficiency syndrome (AIDS) and occurrence of adverse events. Biological marker has been used as surrogate outcome measures; traditionally in HIV, research has focused on changed in CD4+ cell counts. Over the last few years, viral load has been show to correlate with disease progression and prognosis and thus, has become a frequently used outcome measure both in clinical practice and intervention. The research related to health related quality of life in HIV/AIDS patients has been extensive. Must of researches addresses

HIV/AIDS impact factor such as HIV- related event, CDC clinical category, CD4+ count ,pVL, Duration of infected HIV/AIDS , Duration of ARV initiation ,Symptoms, Adherences to ARV and Socio-demographic data are effect on quality of life.

Self report health related quality of life instruments is useful for documenting the burden of chronic disease, tracking changes in health over time, and comparing the overall effects of treatments. Although the efficacy and provision of medical treatment have prevented or delayed disease and prolonged survival in HIV-infected individuals, the duration of treatment effectiveness is sometimes limited, toxicities and side effects of HIV treatment are common, and the interaction with treatment concurrent co-morbidities is increasingly complex (Peninnah Oberdorfer et al., 2008).The benefits of ARV medications are remarkable in their effect on the progress of HIV. If taken correctly, ARV medications have the potential to reduce viral load below the level of detection in some patients, in turn, there is the possibility of slow recover of immune function. Also if taken not correctly such as not correctly time or delay time to taken ARV, which may be dangerous.

The presence of symptoms related to the disease and its treatment has been proposed as the strongest indicator of impaired global quality of life in HIV-positive patients. For the AIDS-defining events (ADEs) and non-AIDS serious adverse events (SAEs) on health-related quality of life (HRQoL) Aslam H. Anis et al (2009) studied in ADEs occurred much less frequently than SAEs (n = 147 vs. n = 821) in the study sample population of 368 patients, during median follow-up of 3.96 years. Although both ADEs and SAEs had significant negative impacts on HRQoL, SAEs had at least as large an impact upon HRQoL as ADEs when both were included in a multivariate linear regression model, controlling for other covariates. However, the effect of ADEs on HRQoL was more persistent, with larger magnitude of effect across all instruments in time intervals further from the onset of the event. Conclusions of the study specify the Non-AIDS SAEs occurring in patients with late-stage HIV/AIDS seem to have at least as important an immediate impact on patient HRQoL as ADEs; however, the impact of ADEs seems to be more persistent. Our findings call for a greater emphasis on the detection and active prevention of non-AIDS SAEs in patients with late-stage HIV/AIDS.

In a sample of 139 patients living with HIV or suffering from AIDS, Marzieh Nojomi and colleagues (2008) found that most important factors, association with decreased quality of life of the patients in this study, were being female, separated or divorced, having less CD4+ count, and being at severe stage of the disease. Michael L Campsmith et al. (2003) studies in Self-reported health-related quality of life in persons with HIV infection Self report health related quality (HRQOL) (n=3,778) found that factors associated with lower Self report health related quality (HRQOL) scores were included older age, female sex, black or Hispanic race/ethnicity, injection drug use, lower education and income, no private health insurance, and lower CD4+count. Looking on several studies, lower CD4+ count was the factor most consistently associated with lower Self report health related quality (HRQOL). Other studies have focused on determining what factors truly represent quality of life in HIV/AIDS patients. S.A. Call and et al. (2000) reported in HIV-positive 158 persons, the study used Self report health related quality (HRQOL) and

found the relationship between viral load, a measure of HIV disease activity, appears to be strong and independent of CD4+cell count. This finding suggests that having a lower viral load positively impacts the quality of life of HIV-positive patients. Peninnah Oberdorfer and et al. (2008) reported in A cross-sectional study conducted among the main caregivers of HIV-infected children aged 5 and above, followed up at the HIV clinic of Chiang Mai University Hospital, and Sanpatong District Hospital in northern Thailand. The study used General Health Assessment for Children (GHAC), the standardized tool developed by the Pediatric AIDS Clinical Trials Group (ACTG), examined scale differences among children who had a normal immunity (CD4 +count $\geq 25\%$) and those who had impaired immunity (CD4+count $< 25\%$), the hypothesized that children with a CD4+count of less than 25% would show lower physical functioning, more symptoms, more psychological problems, and more social and role limitations than children who had a normal level of CD4+ cells, Physical functioning ($p=0.001$), psychological well being ($P=0.02$), symptoms related to HIV infection ($P=0.008$), and social and role functioning ($P=0.002$).

Naveet Wig and et. Al.(2006) reported on The impact of HIV/AIDs on the quality of life in India, using the WHOQOL-Bref (Hindi) in 68 subjects the data show a significant difference of quality of life in the physical domain between asymptomatic patients and patients with AIDS defining illnesses ($p<0.001$). QOL in the psychological domain was significantly poorer in early symptomatic ($p<0.05$) and AIDS patients ($p<0.006$). A significant difference in QOL scores in the psychological domain was observed with respect to the educational status ($p<0.037$) and income of patients ($p<0.048$), significantly better QOL scores in the physical ($p<0.040$) and environmental domain ($p<0.017$) were present with respect to the occupation of the patients. Patients with family support had better QOL scores in environmental domain. QOL is associated with education, income, occupation, family support and clinical categories of the patients.

Jennifer Pitt, Landon Myer and Robin Wood (2009), reported on Health-related quality of life was assessed using a standardised questionnaire, the Medical Outcomes Survey Short Form 36. Physical health summary scores and mental health summary scores were compared pre-HAART and at regular intervals during the first 48 weeks of HAART. Two hundred and ninety-five patients were enrolled into the study. The relationships between socio demographic, baseline and on-treatment variables and decline in health-related quality of life, as well as the impact of drug toxicities on quality of life, were assessed in unadjusted bivariate and adjusted multivariate analyses. There was a significant increase in health-related quality of life during the first 48 weeks on HAART. The median physical health summary score increased from 45 to 53 units ($p < 0.001$) and median mental health summary score increased from 45 to 50 units ($p < 0.001$). The bulk of this increase occurred during the first 16 weeks. Overall, 23% of participants experienced a decline in their physical health summary score, while 34% showed a decline in the mental health summary score. Average drops in median physical and mental health summary scores were 8.4 units (SD 9.31) and 9.9 (SD 11.4) units respectively. Participants with drug toxicity had lowered physical health summary scores than participants without drug toxicity at all time points. However, only three participants with toxicity (27%) reported an actual decline in health-related quality of life by week 48. Drug toxicities had little

impact on mental health summary scores. These results confirm the health-related quality of life benefits of HAART. While the majority of patients experienced a significant improvement in health-related quality of life on HAART, up to a third of patients reported declines in this quality of life. This was largely related to better baseline clinical state. HAART-related drug toxicities did not have a significant impact on health-related quality of life during the first year of HAART, which supports the ongoing use of the current national first-line regimen.

Li Li and et al. (2008) study in 116 PLH enrolled, quality of life (QoL) was measured using the Chinese version of the Short Form of the WHO Quality of Life questionnaire (WHOQOL-BREF; WHO 2004), the report found a significant association between family functioning and individual quality of life for parents living with HIV. In particular, family sociability had a strong relationship with the quality of life of parents living with HIV. Parents living with HIV from families where both parents are HIV-positive reported a lower level of family sociability than those from families with only one HIV-positive parent. HIV disclosure, family sociability, and number of children per family were found to be significant predictors of overall quality of life for the population. Study findings underscore the importance of developing interventions that improve family functioning for people living with HIV/AIDS in China.

Research on quality of life in people living with HIV/AIDS is often problematic as a standardized measurement still eludes researchers. However, the research to date suggests that a variety of physical, psychological, and social factors must all be considered when addressing quality of life issues.

CHAPTER III

RESEARCH METHODOLOGY

3.1 Research design

This study was a cross-sectional study that used data from “The Thai HIV Disease Progression: An Observational Database” “THE PROGRESS” five year observational prospective cohort study-open cohort for person living with HIV/AIDS.

3.2 Study population

The target population for this study was all adult males and females living with HIV/AIDS present to Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital THAILAND from December 2007-December 2008.

3.3 Study Period

First of December 2007 to December 2008.

3.4 Population size

All subjects presenting to the 3 hospitals from December 2007 to December 2008 and willing to participate to the study 3,736 cases.

3.5 Sampling Method

The simple random sampling was not applied to this study. The target population for this study was all adult males and females living with HIV/AIDS present to Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital THAILAND from December 2007-December 2008.

3.6 Inclusion criteria

- (1) Male or female, ≥ 18 years of age and older;
- (2) HIV-positive status;
- (3) Able and willing to provide informed consent.

3.7 Exclusion criteria

There was no exclusion criteria related to ethnicity, gender, severity of disease, or presence of other co-morbidities other than not meeting inclusion criteria.

3.8 Study Area

Study area: adult males and females living with HIV/AIDS patients in Bamrasnaradura Hospital Nonthaburi, Sanpatong Hospital Chiangmai and Lopburi Hospital Lopburi THAILAND. Bamrasnaradura Infectious Disease Hospital, in Nonthaburi, is a major referral hospital for AIDS patients of Thailand. Lopburi Hospital Lopburi is a tertiary hospital in Lopburi province and Sanpatong is a secondary hospital, an administrative subdivision of a Chiangmai province in northern region of Thailand.

3.9 Variable

3.9.1 Independent variable:

3.9.1.1 Socio- demographic factors

- 1). Age
- 2). Gender
- 3). Education
- 4). Occupation
- 5). Income
- 6). Current marital status
- 7). Smoking Status

3.9.1.2 HIV/AIDS Impact Factors

- 1). HIV- related event
- 2). CDC clinical category
- 3). Absolute CD4+ count
- 4). pVL (HIV-RNA)
- 5). Duration of HIV/AIDS infection
- 6). Duration of ARV initiation
- 7). Adherences to ARV

3.9.2 Dependent variable

Health-related Quality of Life of Persons Living with HIV-AIDS was measured by WHOQOL-BREF-THAI.

3.10 Measurement Tool

3.10.1 WHOQOL-BREF-THAI

Measurement tool was Thai version of brief measure (WHOQOL-BREF-THAI). The instrument was the summarized quality of life questionnaire of World Health Organization (WHOQOL-BREF-THAI) that includes 26 questions; each item uses a Likert-type five-point scale. These items are distributed in four domains. The four domains of QOL are, (a) physical health and level of independence (seven items assessing areas such as presence of pain and discomfort; dependence on substances or treatments; energy and fatigue; mobility; sleep and rest; activities of daily living; perceived working capacity); (b) psychological well being (eight items assessing areas such as Affect, both positive and negative self concept, higher cognitive functions; body image and spirituality), (c) social relationships (three items assessing areas such as social contacts, family support and ability to look after family; sexual activity) and (d) environment (eight items assessing areas such as freedom; quality of home environment; physical safety and security and financial status; involvement in recreational activity; health and social care: quality and accessibility) See details of WHOQOL-BREFT-THAI questionnaire in Appendix C

The 5-point response scale ranges from “1” to “5” with the alternatives:

- 1=very poor/very dissatisfied/not at all;
- 2=poor/dissatisfied/a little;
- 3=neither poor nor good/neither satisfied nor dissatisfied/a moderate amount;
- 4=good/satisfied/very much;
- 5=very good/ very satisfied/an extreme amount

For the 26 questions of WHOQOL-BREF-THAI, the possible scores ranged between 26 and 130 points. The QoL was then determined by dividing the scores into three groups as follows (World Health Organization, 1996b):

Table 3.10.1: WHOQOL-BREF-THAI Scoring and Levels

QoL Domains	Low	Moderate	High
1. Physical health	7-16	17-26	27-35
2. Psychological	6-14	15-22	23-30
3. Social relationships	3-7	8-11	12-15
4. Environment	8-18	19-29	30-40
5. Overall QoL	2-4	5-7	8-10
Total scores	26-60	61-95	96-130

Table 3.10.2 WHOQOL-BREF-THAI number of each Domain

QoL Domains	Number
Physical health	2,3,4,10,11,12,24
Psychological	5,6,7,8,9,23
Social relationships	13,14,25
Environment	15,16,17,18,19,20,21,22
Overall QoL	1,26

3.10.2 Case Record Form of HIV/AIDS Clinical history Data/ Socio demographic data

Data of HIV/AIDS Clinical history and Socio-demographic data were reviewed in subject Medical OPD Card and recorded into Case Record Form (CRF), created by experts on HIV/AIDS at the Department of disease control (DDC), Bamrasnaradura Hospital Nontaburi, Sanpatong Hospital Chiangmai and Lopburi Hospital. See details of CRF in Appendix D

3.11 Data collection

At present the data collection over 12 month period (December 2007-December 2008) has already been completed. The study population of PHA was selected by convenience sampling method including all 3,736 PHA attending Medicine OPD card of Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital THAILAND in at least a one year period.

Data were collected by self-administered structured WHOQOL-BREFT-THAI questionnaire or, in case of illiterate patients, by nurse, study co-coordinator administered questionnaire. Data collection was done at outpatient routine clinic preactice appointment in Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital THAILAND. Subject who meet Inclusion and no exclusion criteria were enrolled. Informed written consent of all the respondents enrolled in the study was duly taken. If there was any problem rose while conducting the research because of

some sensitive items in the structured, the researcher comforted the interviewee; provided suggestion/advice, as well as being a good listener and counselor. After interviewing, the nurse or study co-coordinator checked the items of the structured which were required to be answered completely.

The study nurse, study co-coordinator filled an additional questionnaire (Case Record Form) requiring patients' socio-demographic profile such as data on age, gender, income, education, current occupation, years after HIV diagnosis, and adherence to ARV. For data of CDC Clinical category, AIDS-related events, ARV history, CD4+ cell counts and pVL were collected from Medicine OPD card by study nurse, study co-coordinator or doctors after completed WHOQOL-BREFT-THAI questionnaire processing and subjected enrolled were in the study. Data were then recorded into the electronic Case Record Form Database. Researcher had checked the items in electronic Case record Form for correctness and completeness and cleaned the data as required.

3.12 Data Analysis

Statistical package was used for quantitative data analysis.

Descriptive statistics: frequency, percentage, means, standard deviation, median, range and Inter-quartile range were calculated for the socio-demographic factor, and Viral Load at baseline data.

Inferential statistics: The relationships between the independent variables and dependent variable (HRQoL) were presented by-

- 1). Unpaired t- test to study the difference between two continuous variables.
- 2). Pearson's Correlation in the correlation between two variables reflects the degree to which the variables are related.
- 3) .One-way ANOVA for distribution of each group with normally distributed, used for more than two groups. Statistical significance was set as $p < 0.05$, If the statistical significance was found, the method was applied for post hoc comparisons to specify with of the subgroups were responsible for the overall statistical significance.
- 4). Kruskal Wallis test compare three or more groups of sample data. Test is used when assumptions of ANOVA are not met. So Kruskal- Wallis test is a distribution free test. Hence used in cases of Homogeneity of Variances less than 0.05 after test with One-way ANOVA test.

3.13 Ethical Considerations

1) This research has received the approval letter by the DDC MOPH and Bamrasnaradura Ethical committees, see details in Appendix E. Also, the cross-sectional study of quality of life were approved from “THE PROGRESS committee also.

2) Written consent from participants is required and was obtained, See participant information and Inform consent form in Appendix F.

3) Anonymity and confidentiality are assured by not collecting the names of the PHA and the allocating a special code number on each questionnaire.

3.14 Limitations

This study was conducted in Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital THAILAND. Thus, it might not be a representative of all members of patient living with HIV/AIDS in Thailand because the study populations are not randomly selected.

Researcher could not know the QoL of difference subgroups within HIV/AIDS. Because there was a limitation of time for the research and being a cross sectional study, the researcher could not study variations at different point in times (e.g. after one, two, three years from baseline)

3.15 Expected Benefits and Application

This study will give the baseline data on the socio-demographic factor and HIV/AIDS clinical history factor and health related quality of life using WHOQOL-BREF-THAI among person living with HIV/AIDS in Bamrasnaradura Hospital Nontaburi, Sanpatong Hospital Chiangmai and Lopburi Hospital, Thailand.

This study is expected to determine the relationship between socio-demographic factor and HIV/AIDS clinical history factor and health related quality of life, from finding of this are expected to use to assess the factors that related to quality of life in physical, psychological, social, environmental, overall quality of life and spiritual needs of PHA life also.

Information finding obtained from the study will inform the health care policy maker of the quality of HIV/AIDS care guided by the national program and address the immediate and future health needs of people living with HIV/AIDS and their communities.

CHAPTER IV

RESULTS

This study was conducted in Bamrasnaradura Hospital Nonthaburi, Sanpatong Hospital ChiangMai and Lopburi Hospital Lopburi, Thailand during December 2007 to December 2008. Total 3,736 subjects living with HIV/AIDS, were enrolled in the study from THE PROGRESS (The Thai HIV Disease Progression: An Observational Database) cohort study-open cohort for person living with HIV/AIDS. Analyses were based on the 3,596 patients only who completed WHOQOL-BREF-THAI questionnaire.

4.1 Socio-demographic characteristics and Medical History Results

4.1.1 Socio-demographic characteristics

Patient characteristics at baseline are presented in Table 4.1.1,

Age: The median age was 41.7 (IQR 36 to 46). There was age less than 31 years 6.0%, age between 31-40 years 42.8%, between 41-50 years were 37.4% and more than 50 year were 13.8% respectively. Gender: Males were more than females: (57.8%) and (42.2%) respectively.

Marital status: Nearly half (46.8%) were married, 25.7% single, 12.6% windowed, 6.8% was Cohabitants (Common law partners), 4.9% divorced and 3.1% separated.

Educational attainment: 24.2 % primary level certificate, bachelor degree (19.6%) close to secondary level certificate (19.0%).

Table 4.1.1: Socio-demographic characteristics of HIV /AIDS patients

Variables	N	%
Sex (n= 3,736)		
Male	2,159	57.8
Female	1,577	42.2
Age (Years) (n= 3,736)		
Less than 31	224	6.0
31-40	1,600	42.8
41-50	1,396	37.4
>50	516	13.8
Median 41.7 (IQR 36 to 46) ¹		
Race (n= 3,736)		
Asian	3,729	99.8
Others	7	0.2
Ethnicity (n= 3,736)		
Thai	3,727	99.8
Others	9	0.2
Current Marital Status (n= 3,729)		
Widowed	469	12.6
Single	962	25.8
Married	1,745	46.8
Divorced	184	4.9
Separate	115	3.1
Cohabitants (Common law partners)	254	6.8
Educational attainment (n= 3,736)		
No certificate	96	2.6
Primary level certificate	905	24.2
Secondary level certificate	709	19.0
High School certificate	584	15.6
Associates/ Technical/ Vocational certificate	612	16.4
Bachelor of Science or Arts	733	19.6
More than BS/ BA	97	2.6

¹ Age with non-normal distribution, to report the median with its inter-quartile range (IQR), from 25th to 75th percentile, as the measure of center tendency

4.1.2 Socio-economic characteristics of HIV/AIDS patients

Socio-economic characteristics are presented in table 4.1.2, Occupation and income: The largest groups of occupational was wage earner 37.4% .The largest groups of respondents (25.3%) had 5,000-9,999 baths monthly income and 21.3% had less than 5,000 baths respectively.

Insurance status: 89% of participants were covered by health benefits schemes and 11% were not.

Table 4.1.2: Socio-economic characteristics of HIV/AIDS patients

Variables	N	%
Income (Thai Baht) (n= 3,735)		
No income	392	10.5
<5,000	797	21.3
5,000 – 9,999	945	25.3
10,000 – 14,999	672	18.0
15,000 – 19,999	388	10.4
≥ 20,000	541	14.5
Current Occupation(n= 3,736)		
Unemployed	432	11.6
Wage earner	1,397	37.4
Self-employed	647	17.3
Government Official	478	12.8
Working for Government Enterprise	160	4.3
Working for Private or Individual company	507	13.6
Others	115	3.1
Insurance Status (n= 3,736)		
Universal Coverage (UC) Scheme	1,276	34.2
The Social Security Scheme (SSS)	1,325	35.5
The Civil Servant Benefits Scheme (CSBS)	721	19.3
Self-supported	414	11.1

4.1.3 HIV/AIDS Clinical history

The HIV/AIDS clinical history is presented in table 4.1.3,

The median duration of HIV infection was 7.0 (IQR 5 to 10) years. In particular nearly half (46.4%) of HIV infection were more than 8 years infected, 38.5 % infected between 4-7 years and 15.1% infected between 1-3 years respectively.

The Center for Disease Control and Prevention (CDC) Classification System for HIV Infection in Adults and Adolescents found Category A 22.7%, Category B 15.4% and Category C 61.9%.

For the data of AIDS related event, patients experience suffering from AIDs event was 1,702 (45.5%), 1 AIDS related event experienced 1,313 (35.1%), 2 AIDS related events experienced 293 (7.8%) and more than 2 AIDS related event experienced 96 (2.6%).

Table 4.1.3: Medical history of HIV/AIDS patients

Variables	N	%
HIV History (n= 3,736)		
HIV positive duration (Year)		
1-3 years	563	15.1
4-7 years	1,439	38.5
>8 years	1,734	46.4
Median= 7.0 (IQR 5 to 10) ¹		
CDC² Clinical category(n= 3,736)		
A	849	22.7
B	575	15.4
C	2,312	61.9
Patients suffering AIDs Event (n= 3,736)		
Yes	1,702	45.5
No	2,034	54.4
Frequency of AIDs-related events (N=1,702)		
1 Event	1,313	35.1
2 Events	293	7.8
>2 Events	96	2.6

¹ HIV positive duration with non-normal distribution, instead of reporting the mean it is more appropriate to report the median with its interquartile range (IQR), from 25th to 75th percentile, as the measure of center tendency

² Center for Disease Control and Prevention Classification System for HIV Infection in Adults and Adolescents, 1987/1993

4.1.4 ARV therapy, adherence, CD4 count and viral load

ARV therapy, adherence, CD4 count and viral load are presented in table 4.1.4;

Most (95.1%) of all 3,557 subjects had been currently on Antiretroviral therapy (ARV) with a duration median 5.0 (IQR 3 to 7) years. More than half (54.7%) of the patients had been on treatment for 4-7 years, 27.8% for 1-3 years and 17.6% for more than 8 years. Poor adherence to ARV treatment found 10.2% and good adherence to ARV 89.8% at the baseline visit.

In case of data with non-normal distribution, instead of reporting the mean it is more appropriate to report the median with its interquartile range (IQR), from 25th to 75th percentile, as the measure of center tendency.

This study recorded CD4 T-cell lymphocyte (CD4+) count at baseline study. The median CD4 + at baseline was 359.5 (IQR 235 to 507.3).

Viral load was measured at baseline; pVL at baseline was < 50 copies/ml (IQR 49 to 49).

Table 4.1.4: ARV therapy, CD4+ count and viral load

Variables	N	%
Antiretroviral (n= 3,736)		
Current Antiretroviral Therapy		
Yes	3,557	95.2
No	179	4.8
Duration of ARV treatment 1-3 years	988	27.8
Duration of ARV treatment 4-7 years	1,944	54.7
Duration of ARV treatment >8 years	625	17.6
Median 5.0 (IQR 3 to 7) ¹		
Adherence (n= 3,736)		
Poor	380	10.2
Good	3,356	89.8
Mean \pm SD = 14.3 \pm 2.2 ,Median (QD) 15.0		
Group of CD4+ cell count at Baseline (n= 3,736)		
Unknown	446	11.9
1-199	628	16.8
200-499	1,803	48.3
>500	859	23.0
Median 359.5 (IQR 235 to 507.3) ¹		
Group of Viral Load (HIV RNA copies/ml) at Baseline (n= 3,736)		
Unknown	848	22.7
<50	2,406	64.4
50-5,000	379	10.1
5,001-20,000	26	0.7
20,001-100,000	41	1.1
>100,000	36	1.0
Median 49 (IQR 49 to 49) ¹		

¹ Non-normal distribution, instead of reporting the mean it is more appropriate to report the median with its interquartile range (IQR), from 25th to 75th percentile, as the measure of center tendency

4.2 Health-Related Quality of Life among Persons Living with HIV/AIDS

Each domain of quality of life includes low moderate and high QoL score; Most of respondents had a moderate level of quality of life, 65.2% in Overall QoL Domain, and 66.7% in Physical Health Domain, 53.4% in Psychological Health Domain, 70.5% in Social relationships and 71.1% in Environment Domain respectively.

Looking on highest QoL score in each domains, persons living with HIV/AIDS had a highest quality of life score in Physical health Domain 32.7%, Psychological health Domain 43.6%, Social relationships Domain 18.6%, Environment Domain 26.9% and Overall QoL Domain 33.8%. For lowest QoL score, found in Physical health Domain 0.5%, Psychological health Domain 3.0%, Social relationships Domain 10.9%, Environment Domain 2.1% and Overall QoL Domain 0.9% as illustrated in table 4.2;

Table 4.2: Number and percentage of respondents by level of health-related quality of life measured by WHOQOL-BREF-THAI (n=3,596)

Quality of life Scores	Number	Percentage
Level of Overall QoL		
Low	34	0.9
Moderate	2,346	65.2
High	1,216	33.8
Mean \pm SD = 90.5 \pm 11.9	Range= 34-126	Median = 90
Physical Health Domain		
Low	19	0.5
Moderate	2,400	66.7
High	1,177	32.7
Mean \pm SD = 25.0 \pm 3.4	Range= 13-35	Median = 25
Psychological Health Domain		
Low	107	3.0
Moderate	1,921	53.4
High	1,568	43.6
Mean \pm SD = 21.8 \pm 3.7	Range= 6-30	Median = 22
Social relationships Domain		
Low	393	10.9
Moderate	2,535	70.5
High	668	18.6
Mean \pm SD = 9.8 \pm 2.0	Range= 3-15	Median = 10
Environment Domain		
Low	74	2.1
Moderate	2,556	71.1
High	966	26.9
Mean \pm SD = 27.0 \pm 4.2	Range= 10-40	Median = 27

4.2.1 Socio- demographic Characteristics and health related quality of life

4.2.1.1 Gender and health related quality of life

Independent t-test was used to analyze the relationship between gender and health related quality of life as show in table 4.2.1.1,

Male person who have living with HIV/AIDS had higher quality of life score than female in Physical health domain ($p=0.011$), Psychological Health Domain ($p=0.003$) and Overall QOL Domain ($p=0.019$).

Analysis showed no relationship of Social relationships Domain and Environment Domain between male and female person who living with HIV/AIDS.

Table 4.2.1.1: Relationship between gender and health related quality of life by unpaired t-test

Kind of QOL	Mean \pm SD	Mean \pm SD	t	df	P-value
	Male (N=2074)	Female (N=1522)			
Physical health	25.1 \pm 3.3	24.8 \pm 3.5	2.483	3155	0.011
Psychological	21.9 \pm 3.6	21.7 \pm 3.8	1.192	3146	0.003
Social	10.0 \pm 1.9	9.6 \pm 2.0	6.401	3594	0.055
Environment	27.2 \pm 4.1	26.7 \pm 4.2	3.969	3594	0.136
Overall QOL	91.1 \pm 11.6	89.6 \pm 12.2	3.734	3179	0.019

4.2.1.2 Age and health related quality of life

Table 4.2.1.2 shows the significant relationships between age and WHOQOL-BREF THAI in Physical health Domain, Psychological Health Domain, Social relationship Domain and Environment Domain. Pearson Correlation test was used to analyze as following details,

Negative statistic significant relationships found in Physical health Domain ($p=0.040$) and Social relationship Domain (< 0.001), Positive statistic significant relationships found in Psychological Health ($p=0.014$) and Environment Domain ($p<0.001$) respectively.

No statistic significant relationships between overall QoL and age.

Table 4.2.1.2: Correlation between WHOQOL-BREF THAI domain and Age by Pearson Correlation

Details		Physical	Psycho	Social	Environment	Overall QoL
Age	Pearson Correlation	-0.034* (0.040)	0.041* (0.014)	-0.064** (< 0.001)	0.061** (< 0.001)	0.020 (0.231)
	Sig. (2-tailed)					
N		3585	3585	3585	3585	3585

*Correlation is significant at the 0.05 level (2-tailed)

** Correlation is significant at the 0.01 level (2-tailed)

4.2.1.3 Education and health related quality of life

Table 4.2.1.3 displays the WHOQOL-BREF-THAI domain by education level, statistical highly significant difference was found between education level and health related quality of life in all domains. Kruskal Wallis test show that the high education level strong relationship with high QoL in physical health domain ($p<0.001$), Environment ($p<0.001$) and Overall QoL($p<0.001$). For Psychological health ($p<0.001$) and Social relationship ($p<0.001$) was statistical significant test by One-Way ANOVA.

Considering groups of low education level had lower QoL in all domains than groups of high education level ($p<0.001$) in the other hand highest education (More than Bachelor degree) had high quality of life than other groups.

Table 4.2.1.3: Relationship between WHOQOL-BREF-THAI score and Education Characteristics analyzed by One-way ANOVA and *Kruskal-Wallis Test

Variables	N	Physical Mean±SD	Psycho Mean±SD	Social Mean±SD	Environmen t Mean±SD	Overall Mean±SD
Education (n=3596)						
No certificate	94	1606.65*	21.2±3.9 ^a	9.4±2.1 ^h	1653.53*	1598.84*
Primary	852	1560.27*	21.9±3.6 ^b	9.5±2.0 ⁱ	1696.74*	1661.67*
Secondary	676	1741.48*	21.5±3.6 ^c	9.6±1.9 ^j	1614.03*	1652.57*
High School	566	1766.83*	21.7±3.6 ^d	9.8±1.9 ^k	1719.68*	1750.71*
Vocational	594	1862.81*	21.7±3.6 ^e	9.8±1.9 ^l	1765.27*	1798.33*
Bachelor	717	2068.22*	22.2±3.8 ^f	10.4±2.0 ^m	2091.50*	2074.77*
More than BA	97	2271.59*	22.9±3.9 ^g	10.7±2.2 ⁿ	2616.10*	2448.68*
P-value		<0.001*	<0.001	<0.001	<0.001*	<0.001*

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a-f, a-g, b-c, b-g, c-f, c-g, d-f, d-g, e-f, e-g, h-l, h-m, h-n, i-k, i-l, i-m, i-n, j-m, j-n, k-m, k-n, l-m, l-n.

4.2.1.4 Socio economic (employ/income) and health related quality of life

Table 4.2.1.4 displays the WHOQOL-BREF-THAI domain by socio economic (occupational/income), statistical highly significant difference found between groups of each occupation and QoL in all domains ($p < 0.001$). Analysis shows that the Private company had higher QoL than other groups in Physical health Domain ($p < 0.001$). Government Enterprise had higher QoL in Psychological health and Overall QoL Domain; Government Official had higher QoL in Social relationship and Environment Domain respectively. The results showed Unemployed person have statistically highly significant low QoL in all domains than others groups ($p < 0.001$).

Looking for income level, statistical highly significant difference was found between income levels, which reported the high income-high quality of life in all Domains ($p < 0.001$).

Table 4.2.1.4: Relationship between WHOQOL-BREF-THAI score and socio economic (employ/income) Characteristics analyzed by One-way ANOVA and *Kruskal Wallis Test

Variables	N	Physical Mean±SD	Psycho Mean±SD	Social Mean±SD	Environment Mean±SD	Overall Mean±SD
Current Occupation						
Unemployed	411	1288.67*	1468.94*	9.0±2.1 ^a	25.9±4.3 ^h	85.2±12.6 ^o
Wage earner	134	17011.44*	1773.85*	9.7±1.9 ^b	26.5±4.0 ⁱ	89.3±11.2 ^p
	3					
Self-employed	610	1907.07*	1857.88*	9.9±1.9 ^c	27.4±4.0 ^j	91.7±11.2 ^q
Government Official	472	1935.73*	1894.21	10.3±1.9 ^d	28.2±4.1 ^k	93.2±11.8 ^r
Government Enterprise	155	2016.95*	2001.13*	10.3±1.8 ^e	28.1±3.6 ^l	93.8±11.1 ^s
Private company	493	2162.90*	1956.22*	10.2±2.0 ^f	27.4±4.2 ^m	93.1±12.1 ^t
Others	112	1757.33*	1602.03*	9.6±2.1 ^g	26.6±4.5 ⁿ	89.1±12.3 ^u
P-value		<0.001*	<0.001*	<0.001	<0.001	<0.001
Income (Thai Baht)						
No income	372	23.1±3.5 ^{a1}	1381.28*	8.9±2.1 ^{b1}	25.6±4.3 ^{c1}	84.3±12.5 ^{d1}
< 5,000	766	24.2±3.2 ^{a2}	1742.22*	9.4±1.9 ^{b2}	26.3±4.0 ^{c2}	88.3±11.1 ^{d2}
5,000 – 9999	902	25.2±3.2 ^{a3}	1807.59*	9.8±1.9 ^{b3}	26.7±4.1 ^{c3}	90.3±11.3 ^{d3}
10,000 – 14,999	650	25.4±3.4 ^{a4}	1810.23*	10.0±2.0 ^{b4}	27.1±4.0 ^{c4}	91.2±11.7 ^{d4}
15,000 – 19,999	378	25.7±3.3 ^{a5}	1904.66*	10.2±1.8 ^{b5}	27.9±3.9 ^{c5}	93.0±11.0 ^{d5}
≥ 20,000	527	26.2±3.3 ^{a6}	2065.22*	10.4±2.0 ^{b6}	28.8±4.1 ^{c6}	95.5±11.6 ^{d6}
P-value		<0.001	<0.001*	<0.001	<0.001	<0.001

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a-b, a-c, a-d, a-e, a-f, a-g, b-d, b-e, b-f, c-d, c-e, c-f, d-g, e-g, f-g, h-i, h-j, h-k, h-l, h-m, i-j, i-k, i-l, i-m, j-k, k-m, k-n, l-n, o-p, o-q, o-r, o-s, o-t, o-u, p-q, p-r, p-s, p-t, q-r, q-s, q-t, q-u, r-u, s-u, t-u, a1-a2, a1-a3, a1-a4, a1-a5, a1-a6, a2-a3, a2-a4, a2-a5, a2-a6, a3-a5, a3-a6, a4-a6, a5-a6, b1-b2, b1-b3, b1-b4, b1-b5, b1-b6, b2-b3, b2-b4, b2-b5, b2-b6, b3-b5, b3-b6, b4-b6, c1-c2, c1-c3, c1-c4, c1-c5, c1-c6, c2-c4, c2-c5, c2-c6, c3-c4, c3-c5, c3-c6, c4-c5, c4-c6, c5-c6, d1-d2, d1-d3, d1-d4, d1-d5, d1-d6, d2-d3, d2-d4, d2-d5, d2-d6, d3-d5, d3-d6, d4-d5, d4-d6, d5-d6.

4.2.1.5 Current Marital Status and health related quality of life

Table 4.2.1.5; statistical significant difference was found between Psychological health domain ($p=0.003$) and Environment domain ($p=0.004$). Concerning, most of separate status had low QoL than other groups, in the other hand most of Married Status found high QoL than other groups.

Analysis showed none significant difference found between current marital status and QoL in Physical health domain, Social relationship domain and Overall QoL domain.

Table 4.2.1.5: Relationship between WHOQOL-BREF-THAI score and marital status analyzed by One-way ANOVA and *Kruskal Wallis Test

Variables	N	Physical Mean±SD	Psycho Mean±SD	Social Mean±SD	Environment Mean±SD	Overall Mean±SD
Current Marital Status						
Widowed	455	1751.25*	22.0±3.8 ^a	1615.87*	27.2±4.3 ^g	1796.76*
Single	930	1875.64*	21.5±3.7 ^b	1905.05*	27.0±4.2 ^h	1811.27*
Married	1683	1768.61*	22.0±3.5 ^c	1821.70*	27.1±4.1 ⁱ	1815.69*
Divorced	181	1710.72*	21.9±3.6 ^d	1645.68*	26.7±3.7 ^j	1745.52*
Separate	100	1653.55*	21.0±4.1 ^e	1453.44*	26.0±4.6 ^k	1522.44*
Not married	241	1880.17*	21.6±4.0 ^f	1783.43*	26.3±4.3 ^l	1742.08*
P-value		0.115	0.003	0.115	0.004	0.115

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a-b, a-e, b-c, c-e, d-e, g-k, g-l, h-k, h-l, i-k, i-l,

4.3 HIV/AIDS Clinical history and WHOQOL-BREF-THAI

4.3.1 ARV Treatment Duration

Table 4.3.1, Physical health Domain ($p < 0.001$), Psychological Health Domain ($p = 0.010$), Environmental ($p = 0.019$) and Overall QoL Domain ($p < 0.001$) found statistic significant difference between group of ARV treatment between 1-3 years had lower score than group of subject who has been on ARV treatment duration 4-7 years and group of subject who has been on ARV treatment duration more than 8 years respectively (Physical health domain, Environmental Domain, Overall QoL Domain analyzed by One-way ANOVA test.

No statistic significant difference found between Social relationships Domains and ARV treatment duration.

Table 4.3.1: Relationship between WHOQOL-BREF-THAI score and Duration of HIV/AIDS infection analyzed by One-way ANOVA Test and *Kruskal Wallis Test

ARV Treatment	N	Physical Mean \pm SD	Psychological Mean \pm SD	Social Mean \pm SD	Environment Mean \pm SD	Overall QoL Mean \pm SD
1-3 years	944	24.4 \pm 3.4 ^{c1}	1652.25*	9.7 \pm 2.0	26.7 \pm 4.2 ^{d1}	89.0 \pm 12.2 ^{e1}
4-7 years	1905	25.2 \pm 3.4 ^{c2}	1766.88*	9.8 \pm 2.0	27.1 \pm 4.2 ^{d2}	90.9 \pm 11.9 ^{e2}
>8 years	623	25.3 \pm 3.4 ^{c3}	1771.27*	9.9 \pm 1.9	27.3 \pm 3.9 ^{d3}	91.5 \pm 11.2 ^{e3}
P-value		<0.001	0.010	0.072	0.019	<0.001

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between c1-c2, c1-c3, d1-d2, d1-d3, e1-e2, e1-e3,

4.3.2 Adherences to ARV

Table 4.3.2 displays the score of quality of life and Adherences to ARV by Pearson Correlation, statistic highly significant positive correlation was found in Psychological Health Domain ($p < 0.001$), Environment Domain ($p < 0.001$) and Overall QoL ($p < 0.001$). The data show none statistic significant correlation on Physical health and Social Domain and quality of life.

Table 4.3.2: Correlation between WHOQOL-BREF THAI domain and Duration of HIV/AIDS infection, ARV Status and Adherences to ARV by Pearson Correlation

	Details	Physical	Psycho	Social	Environment	Overall QoL
Adherences to ARV	Pearson Correlation	0.014 (0.391)	0.091** (< 0.001)	0.008 0.635	0.087** (< 0.001)	0.071** (< 0.001)
	Sig. (2-tailed)					
	N	3591	3591	3591	3591	3591

*Correlation is significant at the .05 level (2-tailed)

** Correlation is significant at the .01 level (2-tailed)

4.3.3 AIDs-related Events

Table 4.3.3: One-way ANOVA Test found group of subject who has no AIDs-related Event exposure had higher Physical health score than group of AIDs-related Event more than 2 events ($p = 0.015$). The group of only one AIDs-related events had higher Physical health score more than group of more than 2 events ($p = 0.015$).

Statistical significant difference in Overall Health ($p = 0.001$) and Psychological health Domain ($p = 0.005$), the One-way ANOVA test found group of none AIDs-related had higher QoL than group of two and more than 2 events respectively. Group of only one event had higher QoL than group of more than 2 events.

Relationship of Environment Domain was analyzed by Kruskal Wallis Test, statistic significant difference found group of none AIDs-related Event exposure had higher Environment score than other groups ($p < 0.001$).

No statistic significant difference found in Social relationship Domain.

Table 4.3.3: Relationship between WHOQOL-BREF-THAI score and Medical History of HIV/AIDS patients analyzed by One-way ANOVA Test and *Kruskal Wallis Test

	N	Physical Mean±SD	Psychological Mean±SD	Social Mean±SD	Environment Mean±SD	Overall QoL Mean±SD
Frequency of AIDS-related events						
none	1924	25.1±3.3 ^{a1}	22.0±3.6 ^{b1}	9.9±2.0	1847.41	91.0±11.7 ^{c1}
1 Event	1291	24.9±3.5 ^{a2}	21.8±3.8 ^{b2}	9.8±2.0	1783.34	90.2±12.2 ^{c2}
2 Events	288	24.8±3.4 ^{a3}	21.5±3.6 ^{b3}	9.8±2.0	1631.86	89.1±11.6 ^{c3}
>2 Events	93	24.1±3.5 ^{a4}	20.9±4.1 ^{b4}	9.5±1.7	1513.23	86.9±11.7 ^{c4}
P-value		.015	.005	.155	<.001	.001

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a1-a4, a2-a4, b1-b3, b1-b4, b2-b4, c1-c3, c1-c4, and c2-c4

4.3.4 Duration HIV positive Status

One-way ANOVA test found statistic highly significant difference between duration of HIV positive status and QoL in Physical health score, group of HIV infection 1-3 years had lower Physical health score than others group ($p < 0.001$)

No relationship between Group of HIV infection 4-7 years and more than 8 years group. For other domains, none statistic significant differences found.

Table 4.3.4: Relationship between WHOQOL-BREF-THAI score and Medical History of HIV/AIDS patients analyzed by One-way ANOVA Test and *Kruskal Wallis Test

	N	Physical Mean±SD	Psychological Mean±SD	Social Mean±SD	Environment Mean±SD	Overall QoL Mean±SD
Duration HIV Positive Status (Year)						
1-3 years	528	24.3±3.5 ^a	1679.23*	9.7±2.0	1730.98	1658.07
4-7 years	1377	25.2±3.4 ^b	1821.84*	9.9±2.0	1826.34	1836.43
>8 years	1691	25.1±3.4 ^c	1816.73*	9.8±1.9	1796.91	1811.46
P-value		<.001	.197	.194	.197	.197

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a-b, a-c

4.3.5 CDC Classification

One-way ANOVA Test found statistic significant difference between CDC Classification and Health related quality of life. CDC category A had higher QoL in Psychological Health ($p=0.023$), Environment ($p=0.001$) and Overall QoL Domain ($p=0.007$) than CDC category C. No significant relationship between CDC category A and B found.

Table 4.3.5: Relationship between WHOQOL-BREF-THAI score and CDC Classification analyzed by One-way ANOVA Test

CDC	N	Physical Mean±SD	Psychological Mean±SD	Social Mean±SD	Environment Mean±SD	Overall QoL Mean±SD
CDC:A	838	25.1±3.4	22.1±3.6 ^d	9.9±2.0	27.5±4.0 ^g	91.5±11.6 ^j
CDC:B	527	25.1±3.4	21.8±3.7 ^e	9.9±2.0	27.0±4.2 ^h	90.7±12.1 ^k
CDC:C	2231	24.9±3.4	21.7±3.7 ^f	9.8±2.0	26.8±4.2 ⁱ	90.0±11.9 ^l
P-value		0.257	.023	0.225	0.001	0.007

Post Hoc Tests Significant difference found between d-f, g-i, j-l

4.3.6 CD4+ cell count at Baseline Visit

Table 4.3.6., analyzed by One-way ANOVA test found CD4+ cell count before ARV initiation was statistically significant difference in all Domains, Physical health Domain ($p<0.001$), Psychological health Domain ($p=0.001$), Social relationship Domain ($p=0.028$), Environment Domain ($p=0.004$) and Overall QoL Domain ($p<0.001$), the analyzed show group of CD4+ count 1-199 cells/mm³ had lower QoL than others groups.

No statistically significant difference found between group of CD4+ count between 200-499 cells/mm³ and group of CD4+count >500 cells/mm³.

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Table 4.3.6: Relationship between WHOQOL-BREF-THAI score and, CD4+ count, analyze by One-way ANOVA Test and *Kruskal Wallis Test

CD4 +cell count	N	Physical Mean±SD	Psychological Mean±SD	Social Mean±SD	Environment Mean±SD	Overall QoL Mean±SD
1-199	623	24.4±3.4 ^j	21.4±3.6 ^m	9.6±2.0 ^p	26.5±3.9 ^s	88.5±11.5 ^v
200-499	1794	25.2±3.4 ^k	22.0±3.6 ⁿ	9.9±2.0 ^q	27.2±4.2 ^t	91.1±11.8 ^w
>500	858	25.3±3.3 ^l	22.0±3.6 ^o	9.9±2.0 ^f	27.1±4.3 ^u	91.2±11.9 ^x
P-value		<0.001	0.001	0.028	0.004	<0.001

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a-b, a-c, d-e, d-f, g-h, g-i, j-k, j-l, m-n, m-o, p-q, p-r, s-t, s- u, v-w, and v-x

4.3.7 Viral Load at Baseline

This study recorded Viral Load (HIV RNA) at baseline at the last available laboratory assessment, statistic significant difference found in domains of Physical health domain, Psychological Health Domain and Overall QoL Domain.

Physical health domain found statistic significant difference in group of pVL <50 copies/ml had higher QoL than other groups (p=0.012) analyzed by Kruskal Wallis Test.

Statistic significant difference found in domains of Psychological Health Domain, group of pVL 50-5,000 copies/ml had higher Psychological Health score than group of pVL 20,001-100,000 copies/ml (p=0.038), analyzed by One-way ANOVA test. None statistic significant difference found between other pVL groups in Psychological Health Domain.

Statistic significant difference found in Overall QoL Domain, the analyzed found group of pVL 50-5,000 copies/ml had higher Overall QoL than group of pVL 5,001-20,000 and group of pVL 20,001- 100,000 copies/ml (p=0.034). None statistic significant difference found between other groups in Overall QoL Domain, analyzed by One-way ANOVA test.

Table 4.3.7: Relationship between WHOQOL-BREF-THAI score and, CD4+ count, Viral Load and duration of HIV positive status analyze by One-way ANOVA Test and *Kruskal Wallis Test

Viral Load at Baseline	N	Physical Mean±SD	Psychological Mean±SD	Social Mean±SD	Environment Mean±SD	Overall QoL Mean±SD
<50	2395	1449.64*	21.8±3.6 ^{a1}	9.9±2.0	27.0±4.2	90.7±11.9 ^{b1}
50-5,000	376	1427.81*	22.2±3.5 ^{a2}	9.9±1.8	27.4±4.0	91.6±10.9 ^{b2}
5,001-20,000	26	1070.90*	21.0±3.1 ^{a3}	9.5±2.0	25.9±4.0	86.9±10.3 ^{b3}
20,001- 100,000	40	1226.71*	20.7±3.5 ^{a4}	9.5±1.6	26.4±3.8	87.3±10.3 ^{b4}
>100,000	35	1142.26*	21.3±3.9 ^{a5}	9.7±2.2	26.4±4.6	87.9±12.6 ^{b5}
P-value		0.012	0.038	0.623	0.119	0.034

* Use Kruskal Wallis test in cases of Homogeneity of Variances less than 0.05

Post Hoc Tests Significant difference found between a2-a4, b2-b3, b2-b4

CHAPTER V

DISCUSSION

5.1 Discussion

Cross-sectional study, used data from “The Thai HIV Disease Progression: An Observational Database”, five year observational prospective cohort study: THE PROGRESS, for this thesis only the baseline data has been used. The target population for this study was all adult males and females living with HIV/AIDS present to Bamrasnaradura Hospital, Sanpatong Hospital and Lopburi Hospital, THAILAND from December 2007 to December 2008 attending from Medicine OPD and health related quality of life was assessed by using the WHOQOL-BREFF-THAI. A study of psychometric properties of WHOQOL-BREFF-THAI in patients with HIV/AIDS concluded that WHOQOL-BREFF can be useful generic HRQoL instrument in Thai patient with HIV/AIDS because it is brief and shows good internal consistency reliability and construct convergent and discriminate validity (Phantipa et al.,2007). A relationship between the independent variables and HRQoL was analyzed by using one-way ANOVA, Kruskal-Wallis Test, Pearson Correlation and independent t-test.

5.1.1 Health-related Quality of Life of Persons Living with HIV/AIDS

Among the 3,596 subjects who completed WHOQOL-BREF-THAI questionnaire, the mean±SD (range) of the domain score of WHOQOL-BREF-THAI was 25±3.4 (13-35) for Physical health Domain, 21.8±3.7 (6-30) for Psychological Health Domain, 9.8±2.0 (3-15) for Social relationships Domain, and 27.0±4.2 (10-40) for Environment Domain and 90.5±11.9 (34-126) for Overall QoL Domain. Most of respondents had a moderate level of quality of life, 65.2% in Overall QoL Domain, and 66.7% in Physical Health Domain, 53.4% in Psychological Health Domain, 70.5% in Social relationships Domain and 71.1% in Environment Domain respectively.

Previous study of “Middle category endorsement in odd-numbered Likert response scales: Associated item characteristics, cognitive demands, and preferred meanings” found personality assessment respondents may “neither agree nor disagree” with an item prompt because they are undecided, they do not understand the item, their response is conditional, or they have a neutral, moderate, or average construct standing. Given these options, however, there is a predominant general (across items and persons) tendency to endorse the middle category with an “it depends” response orientation, suggesting that conditional response interpretation of the category may be more common than the moderate-standing interpretation and use (John T. Kulas and Alicia A. Stachowski, 2008). The orientation and standard procedure is potentially useful, hence, we have SOP (Standard Operative Procedure) hand book “The Thai HIV Disease Progression: An Observational Database, version 3.0, 12 August 2007 for site staffs who conduct (give QoL questionnaires), contact

subjects and explain details with subject and also before conduct the study, we have site initiation meeting for all staffs who conduct the study.

5.1.2 Socio- demographic Characteristics and health related quality of life

This study revealed that the median age was 41 (IQR 36 to 46) years. There was age less than 31 years 6.0%, age between 31-40 years 42.8%, between 41-50 years were 37.4% and more than 50 year were 13.8% respectively. On the national level in Thailand, reported socio-demographic characteristics of people in Thailand with HIV infection, estimated age of people living with HIV in Thailand, 2009 age 30-34 years (24.92%), and 25-29 (22.13%) respectively (Department of Disease Control Ministry of Public Health, 2009). The sample population for this study might be not closely average for Thailand HIV population, looking for age (IQR 36 to 46), was higher than national level in Thailand.

Occupation and income: Wage earner 37.4%, self employed 17.3%. The largest groups of respondents (25.3%) had 5,000-9,999 baths monthly income and 21.3% had less than 5,000 baths. Insurance status: 89% of participants were covered by health benefits schemes and 11% were Self-supported. Nowadays, there are several health insurance/welfare schemes in Thailand, for example, Voluntary Healthcare Card Scheme, Civil Servants Medical Benefit/Welfare Scheme (CSMBS), Social Security Scheme (SSS; compulsory scheme for formal sector) and Health Welfare for the low income group, the elderly, children under 12 and other underprivileged groups. Although these schemes have covered various population groups, they have not yet covered 100% of the total 60 million Thai population. Besides, there are still some weaknesses in terms of efficiency and equity (Asia-Pacific Health Economics Network: APHEN, 2001).

Study found 11% of subjects were Self-supported; explain that subjects can't use the universal healthcare coverage because coverage system has not been able to provide easy access. According to UC rules people can use free health services in the areas where they are officially resident (i.e. people cannot have free healthcare in hospitals outside their residential area). Socio- economic characteristics of people in Thailand with HIV infection reported the Wage earner more than others group 47.25% (Department of Disease Control Ministry of Public Health, 2009). Hence, the characteristics of sample population closely socio-economic characteristics of national level of people in Thailand with HIV/AIDS infection.

5.1.2.1 Gender and health related quality of life

Independent t-test was used to analyze the relationship between gender and smoking status and health related quality of life. Male person who have living with HIV/AIDS had higher quality of life score than female in all 3 Domains, Physical health domain ($p=0.011$), Psychological Health Domain ($p=0.003$) and Overall QOL Domain ($p=0.019$) respectively.

Same as the study of health related quality of life in patients living with human immunodeficiency virus in Tehran Iran. As the results showed, women with HIV/AIDS had worse condition than men (Marzieh Nojomi, Khatereh Anbary and Mitra Raaanjbar, 2008).

In our study, male perceived a high QoL than female in 3 Domains, this might be extrapolated to present hopefulness and optimism, the majority of male were young, median age was 41 (IQR 36 to 46) and this may reflect their need to be hopeful for future with him safe and family. As results, women had worse conditions than men, that can be said that this issue originates from lack of positive perception of their role in the society, being passive from social and economic point of view and also the impact of factors such as sex inequality, violence against women, lack of social and family supporting, and especial cultural beliefs in addition to stigma of diseases.

Looking the lower QoL of women with HIV symptom this may differ from those experienced by HIV positive. For example, women with lipodystrophy or body fat changes are more likely than men to experience breast enlargement and abdominal fat redistribution; whereas men are more likely to have a dorsocervical fat pad (buffalo hump). Women are more likely to have headaches, with are usually poorly identified and poorly managed. Women tend to have more fatigue. With can be related to disease or stress (Patrice K Nicholas, 2005).

5.1.2.2 Age and health related quality of life

Pearson Correlation found statistic negative significant relationship between age and Physical health Domain ($p=0.040$) and Social relationship Domain ($p<0.001$), respondent with older subjects have lower Physical health score and Social relationship than younger subjects. And the data show highly statistic significant positive correlation in Psychological health Domain (0.014) and Environment Domain and ($p<0.001$) that respondent with older subject had higher Psychological Health and Environment score than younger subjects.

Discussed our results, Increasing age does not necessarily cause a reduction in the quality of life, and in some cases, can even improve it, the positive correlation in Psychological health Domain and Environment Domain, this may be say that older HIV/AIDS were more likely to have a stable home environment and fewer work responsibility. In additional they were more likely to perceive fewer lost opportunities in pursuing their career goals because of HIV status. Other factors that improve quality of life such as trusting relationships with friends and family, frequent contact with friends and living in a good, safe neighborhood were all found to increase the quality of life (Gopal Netuveli, 2006).

The researchers from Imperial College London, Karolinska Institutet, Stockholm and City University, London studied the effect of health factors such as long standing illness, social factors like trusting relationships and socio-economic factors on the quality of life, Dr Gopal Netuveli, and lead researcher,

said: "Although many worry that old age and retirement could be a time of hardship, this study shows that for many their quality of life actually improves as they get older. In particular, social engagement such as volunteering can significantly improve quality of life, even in very old age. (Gopal Netuveli, 2006)

For negative significant relationship between age and Physical health Domain and Social relationship Domain found the results as same as in several previous studies. Studied the effect of health factors such as long standing illness in London reported, factors such as a long standing illness, difficulties in moving about and carrying on with every day activities, depression or financial difficulties can all reduce the quality of life in old ageing people (Gopal Netuveli , 2006). Previous study of Age-related effects on symptom status and health-related quality of life in persons with HIV/AIDS found HRQOL is linked to symptom status and may be related to age in HIV-positive persons younger age predicted higher sexual function ($p < .01$) and older age predicted greater provider trust ($p < .01$). (Kathleen M. Nokes et al., 2009). The study of impact of HIV-associated lipodystrophy on health related quality of life, mental health and medication adherence in Canada found Impact on QOL was greater in younger subjects suggesting that age may mediate the negative impact of LD (Collins EJ et. al., 2002).

Social relationships are defined as social structures made up of contact bonds among individuals or groups of relatives, colleagues, friends and neighbours (Sluzki C, 2000) Hence, the physical Health problem with person living with HIV/AIDS and long standing illness may be effect to problem social relationships that related to low QoL in physical Health and Social relationship Domain that present in this study.

Other Study of health related quality of life in patients living with human immunodeficiency virus in Tehran Iran, used WHO-QOL-BREFF, a significant relationship that have associated with quality of life of the patients were gender, marital status, level of education and occupational. The mean of total score of women, separate or windowed, those with low education (primary) and unemployed were significant less than the score of other groups ($p < 0.005$). Patients age < 35 years were significant better than other age group on physical domain ($p < 0.05$). These patients scored less than older group on psychological, social, and environments ($p < 0.05$) (Marzieh Nojomi, Khatereh Anbary and Mitra Raaanjbar, 2008)

5.1.2.3 Current Marital Status and health related quality of life

Analysis showed no significant difference found between current marital status and QoL in Physical health domain, Social relationship domain and Overall QoL domain. Statistical significant difference was found between Psychological health domain ($p = 0.003$) and environment domain ($p = 0.004$), Concerning, most of separate status had low QoL than other groups; in the other hand most of Married Status found high QoL than other groups.

Several studies of Health related quality of life reported the marital status was associated with quality of life; that say family is the smallest and most

fundamental social unit. Women and men have important role in nurturing members of the family to be physically, emotionally, mentally and intellectually healthy (General Ban Ki Moon,2008).We demonstrated that overall there is a strong association between married and widowed and marital status, maintenance and improvement of life quality are important including this point also.

5.1.2.4 Socio economic (education/ occupational/income) and health related quality of life

Displays the WHOQOL-BREF-THAI domain by education level, statistical highly significant difference was found between education level and health related quality of life in all QoL Domains ($p < 0.001$), that explains the education level strong relationship with high QoL in domain of physical health domain, Psychological health, Social relationship, Environment, and Overall QoL respectively. Considering the group of No certificate had lower QoL in all domains than others group ($p < 0.001$).

Statistical highly significant difference was found between type of occupation and QoL in all domains ($p < 0.001$). Analyzed show that the Private company had higher QoL than other groups in Physical health Domain. Government Enterprise had higher QoL in Psychological health and Overall QoL Domain; Government Official had higher QoL in Social relationship and Environment Domain respectively. The results show statistic highly significant that the Unemployed person had low QoL in all domains than others occupational groups ($p < 0.001$).

Looking for income level, statistical highly significant difference was found between income levels, which reported the high income-high quality of life in all Domains ($p < 0.001$). Education has been widely perceived as one of the important socio-economic determinants of health and mortality. There is considerable evidence that low education attainment is strongly correlated with disease, health risks and mortality. Education affects health and mortality through a number of pathways, such as lifestyle, health behavior, problem-solving abilities, social relations, self esteem, and stress management. IrmaT Elo et al (2008) found High education and being married are associated with lower mortality in all three countries absolute educational differences tend to be smaller among married than unmarried individuals. Absolute differentials by education are largest for Bulgarian men, but in relative terms educational differences are smaller among Bulgarian men than in Finland and the U.S. Among women, Americans experience the largest education mortality gradients in both relative and absolute terms.

Education leads to improved socio-economic determinants of health such as higher productivity better job opportunities, high income and as important for health care and social esteem and etc., all of Quality of life domain were associated with level of education, occupational, income, respondent have high education level lead to high quality of life in person who live with HIV/AIDS infection that show in this study.

5.1.3 HIV/AIDS Clinical history and WHOQOL-BREF-THAI

Baseline Medical History were reported in details of duration of HIV infection, HIV Exposure Category, Duration of ARV treatment, CDC category at baseline, CD4+ count first time check as available in medical recorded, CD4+ count before start ARV, CD4+ count at baseline, and AIDS related Event.

The HIV infection duration median 7.0 (IQR 5 to 10), nearly half (46.4%) of HIV infection were of more than 8 years duration, 38.5%, 4-7 years and 15.1% 1-3 years. HIV transmission were mainly through heterosexual contact (35.2%), homosexual contact (7.7%), and (11.9%) unknown cause, injecting drug use 2.5% and other routes 1.6%. CDC Category were reported as category A; 22.7%, category B; 15.4% and category C; 61.9%. For the data of AIDS related Event, patients suffering AIDS Event was 1,702 (45.5%), 1 AIDS related event 1313 (35.1%), 2 AIDS related events 293 (7.8%) and more than 2 AIDS related event 96 (2.6%).

5.1.3.1 CDC Classification

Displays the quality of life and HIV/AIDS Impact Factor, found statistic significant difference between CDC Classification, CDC category A had higher QoL in Psychological Health ($p=0.023$), Environment ($p=0.001$) and Overall QoL Domain ($p=0.007$) than CDC category C. None significant relationship between CDC category A and B found.

Refer to another studies, in Tehran Iran, used WHO-QOL-BREFF using multivariate analysis, using multiple linear regression, the results showed clinical stage of disease had strongest relationship with the quality of life (Marzieh Nojomi et al., 2008). So the several Studies of health related quality of life in patients living with human immunodeficiency virus used WHO-QOL-BREFF using showed clinical stage of disease had strongest relationship with the quality of life as same as this study.

5.1.3.2 Duration HIV positive Status and ARV treatment

One-way ANOVA test found statistic highly significant difference between duration of HIV positive status and Physical health score, group of HIV infection 1-3 years had lower Physical health score than others group ($p<0.001$).

Refer to results of Duration of HIV positive status, statistic significant positive correlation between ARV duration in Physical health Domain ($p<0.001$), Social relationship Domain ($p=0.027$), Environment Domain ($p=0.030$) and Overall QoL ($p<0.001$) respectively by Pearson correlation. For Physical health Domain ($p<0.001$), Psychological Health Domain ($p=0.010$), Environmental ($p=0.019$) and Overall QoL Domain ($p<0.001$) found statistic significant difference between group of ARV treatment between 1-3 years had lower score than group of subject who has been on ARV treatment duration 4-7 years and group of subject who has been on ARV treatment duration more than 8 years respectively (Physical health domain,

Environmental Domain, Overall QoL Domain analyzed by One-way ANOVA test, for Psychological health Domain analyzed by and Kruskal Wallis Test).

The studied in Taiwan found Long-term care of human HIV and AIDS cases has raised quality of life (QoL) issues, the results of the analysis reveal that multiple factors affect QoL for HIV/AIDS male outpatients receiving HAART, including severity of depression, deterioration of work function, inconvenience resulting from medication schedules and medical appointments, lack of social support, negative stressors, and adverse effects of HAART. The results provide screening factors so that clinicians can intervene to improve the QoL for their HIV patients (Cheng fang yen et al., 2003). Another studied to identify the effects of antiretroviral therapy on quality of life, performed a qualitative content analysis of the Medical Outcomes Study-Human Immunodeficiency Virus (MOS-HIV) Health Survey, used focus groups to elicit views about antiretroviral effects on quality of life from a purposive sample of treatment-experienced participants. Data were analysed using a grounded theory approach. Participants (n=38) viewed the use of antiretrovirals as a trade-off between poorer quality of life and being alive. The net effect was increased longevity but without hope and future. Features of quality of life included the downstream consequences of side effects and toxicities, tensions with health care providers and loss of independent decision-making, dilemmas regarding drugs and career, burdens of medication-taking responsibilities, and the stress of living life under a pretense and hiding an HIV diagnosis. Quality of life concerns of people living with HIV, particularly those related to medication use, are not well captured by the MOS-HIV. A broad concept of quality of life is needed to encompass all dimensions important to people living with HIV (L. Y. Park-Wyllie, 2007)

The results of this study show low QoL in patient living with HIV/AIDS 1-3 years and patient started ARV duration 1-3 years in many QoL Domain that may as reasons of Drug-related in quality of life, Drug-related reduction in quality of life, Drug-related toxicities, unknown durability of current therapies Also the first time of HIV infection, many patients had high anxiety and fear of loss, bore much burden of care, and faced many difficulties.

5.1.3.3 Adherences to ARV

Antiretroviral adherence is the second strongest predictor of progression to AIDS and death, after CD4+ count. Non adherence may eventually undermine the dramatic improvements in HIV-related health parameters seen in resource-rich countries and expected in developing countries as ART becomes more widely available. Adherence to ART is closely tied to virologic, immunologic, and clinical outcomes. Small increases in adherence can result in significant improvements in these outcomes (Edward L et al., 2006).

Also, the good adherence lead to best virologic outcomes and positive effect to quality of life for patient living with HIV/AIDS, hence the data in this study showed high adherence highly significant positive correlation in Psychological Health Domain ($p < 0.001$), Environment Domain ($p < 0.001$) and Overall QoL ($p < 0.001$).

5.1.3.4 AIDS- related event

One-way ANOVA Test found group of subject who has no AIDS-related Event exposure had higher Physical health score than group of AIDS-related Event more than 2 events ($p=0.015$). The group of only one AIDS-related events had higher score more than group of more than 2 events ($p=0.015$). Statistical significant difference in Overall Health ($p=0.001$) and Psychological health Domain ($p=0.005$), the One-way ANOVA test found group of none AIDS-related had higher QoL than group of two and more than 2 events respectively. Group of only one event had higher QoL than group of more than 2 events.

Relationship of Environment Domain was analyzed by Kruskal Wallis Test, statistic significant difference found group of none AIDS-related Event exposure had higher Environment score than other groups ($p<0.001$).

Previous study of Quality of life among people living with HIV/AIDS in northern Thailand found physical health score worsened as the disease progress by Medical Outcome Study HIV Health Survey: MOS-HIV, (Masao Ichikawa and chawalit Natpratan, 2003). The study of Quality of life of patients with advanced HIV/AIDS in United States, Canada, and United Kingdom used MOS-HIV, generic preference-weighted EuroQoL(EQ-5D) reported and Health Utility Index (HU13) HRQoL measures reported, statistic significantly lower HRQoL in comparison to cases to cases in which no event occurred in this interval ($p<0.01$) (Aslam H. Anis et al.,2009)

Our analysis of the impact of AIDS-related Event on Health related quality of life finding the AIDS-related Event had impact on quality of life with contrasted with a previous study.

5.1.3.5 CD4+count before ARV, CD4+count Baseline Visit and pVL at baseline Visit

This study recorded CD4 + count before ARV initiation at the available laboratory report, One-way ANOVA test found CD4+count before ARV initiation was statistically significant difference found in Physical health ($p<0.001$), Social relationship ($p=0.010$) and Overall QoL (0.001), the analyzed show group of CD4+ count 1-199 cells/mm³ had lower QoL than others groups.

For CD4+ count at baseline Visit, statistic significant difference was found in all Domain, Physical health ($p<0.001$), Psychological Health Domain ($p=0.001$), Social relationship ($p=0.028$), Environment Domain ($p=0.004$) and Overall QoL ($p<0.001$), the analyzed show group of CD4+ count 1-199 cells/mm³ had lower QoL than others groups.

Previous studies of health related quality of life in patients living with human immunodeficiency virus in Tehran Iran, used WHO-QOL-BREFF, a significant relationship with quality of life of the patients were gender, marital status, CD4+count, and stage of disease, (Marzieh Nojomi, Khatereh Anbary and

Mitra Raaanjbar, 2008). That say CD4+ count had associated with QoL as same as results finding in this study.

This study recorded Viral Load (HIV RNA) at baseline at the last available laboratory assessment, statistic significant difference found in domains of Physical health domain, group of pVL >50 copies/ml had higher QoL than other groups (p=0.012). Psychological Health Domain found group of pVL 50-5,000 copies/ml had higher Psychological Health score than group of pVL 20,001-100,000 copies/ml (p=0.038) and Overall QoL Domain found group of pVL 50-5,000 copies/ml had higher Overall QoL than group of pVL 5,001-20,000 copies/ml and pVL 20,001-100,000 copies/ml (p=0.034), respectively. The mean finding found Health related quality was higher in group of low pVL than group of subjects present low pVL at baseline. No statistic significant in Social relationship and Environment Domain and pVL at baseline.

The studies of Health –related quality of life and Virologic outcome in HIV clinic , USA found significant negative associations were found between CD4+ cell count and QoL, The relationship between Viral load, a measure of HIV disease activity, and several dimensions of QoL, a patient focused measure of HRQOL, appears to be strong and independent of CD4+ cell count. The findings suggest that having a lower viral load positively impacts the quality of life of HIV-positive patients. (S.A. Call and et al, 2000).

In contrast, the relationship between level of viral load and Health related quality of life was not statistic significant in Social relationship and Environment Domain. Similar to previous study in USA associated found CD4+count and pVL with physical dimensions, but not mental or cognitive dimension (S.A. Call and et al, 2000).

Viral load has been show to correlation with disease progression and prognosis (S.A. Call and et al, 2000). The same finding result fond between subjects who had low pVL and high pVL, so, can summarized that low Viral load positively impacts the quality of life and high Viral load negatively impacts the quality of life of HIV-positive.

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5.2 Conclusion

A cross sectional study looked at the association between socio-demographic factors, HIV/AIDS clinical history and health-related quality of life (QOL) in HIV/AIDS persons. It used the WHOQOL-BREF-THAI questionnaire completed by 3,596 patients during 2008 in three Thai hospitals. The questionnaire explored five QOL domains: Physical, Psychological, Social, Environment and Overall and it was for the first time administered to many HIV/AIDS patients in Thailand. Descriptive statistics and inferential statistics (bivariate and multivariate) were used to test association between independent factors and QOL.

The following associations were all statistically significant. Males had higher QOL than females in Physical, Psychological and Overall domains. Younger age was associated with higher QOL in Physical and Social domains, older age in Psychological and Environment domains. Married had higher psychological QOL than single and separated. Good adherence to, more than 3 year duration of ARV treatment and not suffering AIDS related events were associated with higher QOL in all except social domains. VL <50 copies/ml had higher QOL in all domains except social and environment domain. Higher education, high income and more than 200 CD4+ cell per mm³ had higher QOL in all domains.

Thai HIV/AIDS persons have health-related moderate to high QOL comparable similar person from high income countries. This is mainly due to similarities in some socio-demographic characteristics, free availability of and adherence to ARV, accessibility to other of HIV/AIDS care components. The WHOQOL-BREF-THAI questionnaire is an appropriate instrument to measure QOL in Thai HIV/AIDS persons.

HIV/AIDS is not only one of chronic diseases but make many patients suffer with social problem such, social stigma, may patients stressed and concerned about how to manage their live and how to living with HIV/AID, worry about disease progression and self esteem problem, poverty, depression, substance abuse, and cultural beliefs which can affect their quality of life not only from physical health aspect, but also from mental and social health point of view and cause numerous problems in useful activities and interests of the patients.

5.3 Recommendations

5.3.1 The study has shown that it is feasible to use the WHOQOL BREF-THAI questionnaire at central, provincial and district hospital level. The instrument provide useful information on the physical, psychological, social and environmental life of HIV positive people. It is recommended that the questionnaire use is expanded to other hospitals where there is enough personnel to deal with HIV and AIDS issues.

5.3.2 The involvement of local groups of people living with HIV and AIDS in administering the questionnaire can facilitate its use in hospitals where there is shortage of staff.

5.3.3 Adequate training on the use of the questionnaire is necessary for complete and reliable data collection and QOL assessment. During training and on-the-job the use of the questionnaire should be supported with the Standard Operative Procedure hand book. This handbook has been very useful with site staffs who were involved in the study and introduced the QoL questionnaires to HIV positive patients.

5.3.4 The use of WHOQOL BREF-THAI questionnaire at hospital level will help identify HIV positive patients with low QOL and in need of particular assistance in any of the domains investigated with the questionnaire. These patients with particular needs should receive additional support and care in particular counselling, link with peer support groups and other community based services.

5.3.5 Community based organisations made of groups of people living with HIV and AIDS should be trained in understanding the concepts of QOL in different domains and be involved in helping health care providers to assist those patients with low QOL.

5.3.6 Group of care, support address the immediate and future health needs of people living with HIV/AIDS and their communities, the recommendations are looking community-base organization should be developed for low quality of life patient living with HIV/AIDS, managed by HIV/AIDS patients and healthcare service provider, and serve low quality of life patient in order to improve their quality of life.

5.3.7 the National AIDS programme, and policy makers at different levels should release the importance of measuring QOL as part of the services to be provided to people living with HIV and AIDS

5.3.8 Longitudinal studies, on the model of THE PROGRESS, to explore QOL, of HIV/AIDS patient in other hospitals in rural and in Thailand should be carried out in the future. Research should not focus on quality of life only but also on identifying beneficial ways or interventions to improve QOL.

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ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย



APPENDIX

ศูนย์วิทยทรัพยากร
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APPENDIX A

Used U.S. Centers for Disease Control and Prevention (CDC) classification system and the World Health Organization (WHO) Clinical Staging and Disease Classification System (1993), The CDC categorization of HIV/AIDS is based on the lowest documented CD4+ cell count (Table E 1) and on previously diagnosed HIV-related conditions (Tables E 2 and E3).

Table E1. CDC Classification System for HIV-Infected Adults and Adolescents

CD4+ Cell Categories	Clinical Categories		
	A Asymptomatic, Acute HIV, or PGL	B Symptomatic Conditions,## not A or C	C AIDS-Indicator Conditions*
(1) ≥ 500 cells/ μ L	A1	B1	C1
(2) 200-499 cells/ μ L	A2	B2	C2
(3) < 200 cells/ μ L	A3	B3	C3

Key to abbreviations: CDC = U.S. Centers for Disease Control and Prevention; PGL = persistent generalized lymphadenopathy.
For symptomatic conditions, see [Table E2](#).

* For AIDS-indicator conditions, see [Table E3](#).

Table E2. CDC Classification System: Category B Symptomatic Conditions

Category B symptomatic conditions are defined as symptomatic conditions occurring in an HIV-infected adolescent or adult that meet 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 course or management that is complicated by HIV infection.

Examples include, but are not limited to, the following:

Bacillary angiomatosis
Oropharyngeal candidiasis (thrush)
Vulvovaginal candidiasis, persistent or resistant
Pelvic inflammatory disease (PID)
Cervical dysplasia (moderate or severe)/cervical carcinoma in situ
Hairy leukoplakia, oral
Idiopathic thrombocytopenic purpura
Constitutional symptoms, such as fever ($>38.5^{\circ}\text{C}$) or diarrhea lasting >1 month
Peripheral neuropathy
Herpes zoster (shingles), involving ≥ 2 episodes or ≥ 1 dermatome

Table E3. CDC Classification System: Category C AIDS-Indicator Conditions

Bacterial pneumonia, recurrent (≥ 2 episodes in 12 months)
Candidiasis of the bronchi, trachea, or lungs
Candidiasis, esophageal
Cervical carcinoma, invasive, confirmed by biopsy
Coccidioidomycosis, disseminated or extrapulmonary
Cryptococcosis, extrapulmonary
Cryptosporidiosis, chronic intestinal (>1 -month duration)
Cytomegalovirus disease (other than liver, spleen, or nodes)
Encephalopathy, HIV-related
Herpes simplex: chronic ulcers (>1 -month duration), or bronchitis, pneumonitis, or esophagitis
Histoplasmosis, disseminated or extrapulmonary
Isosporiasis, chronic intestinal (>1 -month duration)
Kaposi sarcoma
Lymphoma, Burkitt, immunoblastic, or primary central nervous system
<i>Mycobacterium avium</i> complex (MAC) or <i>M kansasii</i> , disseminated or extrapulmonary
<i>Mycobacterium tuberculosis</i> , pulmonary or extrapulmonary
<i>Mycobacterium</i> , other species or unidentified species, disseminated or extrapulmonary
<i>Pneumocystis jiroveci</i> (formerly <i>carinii</i>) pneumonia (PCP)
Progressive multifocal leukoencephalopathy (PML)
<i>Salmonella</i> septicemia, recurrent (nontyphoid)
Toxoplasmosis of brain
Wasting syndrome due to HIV (involuntary weight loss $>10\%$ of baseline body weight) associated with either chronic diarrhea (≥ 2 loose stools per day ≥ 1 month) or chronic weakness and documented fever ≥ 1 month

APPENDIX B

Table E4. Adherence questionnaire

ADHERENCE: Please *cross* the corresponding number next to the answer:

A. How often do you feel that you have difficulty taking your HIV medications on time?
By 'on time' we mean no more than one hour before or one hour after the doctor told you to take it.

4) **Never** 3) **Rarely**
2) **Most of the time** 1) **All of the time.**

B. On average, how many days per week would you say that you missed at least one dose of your HIV medications?

1) **Everyday** 2) **4 – 6 days per week**
3) **2 – 3 days per week** 4) **Once a week**
5) **Less than once a week** 6) **Never**

C. When was the last time you missed at least one dose of your HIV medications?

1) **Within the last week** 2) **1 – 2 weeks ago**
3) **3 – 4 weeks ago** 4) **Between 1 and 3 months ago**
5) **More than 3 months ago** 6) **Never**

Total Scores.....

> 10 = good adherence

≤ 10 = poor adherence

Hospital..... Subject initials:..... Date of visit: ___/___/___
 The Progress Subject number:..... HN:.....

เครื่องชี้วัดคุณภาพชีวิตขององค์การอนามัยโลกชุดย่อ ฉบับภาษาไทย

(WHOQOL - BREF - THAI)

คำชี้แจง ข้อคำถามต่อไปนี้จะถามถึงประสบการณ์อย่างใดอย่างหนึ่งของท่าน ในช่วง 2 สัปดาห์ที่ผ่านมา ให้ท่านสำรวจตัวท่านเอง และประเมินเหตุการณ์หรือความรู้สึกของท่าน แล้วทำเครื่องหมาย X ในช่องคำตอบที่เหมาะสมและเป็นจริงกับตัวท่านมากที่สุด โดยคำตอบมี 5 คำเลือก คือ

ไม่เลย	หมายถึง	ท่านไม่มีความรู้สึกเช่นนั้นเลย รู้สึกไม่พอใจมาก หรือรู้สึกแสบมาก
เล็กน้อย	หมายถึง	ท่านมีความรู้สึกเช่นนั้นนาน ๆ ครั้ง รู้สึกเช่นนั้นเล็กน้อยรู้สึกไม่พอใจ หรือ รู้สึกแสบ
ปานกลาง	หมายถึง	ท่านมีความรู้สึกเช่นนั้นปานกลาง รู้สึกพอใจระดับกลาง ๆ หรือ รู้สึกแสบระดับกลาง ๆ
มาก	หมายถึง	ท่านมีความรู้สึกเช่นนั้นบ่อย ๆ รู้สึกพอใจหรือรู้สึกดี
มากที่สุด	หมายถึง	ท่านมีความรู้สึกเช่นนั้นเสมอ รู้สึกเช่นนั้นมากที่สุด หรือรู้สึกว่าสมบูรณ์ รู้สึกพอใจมาก รู้สึกดีมาก

ข้อที่	ในช่วง 2 สัปดาห์ที่ผ่านมา	ไม่ เลย	เล็ก น้อย	ปาน กลาง	มาก	มาก ที่สุด
1	ท่านพอใจกับสุขภาพของท่านในตอนนี้เพียงใด					
2	การเจ็บปวดตามร่างกายเช่นปวดหัวปวดท้องปวดตามตัวทำให้ท่านไม่สามารถทำในสิ่งที่ต้องการ มากนักน้อยเพียงใด					
3	ท่านมีกำลังเพียงพอที่จะทำสิ่งต่างๆ ในแต่ละวัน ไหม (ทั้งเรื่องงานหรือการดำเนินชีวิตประจำวัน)					
4	ท่านพอใจกับการนอนหลับของท่านมากนักน้อยเพียงใด					
5	ท่านรู้สึกพึงพอใจในชีวิต(เช่นมีความสุขความสงบมีความหวัง) มากน้อยเพียงใด					
6	ท่านมีสมาธิในการทำงานต่างๆดีเพียงใด					
7	ท่านรู้สึกพอใจในตนเองมากนักน้อยแค่ไหน					
8	ท่านยอมรับรูปร่างหน้าตาของตัวเองได้ไหม					
9	ท่านมีความรู้สึกไม่ดีเช่นรู้สึกหงาเศร้าหดหู่สิ้นหวังวิตกกังวลบ่อยแค่ไหน					
10	ท่านรู้สึกพอใจมากน้อยแค่ไหนที่สามารถทำอะไรๆ ผ่านไปได้ในแต่ละวัน					
11	ท่านจำเป็นต้องไปรับการรักษาพยาบาลมากนักน้อยเพียงใด เพื่อที่จะทำงานหรือมีชีวิตรอยู่ไปได้ในแต่ละวัน					
12	ท่านพอใจกับความสามารถในการทำงานได้อย่างที่เคยทำมากนักน้อยเพียงใด					
13	ท่านพอใจต่อการผูกมิตรหรือเข้ากับคนอื่นอย่างที่ผ่านมาแค่ไหน					
14	ท่านพอใจกับการช่วยเหลือที่เคยได้รับจากเพื่อนๆแค่ไหน					
15	ท่านรู้สึกว่าชีวิตมีความมั่นคงปลอดภัยดีไหมในแต่ละวัน					
16	ท่านพอใจกับสภาพบ้านเรือนที่อยู่ตอนนี้มากนักน้อยเพียงใด					
17	ท่านมีเงินพอใช้จ่ายตามความจำเป็นมากนักน้อยเพียงใด					
18	ท่านพอใจที่จะสามารถไปใช้บริการสาธารณสุขได้ตามความจำเป็นเพียงใด					
19	ท่านได้รู้เรื่องราวข่าวสารที่จำเป็นในชีวิตแต่ละวันมากนักน้อยเพียงใด					
20	ท่านมีโอกาสได้พักผ่อนคลายเครียดมากนักน้อยเพียงใด					
21	สภาพแวดล้อมคือสุขภาพของท่านมากนักน้อยเพียงใด					
22	ท่านพอใจกับการเดินทางไปไหนมาไหนของท่าน(หมายถึงการคมนาคม) มากน้อยเพียงใด					
23	ท่านรู้สึกว่าชีวิตท่านมีความหมายมากนักน้อยแค่ไหน					
24	ท่านสามารถไปไหนมาไหนด้วยตนเองได้ดีเพียงใด					
25	ท่านพอใจในชีวิตทางเพศของท่านแค่ไหน? (ชีวิตทางเพศหมายถึงเมื่อเกิดความรู้สึกทางเพศขึ้น แล้วท่านมีวิธีจัดการทำให้ผ่อนคลายลงได้รวมถึงการช่วยตัวเองหรือการมีเพศสัมพันธ์)					
26	ท่านคิดว่าท่านมีคุณภาพชีวิต(ชีวิตความเป็นอยู่) อยู่ในระดับใด					

APPENDIX D:

Date of Demographic Data: _____/_____/_____ (Day / Month / Year)					
Date of Birth: _____/_____/_____ (Day / Month / Year)					
Gender (at birth): <input type="checkbox"/> Male			<input type="checkbox"/> Female		
Race : <input type="checkbox"/> Asian <input type="checkbox"/> White			<input type="checkbox"/> Black <input type="checkbox"/> Other, specify:_____		
Ethnicity : <input type="checkbox"/> Thai			<input type="checkbox"/> Others, specify:_____		
Current Marital Status: <input type="checkbox"/> Widowed <input type="checkbox"/> Single <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Not married, in a committed relationship <input type="checkbox"/> Separate					
What is the highest certificate that you have earned? (choose only 1)					
<input type="checkbox"/> No certificate		<input type="checkbox"/> Associates/ Technical/ Vocational certificate			
<input type="checkbox"/> Primary certificate		<input type="checkbox"/> Bachelor of Science or Arts			
<input type="checkbox"/> Secondary certificate		<input type="checkbox"/> More than BS/ BA			
<input type="checkbox"/> High School certificate					
Current Occupation :					
<input type="checkbox"/> Unemployed		<input type="checkbox"/> Working for Government Enterprise			
<input type="checkbox"/> Wage earner		<input type="checkbox"/> Working for Private or Individual company			
<input type="checkbox"/> Self-employed		<input type="checkbox"/> Others : Specify _____			
<input type="checkbox"/> Government Official					
Income (Thai Baht):					
<input type="checkbox"/> No income		<input type="checkbox"/> 10,000 - 14,999			
<input type="checkbox"/> < 5,000		<input type="checkbox"/> 15,000 - 19,999			
<input type="checkbox"/> 5,000 - 9999		<input type="checkbox"/> ≥ 20,000			
Health Benefit Scheme :					
<input type="checkbox"/> Universal Coverage (UC) Scheme			<input type="checkbox"/> The civil Servant Benefits Scheme		
<input type="checkbox"/> The social Security Scheme			<input type="checkbox"/> Self-supported		
5. CDC Clinical category: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C					
7. HIV-related events: <input type="checkbox"/> check if none					
<u>Event</u>	<u>Diagnosis**</u>	<u>Start date</u>	<u>Stop date</u>	<u>tick if Ongoing</u>	<u>Hospitalized?</u>
** Diagnosis : P = Presumptive, D = Definitive					
8. Previous Antiretroviral: <input type="checkbox"/> check if none Start					
				<input type="checkbox"/>	
				<input type="checkbox"/>	

Baseline Visit	CD4	Date	HIV-1 RNA	Date
-----------------------	------------	-------------	------------------	-------------

Hospital name: _____ Subject initials: _____ HN: _____

ARV taking prescribed since the last visit : (Please cross the ARV lists below)
 Yes No Other, specify _____

Has any ARV CHANGED/STOPPED since last visit No Yes, specify below

ARV	Start Date	Stop Date (tick box if ongoing)	Reason for changed/stopped code*
.....	<input type="checkbox"/> <input type="checkbox"/>
.....	<input type="checkbox"/> <input type="checkbox"/>
.....	<input type="checkbox"/> <input type="checkbox"/>
.....	<input type="checkbox"/> <input type="checkbox"/>

*Reason ARV changed / stopped:
 1 = clinical progression/hospitalization, 5 = treatment failure, 8 = other (specify).....
 2 = adverse event (specify), 6 = adherence difficulties,
 3 = patient decision / request, 7 = drug interaction,
 4 = physician decision,

ADHERENCE: Please cross the corresponding number next to the answer:

A. How often do you feel that you have difficulty taking your HIV medications on time? By 'on time' we mean no more than one hour before or one hour after the doctor told you to take it.

- 4) Never 3) Rarely 2) Most of the time 1) All of the time.

B. On average, how many days per week would you says that you missed at least one dose of your HIV medications?

- 1) Everyday 2) 4 - 6 days per week 3) 2 - 3 days per week 4) Once a week
 5) Less than once a week 6) Never

C. When was the last time you missed at least one dose of your HIV medications?

- 1) Within the last week 2) 1 - 2 weeks ago 3) 3 - 4 weeks ago 4) Between 1 and 3 months ago
 5) More than 3 months ago 6) Never

Total Scores.....

(Faint background text from a watermark is visible here, including "มหาวิทยาลัย" and "โรงพยาบาล")

NON AIDS-RELATED EVENTS

- Avascular necrosis (AVN) of the bone*
- Buffalo hump* (enlargement of dorsocervical fat pad)*
- Cancer (excluding lymphoma, Kaposi's sarcoma and invasive cervical cancer)*
- Cirrhosis
- Congestive heart failure
- Coronary artery disease (i.e., angina) requiring drug treatment
- Coronary artery disease requiring an invasive or surgical procedure*
- Diabetes mellitus requiring dietary modification only
- Diabetes mellitus requiring drug treatment
- End-stage renal disease
- Hepatic steatosis as evidenced by Clinical diagnosis, liver biopsy or Autopsy*
- Lactic acidosis*
- Myocardial infarction*
- Myocarditis*
- Pancreatitis*
- Pericarditis*
- Peripheral lipodystrophy (thinning of face, limbs, or upper trunk)
- Peripheral vascular disease, including invasive or surgical procedures for vascular disease (excluding angina, arrhythmia, congestive heart failure, coronary artery disease, hypertension, and valvular disease)*
- Renal insufficiency*
- Significant increase in abdominal girth as subjectively reported by patient or as measured by clinician*
- Stroke*
- Unexplained breast enlargement as subjectively reported by patient or as measured by clinician*
- Anal carcinoma
- others, specify.....

AIDS-RELATED EVENTS

- Aspergillosis, invasive
- Bartonellosis
- Candidiasis, esophageal
- Candidiasis of bronchi, trachea, or lungs
- Cervical cancer, invasive
- Chagas disease (American trypanosomiasis) of the CNS
- CMV disease (other than liver, spleen, or nodes)
- CMV retinitis
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptosporidiosis, chronic intestinal (> 1 month's duration)
- Cryptococcosis, extrapulmonary
- Encephalopathy, HIV-related (including AIDS Dementia Complex)
- Herpes simplex, chronic ulcers (> 1 month's duration) or bronchitis, pneumonitis, or esophagitis
- Herpes zoster, multi-dermatomal (≥ 10 lesions in a non-contiguous site)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (> 1 month's duration)
- Kaposi's sarcoma (mucocutaneous or visceral)
- Leishmaniasis, visceral (kala-azar)
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, Hodgkin's
- Lymphoma, non-Hodgkin's, all cell types
- Lymphoma, primary, of CNS
- Microsporidiosis (> 1 month's duration)
- M.Tuberculosis, any site (pulmonary or extrapulmonary)
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Nocardiosis
- Penicillium marneffei, extrapulmonary
- Pneumocystis carinii, extrapulmonary
- Pneumocystis carinii pneumonia
- Pneumonia, recurrent bacterial (2 documented episodes within 1 year of each other)
- Progressive multifocal leukoencephalopathy
- Rhodococcus equi disease
- Salmonella septicemia, recurrent (2 documented episodes within 1 year of each other)
- Toxoplasmosis of brain
- Wasting syndrome due to HIV (weight loss (over 10% of baseline) with no other cause, and 30 days or more of either diarrhoeas or weakness with fever)

AIDS-RELATED EVENTS:							
<u>EVENT</u> (Add code* in boxes)	<u>DIAGNOSIS**</u>	<u>START DATE</u> (work up initiated)	<u>STOP DATE</u> (treatment completion)	tick if Ongoing	<u>HOSPITALIZED?</u>		
.....	<input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/>	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
.....	<input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/>	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
.....	<input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/>	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
.....	<input type="checkbox"/> P <input type="checkbox"/> D	<input type="checkbox"/>	<input type="checkbox"/> No	<input type="checkbox"/> Yes	

** Diagnosis : P = Presumptive, D = Definitive

CDC Clinical Category: Any progression?
 No progression or Progression to B C

COMMENT / PLAN:

ศูนย์วิทยทรัพยากร
 จุฬาลงกรณ์มหาวิทยาลัย



The Ethical Committee for Research in Human Subjects

Department of Diseases Control

.....

List of Approved Documents

1. Study Title : Ref.No. 6 / 50 – 166_ : “The Thai HIV Disease Progression: An Observational Database, version 3.0, 12 August 2007.”

2. Name List and Location of Key Researcher :

Tanarak Plipat, MD, Ph.D

Bureau of Knowledge Management,

Tiwanon Road, Amphur Maeng, Nonthaburi, Thailand 11000

3. Documents Approved:

3.1 Thai version of research plan titles “The Thai HIV Disease Progression: An Observational Database, version 3.0, 12 August 2007.” version 2 date 12 August 2007

3.2 Thai version of Informed consent form : version 2 date 12 August 2007

4. Study Duration : 5 years

Approval Period : 12 months (October 2007 – September 2008)

Committee Meeting Date : 11 July 2007

Committee Signature :


(Dr. Supachai Rerkngarm, M.D.)

Position : Chairman

Date of Approval : 9 November 2007

The statement : “We confirm that we are an ethics committee constituted in agreement and in accordance with the ICH-GCP”

สำเนาฉบับ บันทึกข้อความ

ส่วนราชการ กรมควบคุมโรค สำนักจัดการความรู้ โทร.0 2590 3251-3 ต่อ 17 โทรสาร ต่อ 16
ที่ ศธ 0435.3/ ๑๖๑ วันที่ 26 สิงหาคม 2551
เรื่อง ขออนุมัติขยายพื้นที่ในการเก็บข้อมูลงานวิจัย

เรียน อธิบดีกรมควบคุมโรค

ความเป็นมา

1. คณะกรรมการจริยธรรมการวิจัย กรมควบคุมโรค ได้อนุมัติ “โครงการฐานข้อมูลผู้ป่วยเอดส์เพื่อศึกษาการดำเนินโรคเอดส์ในประเทศไทย ฉบับที่ 3.0 ลงวันที่ 12 สิงหาคม 2550 ” (รหัส 6 / 50 - 166) ของ นายแพทย์ชนรินทร์ พลิพัฒน์ สำนักจัดการความรู้ ให้ดำเนินการ เมื่อวันที่ 9 พฤศจิกายน 2550

2. ด้วยสำนักจัดการความรู้ได้ขออนุมัติคณะกรรมการจริยธรรมการวิจัยฯ แก้ไขปรับปรุงโครงการ “โครงการฐานข้อมูลผู้ป่วยเอดส์เพื่อศึกษาการดำเนินโรคเอดส์ในประเทศไทย” (รหัส 6 / 50 - 166) ของ นายแพทย์ชนรินทร์ พลิพัฒน์ ดังนี้

2.1 ขอเพิ่มสถานศึกษาวิจัย อีก 2 โรงพยาบาล คือ โรงพยาบาลตากสิน และโรงพยาบาลวชิรพยาบาล เนื่องจากมีการย้ายสิทธิการรักษาผู้ป่วยเอดส์ด้วยยาต้านไวรัสเอดส์ครั้งใหญ่ มีการเปลี่ยนแปลงผู้บริหารอาสาสมัคร โครงการยาต้านไวรัสกรมควบคุมโรค ไปเป็นสำนักงานหลักประกันสุขภาพแห่งชาติ (สปสช.) อาสาสมัครจำนวนมากที่เคยรับการรักษาอยู่ที่สถาบันบำราศนราดูร ซึ่งเป็นหน่วยวิจัยที่ใหญ่ที่สุดของโครงการได้ทำการย้ายสิทธิการรักษาไปที่โรงพยาบาลในเขตภูมิภาคเพิ่มเติมหรือ โรงพยาบาลอื่น ๆ

2.2 โรงพยาบาลบำราศนราดูรได้เปลี่ยนแปลงวิธีการนัดติดตามผู้ป่วย โดยนัดให้ห่างขึ้น(ติดตามให้มารับการรักษาทุก 6 เดือน) ทำให้ผู้ป่วยมาโรงพยาบาลน้อยครั้งลง ซึ่งจากเหตุผลข้อ 1) และ 2) ทำให้โครงการวิจัยฯรับอาสาสมัครเข้าร่วมโครงการได้ล่าช้ากว่าที่กำหนดไว้ในแผน

2.3 โรงพยาบาลตากสินเป็นโรงพยาบาลที่รับดูแลรักษาผู้ป่วยเอชไอวีมากกว่า 2,000 คน ส่วนวิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาลรับดูแลรักษาผู้ป่วยเอชไอวีมากกว่า 1,000 คน โดยทั้งสองสถาบันมีแพทย์ผู้เชี่ยวชาญด้านโรคติดเชื้อ โดยเฉพาะดูแลผู้ป่วยอยู่ทั้งสองโรงพยาบาลมีผู้ป่วยติดเชื้อเอชไอวีที่มีความหลากหลายทั้งในแง่ของอายุ เพศ ระยะของโรค การติดเชื้อฉวยโอกาส สูตรยาต้านที่กิน ประกอบกับการที่มีแพทย์โรคติดเชื้อที่มีประสบการณ์ดูแลอยู่ จึงจะทำให้ข้อมูลที่ได้มีคุณภาพสูง

2.4 การเพิ่มโรงพยาบาล...

2.4 การเพิ่มโรงพยาบาลในโครงการวิจัยอีก 2 โรงพยาบาล นอกจากจะช่วยให้ได้จำนวนอาสาสมัครตามที่กำหนดไว้ในแผนแล้ว จะช่วยให้โครงการวิจัยสามารถที่จะติดตามแนวทางการดูแลรักษาและลักษณะผู้ป่วยที่แตกต่างกันได้กว้างขวางกว่าเดิมอีกด้วย

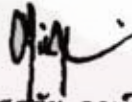
3. จากการประชุมคณะกรรมการจริยธรรมการวิจัยฯ ครั้งที่ 11/2551 วันที่ 13 สิงหาคม 2551 มีมติอนุมัติ โดยให้หัวหน้าโครงการวิจัยส่งหนังสือยินยอมให้เก็บข้อมูลจากโรงพยาบาลตากสิน และโรงพยาบาลวชิรพยาบาล และลายมือชื่อยินยอมเข้าร่วม โครงการฯ ของผู้เข้าร่วม โครงการฯ ทั้ง 2 โรงพยาบาล

ข้อพิจารณา

ในการนี้คณะกรรมการจริยธรรมการวิจัยฯ ขอเรียนว่าเพื่อให้การดำเนินงานวิจัยได้ตามเป้าหมายที่กำหนด เห็นสมควรอนุมัติขยายพื้นที่ในการเก็บข้อมูลงานวิจัยอีก 2 โรงพยาบาล คือ โรงพยาบาลตากสิน และ โรงพยาบาลวชิรพยาบาล

ข้อเสนอ

จึงเรียนมาเพื่อพิจารณา หากเห็นชอบ โปรดอนุมัติขยายพื้นที่ในการเก็บข้อมูลงานวิจัยด้วย จะเป็นพระคุณ



(นายสุชาย ฤกษ์งาม)

นายแพทย์ ๑๐ ว.ด้านเวชกรรมป้องกัน
กรมควบคุมโรค

ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย

.....ร่าง
.....พิมพ์
.....ตรวจ

**Documentary Proof of
Institutional Review Board of
Bamrasnaradura Infectious Diseases Institute**

Protocol Title: โครงการฐานข้อมูลผู้ป่วยเอดส์เพื่อศึกษาการดำเนินโรคเอดส์ในประเทศไทย ฉบับที่ 3.0 ลงวันที่ 12 สิงหาคม 2550

Protocol No.: The Thai HIV Disease Progression : An Observational Database, version 3.0, 12 August 2007

Investigator: Wisit Prasithsirikul

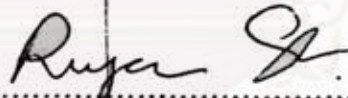
Official Address: 126 Bamrasnaradura Infectious Diseases Institute
Tiwanon Road, Nonthaburi, Thailand, 11000

Document Reviewed:

1. แบบเสนอโครงการวิจัยฉบับภาษาไทยฉบับปรับปรุง
2. เอกสารคำชี้แจงสำหรับอาสาสมัครผู้เข้าร่วมโครงการวิจัย
3. เอกสารแสดงความยินยอมการเข้าร่วมโครงการวิจัย

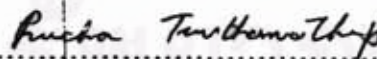
The aforementioned documents have been reviewed and acknowledged by Committee on Human Right Related to Researches Involving Human Subjects, based on the ICH-GCP.

Signature of Chairman
Committee on Human Rights Related to
Researches Involving Human Subjects



(Rujanee Sunthornkachit)

**Signature of Director of
Bamrasnaradura Infectious
Diseases Institute**



(Preecha Tunthanathip)

Date of Reviewed

- 3 JAN 2008

Date of Approval

- 9 JAN 2008

ตัวอย่างเอกสารแจ้งข้อมูลและใบยินยอมด้วยความสมัครใจสำหรับโครงการหลัก

ข้อมูลสำหรับผู้เข้าร่วมโครงการศึกษา

ชื่อโครงการ:	โครงการฐานข้อมูลผู้ป่วยเอดส์เพื่อศึกษาการดำเนินโรคเอดส์ในประเทศไทย ฉบับที่ 3.0 ลงวันที่ 12 สิงหาคม 2550 (The Thai HIV Disease Progression: An Observational Database, version 3.0, 12 2007)
ชื่อสถาบันศึกษา:	สถาบันปวราศนราคร
ที่อยู่	126 ถ.ติวานนท์ อ.เมือง จ.นนทบุรี 11000
ชื่อหัวหน้าโครงการ	นพ. วิศิษฐ์ ประสิทธิ์ศิริกุล
หมายเลขโทรศัพท์	02 5903408

ท่านถูกเชิญให้เข้าร่วมในการศึกษาที่ใช้วิธีเก็บรวบรวมข้อมูลจากการเฝ้าดูผู้ติดเชื้อเอชไอวีในประเทศไทยจุดประสงค์เบื้องต้นในการศึกษานี้คือการติดตามคุณลักษณะของโรคเอชไอวี (เอดส์) การดำเนินโรคและการรักษา ซึ่งจะช่วยให้ผู้วิจัยได้เรียนรู้เพิ่มเติมเกี่ยวกับการรักษาโรคเอชไอวีในประเทศไทย และเพื่อวางแผนยกระดับการรักษาโรคติดเชื้อเอชไอวีให้ดีขึ้น

มีหลายคลินิกที่ต่างเก็บรวบรวมข้อมูลเกี่ยวกับการรักษาผู้ติดเชื้อเอชไอวีด้วยยาต้านเอดส์ที่มารักษาคตามปกติ และข้อมูลเหล่านี้มักเก็บอยู่ในระบบคอมพิวเตอร์ การศึกษานี้มุ่งหมายที่จะรวบรวมเฉพาะข้อมูลสำคัญในคอมพิวเตอร์จากแต่ละคลินิกเข้าด้วยกันเพื่อทำเป็นฐานข้อมูลขนาดใหญ่เดียวกัน ข้อมูลเกี่ยวกับประวัติโรคเอชไอวี การรักษา และผลตรวจเลือดของท่านจะถูกส่งเพื่อรวบรวมเข้าเป็นฐานข้อมูลอันเดียวที่ศูนย์จัดการข้อมูลส่วนกลาง ฐานข้อมูลส่วนกลางนี้จะถูกปรับตามข้อมูลใหม่ของผู้ป่วยทุก 6 เดือน การศึกษานี้จึงเป็นการเก็บรวบรวมข้อมูลจากการเฝ้าดูทั้งสิ้น ซึ่งจะเก็บข้อมูลเมื่อท่านมาพบแพทย์เท่านั้น ทั้งนี้การศึกษานี้จะไม่กำหนดการดูแลรักษาทางสุขภาพของท่านแต่อย่างใด การดูแลรักษาทางสุขภาพของท่านจะขึ้นอยู่กับแพทย์ประจำตัวของท่านทั้งสิ้น และท่านยังสามารถเข้าร่วมในการศึกษาวิจัย อื่น ๆ ที่ท่านต้องการได้

การเข้าร่วมในโครงการศึกษาเป็นไปด้วยความสมัครใจของท่าน

เอกสารให้ข้อมูลและแบบฟอร์มการยินยอมนี้จะให้ข้อมูลท่านเกี่ยวกับโครงการ ท่านโปรดอ่านอย่างถี่ถ้วน ท่านมีโอกาสเต็มที่ที่จะสอบถามแพทย์และพยาบาลผู้ศึกษาจนเข้าใจโดยต้องแจ้งก่อนการเข้าร่วม เมื่อท่านตกลงที่จะเข้าร่วม กรุณาเซ็นชื่อในใบยินยอม และจะมีสำเนาหนึ่งชุดให้ท่านเก็บรักษาไว้

ก่อนที่ท่านจะเข้าร่วมการศึกษานี้ สิ่งสำคัญที่ท่านควรจะมีดังต่อไปนี้

1. การเข้าร่วมในโครงการศึกษาเป็นไปด้วยความสมัครใจของท่าน

2. ท่านอาจตัดสินใจไม่เข้าร่วมหรือถอนตัวออกจากโครงการศึกษาไม่ว่าเวลาใดก็ได้ โดยท่านจะไม่เสียประโยชน์ในการดูแลรักษาทางการแพทย์ตามปกติ

3. ทางโครงการศึกษาจะไม่จ่ายค่าเข้าร่วมการศึกษาและยาด้านเอคส์แก่ท่านแต่อย่างใด
ประโยชน์ที่คาดว่าจะได้รับจากการวิจัย

ข้อมูลจากการวิจัยนี้จะช่วยให้คณะที่ดูแลผู้ติดเชื้อ ผู้กำหนดนโยบาย หน่วยงานทางด้านสาธารณสุขทราบถึงคุณภาพของการรักษาโรคติดเชื้อเอชไอวีในประเทศไทย เพื่อเป็นการวางแผนพัฒนาปรับปรุงคุณภาพการรักษาให้ลดอัตราการเจ็บป่วย อัตราการตาย และเพิ่มคุณภาพชีวิตให้ได้มากที่สุด
จะมีผู้เข้าร่วมโครงการวิจัยนี้จำนวนเท่าไร

มีผู้เข้าร่วมโครงการนี้ทั้งสิ้นประมาณ 6,400 คน
จะมีการเก็บข้อมูลไปนานแค่ไหน

โครงการนี้จะทำการติดตาม และเก็บข้อมูลของผู้ป่วยเป็นระยะเวลา 5 ปี
ขั้นตอนการศึกษา

การศึกษานี้จะเก็บรวบรวมข้อมูลเกี่ยวกับประวัติโรคติดเชื้อเอชไอวีเท่านั้น และไม่กำหนดให้ท่านต้องมาคลินิกหรือตรวจเลือดบ่อยขึ้นหรือเพิ่มการรักษาไปจากเดิมที่ท่านได้รับ ดังนั้นท่านจึงมาตามนัดกับแพทย์ที่ดูแลท่านอยู่ตามปกติ

จะมีการเก็บข้อมูลอะไรบ้างในการศึกษานี้

โครงการจะดำเนินการเก็บข้อมูลดังต่อไปนี้

1. ระยะของโรคติดเชื้อเอชไอวี ซีดี4 ซีดี 8 จำนวนเชื้อเอชไอวี ภาวะแทรกซ้อนจากโรคเอคส์ ข้อมูล สาเหตุการตาย
2. การรักษา เช่น ประวัติการกินยาด้าน เหตุผลการเปลี่ยนยา การได้รับยาป้องกันการติดเชื้อฉวยโอกาส เป็นต้น
3. ยาอื่นๆ ที่ได้รับร่วมกับยาด้านไวรัสเอคส์
4. ผลข้างเคียงที่เกิดจากยาด้านไวรัสเอคส์ และยาป้องกันการติดเชื้อฉวยโอกาส
5. ภาวะแทรกซ้อนที่เกิดจากโรคเอชไอวีและจากยาด้าน เช่น ภาวะไขมันย่ำส่วนโรคหัวใจ เบาหวาน โรคไขมันในเส้นเลือดสูง ภาวะกรดในเส้นเลือดสูง ภาวะแทรกซ้อนของระบบทางเดินอาหาร เช่น ตับแข็ง ไขมันคั่งในตับ ตับอ่อนอักเสบ ภาวะแทรกซ้อนทางไต เช่น ไตทำงานต่ำกว่าปกติ โรคมะเร็ง อัมพาต/อัมพฤกษ์ เป็นต้น
6. คุณภาพชีวิตของผู้ป่วยเอคส์โดยใช้แบบสอบถาม
7. อาการซึมเศร้าและวิตกกังวล

8. การคิดเชื้อร่วมของ เชื้อซิฟิลิส วัณโรคดับอักเสบ บี และซี ความเสี่ยงและ/หรือความไม่สบายที่อาจเกิดขึ้น

เนื่องจากการศึกษานี้เป็นการเก็บรวบรวมข้อมูลจากการเฝ้าดูทั้งสิ้นดังนั้นความเสี่ยงที่เกิดขึ้นจึงน้อย ท่านอาจมีความเสี่ยงที่ผู้อื่นนอกโครงการศึกษาจะทราบเรื่องการติดเชื้อเอชไอวีจากการตรวจสอบการเสียชีวิตเมื่อสิ้นสุดโครงการศึกษาเฉพาะในกรณีที่ท่านขาดการติดต่อและเราไม่สามารถติดต่อท่านได้ โดยวิธีการใดๆ เท่านั้น

การตั้งครุภและกาให้มมารดาแก่บุตร

หญิงมีครุภหรือหญิงที่ให้นมบุตรสามารถเข้าร่วมโครงการศึกษานี้ได้ ทางเลือกอื่นนอกจากการเข้าร่วมโครงการศึกษา

ก่อนที่ท่านจะตัดสินใจเข้าร่วมในโครงการศึกษานี้ ผู้ศึกษาจะพูดคุยกับท่านเกี่ยวกับทางเลือกอื่นๆ ที่เป็นไปได้ เช่น ติดตามเหมือนผู้ป่วยทั่วไปในคลินิกผู้ป่วยนอก เป็นต้น

การรักษาความลับ

ข้อมูลทั้งหมดจะถูกเก็บเป็นความลับและจะรวบรวมเป็นฐานข้อมูลส่วนกลางแบบนิรนามคือไม่สามารถระบุถึงตัวท่านได้ ถ้าท่านยินยอมโดยการเซ็นชื่อของท่านในเอกสารนี้ ผู้วิจัยวางแผนว่าจะตีพิมพ์ผลเป็นรายงานประจำทุก 1 ปี รวมทั้งวางแผนที่จะเตรียมทำรายงานฉบับพิเศษและนำเสนอผลในการประชุมทางวิทยาศาสตร์ในอนาคตด้วย ข้อมูลที่ตีพิมพ์ใด ๆ จะต้องไม่สามารถระบุถึงตัวท่านได้

ปัญหาหรือข้อสงสัย

หากท่านมีข้อข้องใจหรือต้องการร้องทุกข์โปรดติดต่อโดยตรงได้ที่ คณะกรรมการจริยธรรมการวิจัย กรมควบคุมโรค การเข้าร่วมในการศึกษานี้ของท่านเป็นไปโดยความสมัครใจ ท่านมีอิสระที่จะถอนตัวเวลาใดก็ได้ ซึ่งจะไม่มีผลต่อการรักษาที่ท่านได้รับจากแพทย์ผู้ศึกษาหรือโรงพยาบาล

ถ้าท่านมีคำถามใด ๆ โปรดสอบถามได้จาก

นางพรศิริ เรือนสว่าง

หมายเลขโทรศัพท์

02 5903437

ซึ่งจะตอบคำถามหรือข้อสงสัยของท่านทุกประการด้วยความยินดี

ศูนย์วิทยทรัพยากร
จุฬาลงกรณ์มหาวิทยาลัย

ใบยินยอมด้วยความสมัครใจ

ชื่อโครงการ: โครงการฐานข้อมูลผู้ป่วยเอดส์เพื่อศึกษาการดำเนินโรคเอดส์ในประเทศไทย ฉบับที่ 3.0 ลงวันที่ 12 สิงหาคม 2550
(The Thai HIV Disease Progression: An Observational Database, version 3.0, 12 2007)

ชื่อสถาบันศึกษา: สถาบันปαραศนราคร

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วันที่ให้คำยินยอม วันที่ เดือน พ.ศ.

ก่อนที่จะลงนามในใบยินยอมให้ทำการศึกษาวิจัยนี้ ข้าพเจ้าได้รับคำอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย ความเสี่ยง อันตราย หรืออาการที่อาจเกิดขึ้นจากการวิจัยรวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียด และมีความเข้าใจดีแล้ว

ผู้วิจัยได้ตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัย ด้วยความเต็มใจ ไม่ปิดบัง ซ่อนเร้น จนข้าพเจ้าพอใจ

ข้าพเจ้าเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ และสามารถบอกเลิก ยุติ หรือถอนตัวจากการศึกษานี้เมื่อใดก็ได้ และไม่ว่าข้าพเจ้าจะเข้าร่วมในการศึกษาหรือไม่ก็ตาม หรือถอนตัวจากการศึกษานี้ในภายหลัง จะไม่มีผลต่อการเข้ารับบริการป้องกัน และรักษาโรคที่ข้าพเจ้าพึงจะได้รับตามสิทธิต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ จะเปิดเผยข้อมูลได้เฉพาะในรูปแบบที่เป็นสรุปผลการวิจัย หรือเป็นการเปิดเผยข้อมูลต่อผู้มีหน้าที่เกี่ยวข้องกับการสนับสนุน และ/หรือกำกับดูแลการวิจัยเท่านั้น

ผู้วิจัยรับรองว่าหากเกิดอันตรายใดๆ จากการวิจัยดังกล่าว ข้าพเจ้าจะได้รับการรักษาพยาบาลโดยไม่คิดมูลค่า และรายละเอียดเกี่ยวกับการรักษาพยาบาลดังกล่าวข้าพเจ้าสามารถติดต่อได้ที่ นพ. วิศิษฐ์ ประสิทธิ์ศิริกุล สถาบันปαραศนราคร

ข้าพเจ้าได้อ่าน คำอธิบายโครงการวิจัย รวมทั้งใบหนังสือยินยอมด้วยความสมัครใจ และได้รับ คำตอบต่อทุกข้อสงสัยทั้งหมดแล้ว ข้าพเจ้ามีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมนี้ ด้วยความเต็มใจ

ลงนาม ผู้ยินยอม
 ลงนาม ผู้วิจัย
 ลงนาม ผู้ที่ได้รับมอบหมาย

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านคำอธิบายโครงการวิจัย รวมทั้งใบหนังสือยินยอม ด้วยความสมัครใจ และได้รับคำตอบต่อทุกข้อสงสัยทั้งหมดแล้ว ข้าพเจ้ามีความเข้าใจดีทุกประการ และได้ ลงนาม/มอบหมายให้ผู้แทนลงนาม ในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม ผู้ยินยอม/ผู้แทน
 ลงนาม ผู้วิจัย
 ลงนาม ผู้ที่ได้รับมอบหมาย

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