FACTORS INFLUENCING ADHERENCE TO ANTIRETROVIRAL MEDICATION IN CHILDREN WITH HIV INFECTION

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FACTORS INFLUENCING ADHERENCE TO ANTIRETROVIRAL MEDICATION IN CHILDREN WITH HIV INFECTION.

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ABSTRACT

Medication adherence is crucial to the success of antiretroviral treatment in children with HIV infection. However, there are limited studies examining factors that influence adherence to antiretroviral medication. The objectives of this study were 1. to examine adherence to antiretroviral medication in children with HIV infection and 2. to investigate predicting power of independent variables: Child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication on adherence to antiretroviral medication in children with HIV infection. The study sample consisted of 110 primary caregivers of children with HIV infection aged < 13 years who had received antiretroviral medication as treatment. Data were collected by interviews and questionnaires. Descriptive statistics and Hierachical multiple regression were used for data analysis.

Results revealed that the majority of children (77.30%) had good adherence to antiretroviral medication (≥ 95%). Taste was negatively related to adherence to antiretroviral medication in children with HIV infection ($r = -.37$, $p < .01$). Caregiver ability in administering antiretroviral medication was positively related to adherence to antiretroviral medication in children with HIV infection ($r = .24$, $p < .05$). All independent variables could jointly explain 16% of variance in adherence to antiretroviral medication in children with HIV infection. Taste was the only significant predictor of adherence to antiretroviral medication in children with HIV infection (Overall $F_{(7,101)} = 2.72$, $p < .05$).

These findings suggest that nurses and other health care providers involved with care of children with HIV infection who receive antiretroviral treatment should provide informational support to the caregivers to help improve their ability in administering antiretroviral medication. Concerted action between physicians and pharmacists is also needed to plan simplified schedules of antiretroviral medication for children.

KEY WORDS: MEDICATION ADHERENCE / CHILDREN WITH HIV

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ปัจจัยที่มีอิทธิพลต่อการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี
(FACTORS INFLUENCING ADHERENCE TO ANTIRETROVIRAL MEDICATION IN CHILDREN WITH HIV INFECTION)

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บทคัดย่อ

การรับประทานยาอย่างต่อเนื่องสม่ำเสมอมีความสำคัญอย่างยิ่งต่อความสำเร็จในการรักษาด้วยยาต้านไวรัสเอดส์ในเด็กที่ติดเชื้อเอชไอวี อย่างไรก็ตามยังมีงานวิจัยจำนวนน้อยที่ศึกษาเกี่ยวกับปัจจัยที่มีอิทธิพลต่อการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอ การวิจัยครั้งนี้มีวัตถุประสงค์เพื่อ 1. ศึกษาการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวีและ 2. เพื่อศึกษาอำนาจการทำนายของตัวแปรอิสระ ได้แก่ อายุของเด็ก ภาระของการรับประทานยา รสชาติของยา อาการข้างเคียงของยา การสนับสนุนทางสังคมของผู้ดูแล ความรู้ของผู้ดูแลในการดูแลเด็กที่ติดเชื้อเอชไอวี และความสามารถของผู้ดูแลในการจัดการให้เด็กรับประทานยาต้านไวรัสเอดส์ ที่มีต่อการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี กลุ่มตัวอย่างเป็นผู้ดูแลหลักของเด็กที่ติดเชื้อเอชไอวี อายุ < 13 ปี ที่ได้รับยาต้านไวรัสเอดส์เพื่อการรักษา จำนวน 110 ราย เก็บรวบรวมข้อมูลโดยใช้แบบสัมภาษณ์และแบบสอบถามผู้ดูแลเด็ก และวิเคราะห์ข้อมูลด้วยสถิติเชิงพรรณนาและการวิเคราะห์ความถดถอยเชิงพหุแบบเชิงชั้น

ผลการวิจัย พบว่า การรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวีส่วนใหญ่อยู่ในระดับดี ≥ 95% (ร้อยละ 77.30) รสชาติของยามีความสัมพันธ์ทางลบกับการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี ($r = -.37$, $p < .01$) ความสามารถของผู้ดูแลในการจัดการให้เด็กรับประทานยาต้านไวรัสเอดส์มีความสัมพันธ์ทางบวกกับการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี ($r = .24$, $p < .05$) ตัวแปรอิสระทั้งหมดสามารถร่วมกันทำนายการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวีได้ร้อยละ 16 โดยรสชาติของยาเป็นปัจจัยที่ทำนายการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวีได้อย่างมีนัยสำคัญทางสถิติ (Overall $F_{(7,101)} = 2.72$, $p < .05$).

ข้อเสนอแนะจากการวิจัยครั้งนี้คือ พยาบาลและบุคลากรที่เกี่ยวข้องกับการดูแลเด็กที่ติดเชื้อเอชไอวีที่ได้รับการรักษาด้วยยาต้านไวรัสเอดส์ ควรช่วยให้ผู้ดูแลเด็กได้รับข้อมูลเกี่ยวกับการดูแลเด็กที่ติดเชื้อเอชไอวีและการใช้ยาต้านไวรัสเอดส์ เพื่อพัฒนาความสามารถของผู้ดูแลในการจัดการให้เด็กรับประทานยาต้านไวรัสเอดส์ และขอความร่วมมือจากแพทย์และเภสัชกรในการจัดรูปแบบการรับประทานยาต้านไวรัสเอดส์ให้เหมาะสมกับเด็ก

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CHAPTER I
INTRODUCTION

Background and Significance of the Study

HIV infection in children is mostly acquired through vertical transmission. In Thailand, epidemiological studies revealed that rate of HIV infection through heterosexual transmission was still high as 83.75% of HIV-infected patients were heterosexual (Division of Epidemiology, Ministry of Public Health, 2005). As a result, the possibility of HIV transmission from mothers to their babies increases during pregnancy, delivery, and postpartum. In 2005, the Thai Working Group predicted that the accumulated number of children with HIV infection younger than 14 years old were about 50,620. It is expected that in 2006 there will be 53,400 accumulated children with HIV infection younger than 14 years old (Division of Epidemiology, Ministry of Public Health, 2005). At present, the Ministry of Public Health provides extended opportunity for HIV-infected patients to receive antiretroviral treatment under the National Access to Antiretroviral Programme for People Living with HIV/AIDS (NAPHA). Children with HIV infection also have higher chance to receive antiretroviral medication.

The major goals of adherence to antiretroviral medication in children with HIV infection are to decrease viral load and to restore the immune system by making sure that the children will take antiretroviral medication correctly and regularly according to the treatment regimen. Previous studies indicated that adherence to antiretroviral medication had an effect on viral load in HIV- infected patients. In the study of Paterson et al. (2000) conducted in 99 HIV-infected adults who received antiretroviral medication, 22% of patients with adherence of 95% or greater had virologic failure and blood viral load less than 400 copies/ml (undetectable). It is consistent with the study of Demasi, Tolson, and Pham (1998, February) examining adherence to antiretroviral medication in 194 HIV-infected patients. In this study, the

subjects who reported that they forgot to take antiretroviral medication more than once had increased level of HIV Ribonucleic Acid (RNA) in their blood.

In the study of Reddington et al. (2000) about adherence to antiretroviral medication of 90 children with HIV infection, the children whose caregivers reported no missed doses in the previous week were more likely to have HIV viral load < 400 copies/ml (undetectable). In addition, if the children did not take antiretroviral medication regularly or took it in low doses, drug resistance was likely to occur. It is consistent with the study of Perelson, Neuman, Markowitz, Leonard, and Ho (1996) who found that HIV duplicated 10^{10} copies a day and a possibility of mutation could occur at any time. Nonadherence to antiretroviral medication may lead to drug resistance and cause treatment failure. In the present, Thailand has a limited number of antiretroviral medications. If drug resistance occurs, there will be no effective antiretroviral medications to treat children with HIV infection and this will eventually affect their health. They may have various complications such as septicemia, pneumonia from multi-microorganisms, deafness, gastroenteritis from Salmonella, skin bacterial infections, and encephalitis that could cause death in HIV-infected children (Terapong, 2003).

Nonadherence to antiretroviral medication is a major problem of the treatment for children with HIV infection. VanDyke, Lee, Stanley, Morse, Krogstad, and Nachman (2002) conducted a study on adherence to antiretroviral medication in 125 children with HIV infection aged 4 months to 17 years. This study revealed that 30% of the sample reported non-full adherence (missed at least one dose in the past 3 days). Farley, Hines, Musk, Ferrus, and Tapper (2003) studied the methods of adherence assessment in 26 children with HIV infection aged 21 months to 12.5 years. They found that 42% of the sample had less than 80% of adherence using electronic Medication Event Monitoring System, MEMS. Reddington et al. (2000) studied adherence to antiretroviral medication in 90 children with HIV infection and found that 17% of the sample missed one dose in the previous 24 hours and 43% reported missed at least one dose in the previous week. Boni, Pontali, DeGol, Pedemonte, and Bassetti (2000) studied antiretroviral medication adherence in 37 children with HIV infection. They found that 24% of children had missed at least one dose in the 3 days before the visit and 44% of children had missed at least one dose since the last visit.

From studies on adherence to antiretroviral medication in children with HIV infection, the causes of nonadherence to antiretroviral medication were from characteristics of the drugs such as high pill burden (formulation of medications, number of medications, number of pill per day, and frequency of doses per day), taste and side effects (Belzer, Fuchs, Luftman, & Tucker, 1999; Boni et al., 2000; Mellins, Brackis-Cott, Dolezal, & Abrams, 2004; Temple, Koranyi, & Nahata, 2001). Besides these characteristics, caregiver factors may also have an influence on adherence to antiretroviral medication in HIV-infected children. They include socio-economic status, knowledge about the disease and antiretroviral medication in children, caregiver's health belief and perception of medication efficacy, caregiver's ability in administering antiretroviral medication, and social support (Belzer et al., 1999; Berrien, Salazar, Reynolds, & McKay, 2004; Goode, McMaugh, Crisp, Wales, & Ziegler, 2003; Hansell et al., 1998; Reddington et al., 2000).

Knowledge of disease and HIV treatment are major factors that increase good cooperation for treatment. Goujard et al. (2003) evaluated the impact of an educational intervention on adherence to antiretroviral treatment in 326 HIV-infected adults and found that 188 patients who received the educational intervention had improved adherence to antiretroviral regimens. Katko, Johnson, Fowler, and Turner (2001) studied the ability of the caregivers to describe the medication regimen in 35 caregivers of children with HIV. The results showed that 54% of the caregivers were able to describe the child's medication regimen. Sixty-three percent of the caregivers reported less than 90% of medication adherence; none of them had knowledge about the medication regimen. It is consistent with the study of Marhefka, Farley, Rodrigve, Sandrik, Sleasman, and Tepper (2004) examining a relationship between caregiver's regimen knowledge and adherence to antiretroviral medication in 51 caregivers of HIV-infected children. Findings of the study showed that caregiver's regimen knowledge was significantly associated with medication adherence. However, these studies are mostly conducted in foreign and developed countries, not in Thailand. Differences in caregiver's knowledge about the disease, lifestyle, and culture may make it difficult to apply these findings to HIV-infected children in Thailand.

In Thailand, most studies on antiretroviral medication were conducted in HIV-infected adults who were responsible for taking their medications. Tulathong

(2004) examined factors that contributed to medication adherence among patients aged 20-68 years who receivied highly active antiretroviral therapy. This study revealed that social support had an influence on adherence to antiretroviral medication. For research in caregivers, Deekong (2004) studied caregiver factors related to medication adherence among HIV-infected adults receiving highly active antiretroviral therapy. The study findings indicated that social support was a significant predictor of medication adherence in AIDS patients.

There are few studies about factors that influence adherence to antiretroviral medication in children. Siripong, Pancharoen, Apateerapong, and Anaworanich (2004, 11-16 July) studied barriers to adherence to antiretroviral therapy in Thai children with HIV infection. The findings revealed that caregivers who were not aware of the child's HIV status can often lead to nonadherence. Hansudewechakul, Plangraun, and Yodsuwan (2004, 11-16 July) studied methods to achieve > 95% adherence in children who received antiretroviral therapy. The findings revealed that caregivers and children who were under comprehensive care of the provider-team achieved adherence rate of over 95%. From literature review, there is limited information on the factors influencing adherence to antiretroviral medication in children with HIV infection.

Based on the above studies, the investigator is interested in studying the factors influencing adherence to antiretroviral medication in children with HIV infection. They include child factor (age), medication factors (pill burden, taste, side effects), and caregiver factors (social support, knowledge on care of children with HIV infection, ability in administering antiretroviral medication).

The findings of this study will be beneficial to health professionals who care for HIV-infected children who receive antiretroviral medication. They need to know the problems of medication adherence in children with HIV infection and provide support to caregivers of these children to promote medication adherence. Particularly, new registered nurses who work in infectious clinic/wards and provide direct care for children with HIV infection need to know the factors influencing adherence to antiretroviral medication in children with HIV infection. The nurses can apply the knowledge gained from this study as they perform their roles as a clinician, an educator, a counselor, and a coordinator in preparing children for antiretroviral therapy

and enhancing caregiver's ability before initiation of antiretroviral treatment. These actions will help enhance the effectiveness of antiretroviral treatment which will lead to better quality of life and longevity of children with HIV infection.

Research Question

How do child factor, medication factors, and caregiver factors have an influence on adherence to antiretroviral medication in children with HIV infection?

Purposes of the Study

1. To examine adherence to antiretroviral medication in children with HIV infection.
2. To investigate predicting power of child factor (child's age) medication factors (pill burden, taste, side effects), and caregiver factors (caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication) on adherence to antiretroviral medication in children with HIV infection.

Hypothesis

Child factor (child's age), medication factors (pill burden, taste, side effects), and caregiver factors (caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication) can predict adherence to antiretroviral medication in children with HIV infection.

Conceptual Framework

This study aims to examine the factors influencing adherence to antiretroviral medication in children with HIV infection. Based on literature review, the selected factors are as follows:

Child factor Age is a factor that influences self-care. Orem, Taylor, and Renpenning (2001) stated that the ability of self-care depended on age because intellectual ability on sequential thinking, understanding about health status and response to health status depended on age. When children are getting older, they will

have the intellectual development, maturity of thinking, reason and/or abstract thinking that enable them to estimate the situation and make their own decision. They also have increased responsibility for actions and creative ideas. Thus children in different ages will have different development of self-care agency. Self-care agency tends to be low in childhood and reaches its increase in older age.

For the study on children with HIV infection, there are few studies examining how the age of children affects adherence to antiretroviral medication. Mellins et al. (2004) examined child psychosocial status and caregiver/family factors that influenced adherence to antiretroviral medication in 75 HIV-infected children. The findings revealed that older children were likely have poor adherence to antiretroviral medication. It seems that age of children is a factor that may relate to adherence to antiretroviral medication.

Medication factors include pill burden, taste, and side effects. These factors may have a direct effect on adherence to antiretroviral medication in children with HIV infection. Research evidence showed that medication characteristics including medication forms, taste, high pill burden and side effects made children deny to take antiretroviral medications (Chesney, Morin, & Sherr, 2000; Gifford, Bormann, Shively, Wright, Richman, & Bozzette, 2000). It is consistant with the study of Boni et al. (2000) examining the main problems and barriers of adherence to antiretroviral medication in 37 parents of children with HIV infection. Thirty-six percent of the sample reported that too many medications and have to take medication at school or out of home were problems in administration of antiretroviral treatment. Twenty-four percent of the sample reported that bad taste was a barrier. Belzer et al. (1999) studied adherence to complex medication regimens and explored associated factors in 31 HIV-infected adolescents aged 13-24 years. Forty-three percent of the sample reported that too many pills was the most common reason for missing their medication. Twenty-nine percent of the sample reported the side effects as the reason of nonadherence to antiretroviral medication.

Caregiver factors include social support, knowledge on care of children with HIV infection, and ability in administering antiretroviral medication. Social support represents a significant factor which both directly and indirectly affects health behaviors. The concept of social support is defined by Cobb (1976) and Schaefer,

Coyne, and Iazanls (1981) as the information leading a person to believe that he or she is cared for, loved, esteemed, and valued, and that he or she is a part of a network of communication and mutual obligation. These feelings encouraged them to perform appropriate behavior leading to have good health. Orem et al. (2001) addressed that social support was a useful resource to increase self-care ability and responsibility by elevating motivation to do that kind of actions for other people who were under their care. Orem (1985) postulated that social support might facilitate self-care for meeting social interaction needs. In the course of social interaction, knowledge is acquired, values and expectation are formed, and security, fulfillment, and material resources are achieved. Thus, informational, emotional, and tangible support also facilitate self-care or dependent-care.

To examine if perceived social support influences adherence to antiretroviral medication, Deekong (2004) conducted a study on factors influencing adherence to antiretroviral medication in 128 caregivers who took care of HIV-infected adults. The findings showed that perceived social support affected adherence to antiretroviral medication in HIV-infected adults. Reddington et al. (2000) studied the experience of 90 caregivers of children with HIV infection. It was suggested that caregiver's social support could help increase adherence to antiretroviral medication in children with HIV infection. There is no studies exploring the relationship between caregiver's social support and adherence to antiretroviral medication in children with HIV infection.

Caregiver's knowledge and understanding about the disease, child care and significance of antiretroviral medication have direct affect on adherence to antiretroviral medication. Goode et al. (2003) studied adherence to antiretroviral medication in children with HIV infection by interviewing 18 parents. The findings revealed that parents who had knowledge about the disease and understood the reason of adherence to antiretroviral medication were likely to strictly follow the medication schedule. It is consistent with the study of Berrien et al. (2004) who found that the intervention increasing knowledge and understanding of caregivers on adherence to antiretroviral medication increased the scores of medication adherence.

In addition, ability of caregiver in administering antiretroviral medication may have an effect on adherence to antiretroviral medication in children. Orem et al.

(2001) stated that competence of caregiver was enhanced by the social support they perceived because social support was a useful resource to develop the capabilities to perform specific kinds of action for dependent-care. For children with HIV infection, there is no study on the competence of caregiver on this issue yet. However, from the research in HIV-infected adults, lack of patients' competence on self-management was a factor of nonadherence to antiretroviral medication (Ammassari et al., 2001) because it was daily mandatory and punctual activity that could be a burden for caregivers (Kuntana, 2000). From the study of Goode et al. (2003) with 18 parents of children with HIV infection on management of antiretroviral medication, 78% of the subjects reported that number of medicines, frequent doses, taste, side effects and adjustment of medication to daily life pattern were difficult burdens for adherence to antiretroviral medication. From literature review as mentioned, adherence to antiretroviral medication in children depends on the ability of caregiver in administering antiretroviral medication, adjustment due to the situation and good problem solving skill including seeking for help from medical professionals.

Conceptual framework of this study was presented in Figure 1 to illustrate relationships between seven independent variables and one dependent variable.

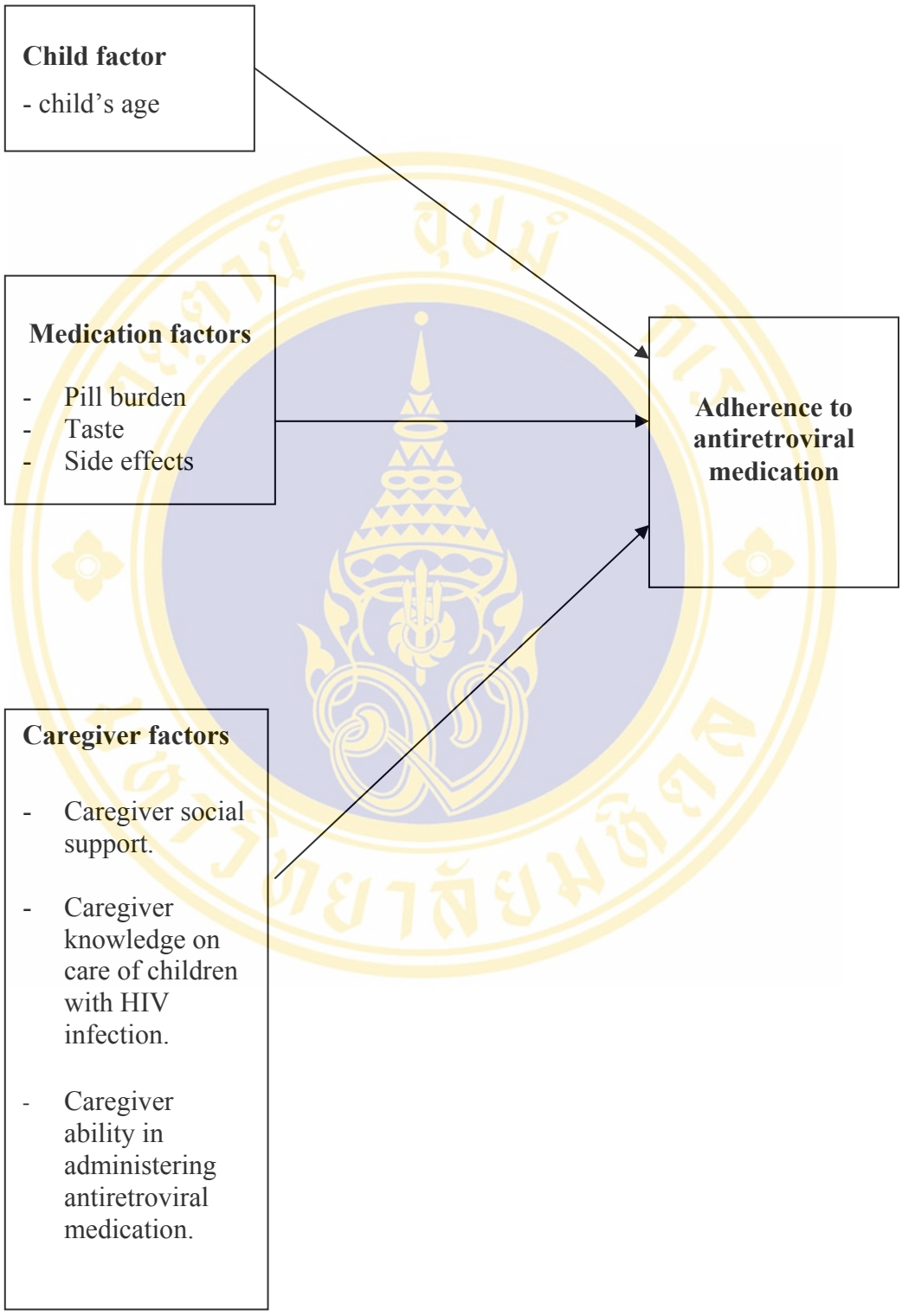


Figure 1 Conceptual Framework

Scope of the Study

This was a descriptive study aiming to examine adherence to antiretroviral medication and investigate the predicting power of 7 independent variables (child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication) on adherence to antiretroviral medication in children with HIV infection. The sample consisted of primary caregivers of children with HIV infection aged < 13 years old who received antiretroviral medication and were treated at the Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute, Nonthaburi province.

Definition of Terms

Child's age refers to the full number of years of age of children with HIV infection from their birthday until the date of data collection.

Pill burden is defined as a total number of tablets or spoons (if in liquid form) of antiretroviral medications that an HIV-infected child needs to take daily, which can be calculated by number of tablet/spoon plus daily of all antiretroviral medications (Mellins et al., 2004). It can be assessed by item 4 of the Antiretroviral Treatment Interview.

Taste is defined as a total score of difficulty or ease in taking antiretroviral medications by an HIV-infected child. It is rated by a primary caregiver who observes the child's expression while taking antiretroviral medications (Boni et al., 2000). Taste of medication is classified into 2 groups as easy-taking medication and difficult-taking medication. It can be assessed by item 5 of the Antiretroviral Treatment Interview.

Side effects is defined as a total score of side effects of antiretroviral medications, which can be skin rash, nausea/vomiting, headache/dizziness, stomachache/diarrhea, peripheral neuropathy, muscleache, jaundice/hepatitis, insomnia, and anemia. It can be assessed by item 6 of the Antiretroviral Treatment Interview.

Caregiver social support refers to the perception of primary caregivers of children with HIV infection about social support that they received from their spouse,

children, relatives, neighbors, physicians, nurses or other healthcare providers. It can be measured by Caregiver Social Support Interview. This interview was first developed by Kittithongsopon (1998) based on the concept of social support defined by Cobb (1976) combining with the concept of social support defined by Schaefer et al. (1981). This interview was then modified by the investigator to be suitable for use with caregivers of children with HIV infection. It comprises 20 items with scores ranging from 20-100. It includes 5 aspects of social support as follows:

1. **Emotional support** refers to the caregivers' perceived receiving of love, care, sympathy, praise, honor and encouragement in the care of children with HIV infection.

2. **Esteem support** refers to the caregivers' perceived receiving of acceptance and praise from other people for their competence and performance in caring for children with HIV infection.

3. **Informational support** refers to the caregivers' perceived receiving of information and advice which could help them deal with their and children's health problem and appropriate care for children with HIV infection including intervention to solve present problems.

4. **Instrumental support** refers to the caregivers' perceived receiving of direct material supports on things, money and labor for caring children with HIV infection.

5. **Network support** refers to the caregivers' perception of their interaction with others in society and their participation in social activities while providing care for children with HIV infection.

Caregiver knowledge on care of children with HIV infection refers to caregivers' knowledge on HIV infection in children, antiretroviral medication in children and side effects of antiretroviral medication. It can be measured by Caregiver Knowledge on Care of Children with HIV infection Questionnaire developed by the investigator based on the literature review and the education and counseling guidelines of American Society of Health-System Pharmacists (ASHP) (1997) to prepare and motivate patients to follow their phamacotherapeutic regimens and monitoring plans. This 20-item questionnaire with scores ranging from 0-20 is composed of 3 sections as follows:

1. Knowledge on HIV infection in children refers to caregivers' knowledge about the impact of HIV infection on children's health, treatment, how to live with children with HIV infection, and prevention of opportunistic infection.

2. Knowledge on antiretroviral medication in children refers to caregivers' knowledge about the benefits and the actions of antiretroviral medication, significance of adherence to antiretroviral medication, and consequences of non adherence to the medication. It also includes medication administration in relation to meals, medication storage, medication adherence, and drug interaction.

3. Knowledge on side effects of antiretroviral medication in children with HIV infection refers to caregivers' knowledge about side effects of antiretroviral medication and how to deal with the side effects.

Caregiver ability in administering antiretroviral medication refers to specific and essential ability of caregivers to manage antiretroviral medication in children with HIV infection. It can be measured by the Caregiver Ability in Administering Antiretroviral Medication Questionnaire. The investigator developed this questionnaire based on dependent care agency of Orem (2001). It comprises 20 items with the range of scores from 20-100. This questionnaire evaluates 10 aspects of caregivers' ability as follows:

1. Ability to maintain attention and care for the dependent is defined as caregivers' ability to give time and concern including responsibility to care for children with HIV infection so that they can take antiretroviral medication with proper dose and time.

2. Ability to self-controlled use of available physical energy is defined as caregivers' ability to control their energy with no complaint about tiredness, fatigue or exhaustion when having activity. They earn their satisfaction in providing care for HIV- infected children who receive antiretroviral medication.

3. Ability to control the position of the body is defined as caregivers' ability to fully move muscles to complete care for HIV-infected children who receive antiretroviral medication.

4. Ability to reason within a dependent-care frame of reference is defined as caregivers' ability to care for children who receive antiretroviral medication by

using information and facts. They can distinguish the reasons of punctual time and dose for adherence to antiretroviral medication.

5. Motivation to care for the dependent is defined as caregivers' ability to manage antiretroviral medication in children. They realize the value and significance of adherence to antiretroviral medication to prolong children's lives.

6. Ability to make decisions about care for the dependent and successful implementation is defined as caregivers' ability to understand probable side effects of antiretroviral medication and can make decision to stop or continue the medication. They can also report these side effects to a physician for immediate treatment and take the children to the clinic as appointed.

7. Ability to acquire technical knowledge about care for the dependent is defined as caregivers' ability to seek information and knowledge on HIV infection in children and use and side effects of antiretroviral medication from appropriate healthcare providers such as physicians and nurses. They should be able to remember and implement these kinds of knowledge to promote adherence to antiretroviral medication in children with HIV infection.

8. A repertoire of cognitive, perceptual, manipulative, communication, and interpersonal skill adapted to the performance of dependent-care operation is defined as caregivers' ability and skills in communicating with physicians, nurses or others when they encounter problems or have questions about antiretroviral medication and side effects. They are able to used information received from health care providers to care for children with HIV infection to help them adhere to antiretroviral medication.

9. Ability to order discrete dependent-care action is defined as caregivers' ability to know about mandatory activities and can set priority of task.

10. Ability to consistently perform dependent-care operations, and integrating them with relevant aspects of lifestyle is defined as caregivers' ability to perform the roles of caregivers and be responsible for children with HIV infection while maintaining relationship with others. They can also integrate care of HIV-infected children to be a part of their life, family and society.

Adherence to antiretroviral medication refers to the average percent of how children with HIV infection take antiretroviral medication correctly and regularly

in the past 30 days. It can be measured by Adherence to Antiretroviral Medication Interview for caregivers of children with HIV infection. The interview was developed from Visual Analog Scale of Maneesriwongkul and Williams (2004) combined with the Pediatric International Adherence Questionnaire Behavior/Identification of Pediatric AIDS Clinical Trails Group (PACTG) (1998) with the range of percents from 0-100%.

Expected Outcomes

1. The findings of this study can be used by nurses. Information gained from this study will be used to prepare caregivers before initiation of antiretroviral treatment and to support them during antiretroviral treatment.

2. The findings of this study can be used to teach nursing students, so that they are able to effectively care for children with HIV infection and their caregivers.

3. The findings of this study can be used as information for further research aiming to develop an educational program and a competency development program for caregivers of children with HIV infection.

CHAPTER II
LITERATURE REVIEW

This research aims to investigate the factors influencing adherence to antiretroviral medication in children with HIV infection, which covers the scope of literature review as follows:

1. HIV Infection in Children
2. Antiretroviral Medication in Children with HIV Infection
3. Adherence to Antiretroviral Medication
4. Factors Influencing Adherence to Antiretroviral Medication in Children with HIV Infection.

HIV Infection in Children

Human Immunodeficiency Virus (HIV) causes the immune impairment leading to Acquired Immunodeficiency Syndrome (AIDS) (Pancharoen, 2002). Most HIV infection in children is transferred from mothers to children during pregnancy, delivery, or postpartum through breast-feeding (Chokephaibulkit, 2004).

As of December 2003, the world had approximately 2.5 million children with HIV infection that mostly received the virus from their mothers (UNAIDS & WHO, December 2003). In Thailand, prevalence of HIV infection in pregnant women increased from 0% in 1989 to 2.3% in 1998. However, the prevalence has decreased to 1.2% in 2002 (Chokephaibulkit, 2004). In Thailand, the estimate of pregnant women with HIV infection who delivered babies is about 14,000-18,000 persons a year. Rate of HIV transmission from mothers to children depends on many factors such as maternal factor, child factors, and obstetrical factor. Maternal factor is HIV viral load in blood. If HIV viral load is high, it is high risk of HIV transferring to fetus. Child factors include fetal cell susceptibility and fetal and neonatal immune response. Obstetrical factor is a cesarean section before labor pain, which can reduce possibility of HIV transmission from mothers to children. For breast feeding factor,

some study findings revealed that rate of HIV infection through breast feeding was about 25% (Sriminiparn, 1996). Studies showed that rates of HIV transmission from mothers to children in Thailand were 21-28% (Chokephaibulkit, 2004). At present, various regimens of antiretroviral medication are given to pregnant women to decrease the rates of HIV transmission from mothers to children to 2-4%. It is estimated that there will be about 1,500 children with HIV infection a year in Thailand (Chokephaibulkit, 2004). From the report of Department of Disease Control, Ministry of Public Health, Thailand, 2004 there were 10,799 children with AIDS and 2,954 cases of death from AIDS in 2004. Children with HIV infection who are survivors are the target group that needs appropriate care.

Diagnosis of HIV infection in children

The Ministry of Public Health, Thailand set up two guidelines of laboratory diagnosis (Chasombut, Lerdpiriyasuwat, & Yootanon, 2004):

1. Guideline of laboratory diagnosis for children age < 18 months

Laboratory diagnosis for HIV infection in children age < 18 months that can test in HIV-exposed infants at the age of 4-6 weeks is based on virologic tests: HIV Deoxyribonucleic Acids (DNA) Polymerase Chain Reaction (PCR), HIV RNA PCR, P24 antigen, and viral culture. The gold standard is HIV DNA PCR in which HIV infection can be diagnosed if there are 2 positive results of PCR from different blood tests. The children are not HIV-infected if 2 negative results of PCR are detected from different blood tests. The first test will be performed when the children are more than 1 month old and another blood test at more than 4 months of age for children with no sign or symptom of HIV infection.

Another virologic test for HIV infection is P24. The presence of P24 antigen by the boosted immune complex-dissociation (ICD) blood test is used to assist the diagnosis of HIV infection in children. The results have shown that this test is no less effective than PCR. Furthermore, the test is easy to do and less expensive, therefore, it can be used as a substitute for the PCR test. The HIV- serology test is suggested to do in all cases when children are 12 months old. If a positive result is confirmed, another test should be repeated at the age of 18 months old. If a positive result is still confirmed at 18 months, it indicates that the children actually have HIV infection.

2. Guideline of laboratory diagnosis for children age > 18 months

The guideline of laboratory diagnosis in children age > 18 months can be done as follows (Chasombut et al., 2004):

2.1 HIV antibody test should be done in both screening test and confirmatory test.

- Screening test. The tests mostly used are Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination (PA), Immunofluorecence and Immuno-precipitation. For ELISA, it needs to be positive twice to prove the positive result. If the first test is positive and the second is negative, the ELISA result will be considered as negative.

- Confirmatory test. The screening test usually is very sensitive but the specificity may not be 100%. Its result can be false positive or false negative. Hence, it is necessary to have various confirmatory tests such as ELISA test in another time or use the Particle Agglutination (PA), Immunofluorescence and Western blot that is widely known and most accepted.

2.2 HIV Antigen Test

2.3 Test for relevant immunity cells such as CD4 and CD8 lymphocytes. A proportion between CD4 and CD8 lymphocytes should be lower than 0.5.

Classification of HIV infection in children

The Centers for Disease Control and Prevention (CDC) of the United States of America set up criteria for classification system of Human Immunodeficiency Virus Infection in children age < 13 years (CDC, 1994).

Table 1 Pediatric Human Immunodeficiency Virus (HIV) Classification

Immunologic categories	**Clinical categories**			
	N (Not symptomatic)	**A (Mildly symptomatic)**	**B (Moderately symptomatic)**	**C (Severely symptomatic)**
1. No immune suppression	N1	A1	B1	C1
2. Moderate immune suppression	N2	A2	B2	C2
3. Severe immune suppression	N3	A3	B3	C3

Table 2 Immune Categories Based on Age-Specific CD4 T-Lymphocyte Count and Percentage

Immune category	**Age of children**		
	< 12 months	**1-5 years**	**6-12 years**
	Cell/cubic mm(%)	**Cell/cubic mm (%)**	**Cell/cubic mm (%)**
1. No immune suppression	≥1,500 (≥25)	≥1,000 (≥25)	≥500 (≥25)
2. Moderate immune suppression	750-1,499 (15-24)	500-999 (15-24)	200-499 (15-24)
3. Severe immune suppression	< 750 (< 15)	< 500 (< 15)	< 200 (< 15)

Table 3 Classification System: Clinical Categories in Children with HIV Infection Age < 13 years (Terapong, 2003)

Category N: not symptomatic
Category A: mildly symptomatic
At least two of: lymphadenopathy, hepatomegaly, splenomegaly, parotitis, rash, ear, nose and throat infections
Category B: moderately symptomatic
Single episode of severe bacterial infection
Lymphocytic interstitial pneumonitis
Anemia, neutropenia, thrombocytopenia
Cardiomyopathy, nephropathy, hepatitis, diarrhea
Candidiasis, severe varicella/ zoster or herpes simplex virus
Category C: severely symptomatic (AIDS)
Two serious bacterial infections
Encephalopathy (acquired microcephaly, cognitive delay, abnormal neurology)
Wasting syndrome (severe failure to thrive or downward crossing two weight percentiles)
Opportunistic infections (PCP, cytomegalovirus, toxoplasmosis, disseminated fungal infections)
Disseminated mycobacterial disease
Cancer (Kaposi's sarcoma, lymphomas)

The World Health Organization has developed a system for diagnosing probable HIV infection in children based only on clinical signs to use in developing countries. AIDS diagnosis is likely if a child is found to have at least two major signs and two minor signs, without any immune impairment from other causes. Major and minor signs are as follows: (Pancharoen, 2002).

Major signs are:

1. Weight loss > 10% or failure-to-thrive

2. Chronic diarrhea for longer than one month, whether constant or intermittent.

3. Prolonged fever without a source for longer than one month, whether intermittent or continuous in which the definition of fever is body temperature as 37.5 ºC or more

4. Chronic lower respiratory tract infection or related symptoms combined with pulmonary imaging studies that spontaneously reveal bilateral reticulonodular pulmonary infiltration for 2 or more months, in absence of any microorganisms and not respond to antimicrobial therapy or recurrent infection at the location of the previous lesion or at a new location for two or more times within 1 year after remission.

Minor signs are:

1. Generalized lymphadenopathy, hepatomegaly or spleenomegaly.
2. Oro-pharyngeal candidiasis.
3. Repeated common infections such as otitis media, pharyngitis which do not respond to antimicrobial therapy.
4. Persistent cough over 1 month.
5. Generalized skin infection.
6. Confirmed maternal HIV infection during pregnancy or prior to delivery or HIV infection in children or detection of HIV antibodies in children.

In Thailand, the diagnosis of HIV infection is based on the laboratory findings combining with the clinical assessment of signs and symptoms to early detect HIV infection and start antiretroviral treatment as soon as possible, which can help the children maintain good health and good quality of life. As a result, they will not be a burden to the society.

Prognosis of the disease in children

Prognosis of HIV infection in children is different from that in adults. Symptoms of HIV infection in children are uncertain and indefinite. Signs of complications involved with many systems may be detected, which are the direct result from HIV infection or immune impairment and opportunistic infection. Clinical characteristics of children with HIV infection are separated into 2 groups as follows (Chotipitayasunon, 2001):

1. Rapid progressor has immediate and severe onset of illness that may express when children are at 2-3 months. These illnesses may include failure to thrive, oro-pharyngeal candidiasis, chronic diarrhea, and pneumonitis. The children in this group contracted the virus in utero. The virus has damaged the development of immune system and the children often die within 1-2 years.

2. Slow progressor has gradual progress of symptoms with less severity of the disease. The symptoms usually show when the children get older. The children in this group may have such symptoms as low body weight, hepatomegaly, spleenomegaly, lymphadenopathy, lymphoid interstitial pneumonitis (LIP), parotitis, and rash. The children contracted the virus during labor or postpartum phase.

In other countries, there are some studies about prognosis of HIV infection in children. Barnhart et al. (1996) conducted a study about the progression of HIV disease through clinical stages from birth to death among 2,148 perinatally infected children. The study results revealed that 50% of children born with HIV infection expressed signs and symptoms within the first five years and the progression of the disease from birth until expression of clinical signs and symptoms in level C took about 6.6 years. In Thailand, Lumpiganon, Kosararuk, and Lhoulpiboon (2000) conducted a study to explore survival in 90 children with AIDS by follow-up them from birth. All of the children showed the first signs of HIV infection when they were 4 months old. They met the criteria of AIDS diagnosis by WHO when they were 13 months old. The differences of HIV/AIDS progression in children who were perinatally infected may depend on various factors in term of interaction between the virus and infected children, child rearing, and appropriate antiretroviral treatment.

Antiretroviral Medication in Children with HIV Infection

Antiretroviral medications are medications for the treatment of HIV infection. This medication can reduce the ability of the virus to replicate. Highly Active Antiretroviral Therapy (HAART) refers to the treatment including at least 3 combined antiretroviral medications which can improve the patients' quality of life while prolonging life expectancy (Terapong, 2003).

Antiretroviral medications that are generally used in children are classified into 3 groups as follows:

1. Nucleoside analogues reverse transcriptase inhibitors (NRTIs) are a group of medications that prohibit the enzyme reverse transcriptase through the phosphorylation process prior to action. Examples are Zidovudine (ZDV), Stavudine (d4T), Lamivudine (3TC), Didanosine (ddl), Abacavir (ABC). At least two of these medications should be used as a backbone of HAART. Some medications can be combined together in one tablet such as Combivir (ZDV/3TC/ABC).

2. Non-nucleoside analogues reverse transcriptase inhibitors (NNRTIs) are a group of medications consisting of reverse transcriptase inhibitors. A similarly target reverse transcriptase inhibitors as NRTIs, but work in a slightly different way than do NRTIs. They directly inhibit the activity of reverse transcriptase without phosphorylation process. Examples are Nevirapine (NVP) and Efavirenz (EFV).

3. Protease inhibitors (PIs) are a group of medications consisting of protease enzyme inhibitors. Examples are Saquinavia (SQV) with hard gel capsule and soft gel capsule, Indinavir (IDV), Ritonavir (RTV), Nelfinavir (NFV), and Lopinavir/ ritonavir (LPV/r).

In Thailand, there are 10 antiretroviral medications that are registered with Food and Drug Administration. There are AZT, ddC, ddI, d4T, 3TC, Nevirapine, Efavirenz, Suquanavir, Fortavase, Indinavir, Ritonavir and Nelfinavir. AZT and ddI are on the national list of major medications (Ministry of Public Health, 2004).

Antiretroviral regimens for children (Ministry of Public Health, 2004)

1. For cases with mild to moderate severity of disease such as level A, B, and CD 4 > 15%, use the following medications:

1.1 Triple therapy includes 2NRTIs+PI or 2NRTIs+NNRTIs

1.2 Dual therapy includes 2NRTIs, only in case that there will be a problem in using the third medication because of poor adherence.

2. For cases with advance stage of disease such as Level C and CD 4 < 15%, they should be treated with Triple therapy except some cases that have problem in taking the third medication, for instance, cannot tolerate or cannot find the medication.

Criteria for initiation of antiretroviral treatment in children

In Thailand, the Ministry of Public Health set up a guideline for initiation of antiretroviral treatment in children as follows: (Ministry of Public Health, 2004)

1. In children age < 12 months, consider to give antiretroviral medications regardless of their clinical symptoms or immune status. In children aged almost 12 months who have no symptoms and have normal immune, may consider to use the same criteria as older children.

2. In children age > 12 months, antiretroviral medications are recommended when:

2.1 Clinical category B, C by CDC classification system

2.2 CD4 is less than 20% (consider individually if CD4 is between 20-24% with clinical stage A).

For those with clinical stage A, antiretroviral medications may be given like in other countries. However, symptoms of stage A are unspecific. It is still safe if antiretroviral medications have not started yet, particularly if CD4 is still high (> 25%). If CD4 is less than 25%, it means that there is immunological suppression. In other countries, the experts may suggest to give antiretroviral medications to all children who have CD4 < 25%. However, Thai experts believe that it is still safe if antiretroviral medications are not given when CD4 is between 20-25%.

In addition to consideration of the practice guidelines, we must also consider other significant child-related factors involved with antiretroviral treatment and affecting adherence to antiretroviral medications in children. Therefore, prior to beginning these medications, the following assessment should be performed (Chasombut et al., 2004):

1. Adherence to antiretroviral medications (Short-term and long-term)

1.1 Caregivers must understand that the children need to take antiretroviral medication regularly and have long-term monitoring.

1.2 Family support

1.3 Ability to follow up the treatment

2. Access to health care services and antiretroviral medication.

3. Access to laboratory investigation service to monitor the treatment outcome (at least test of CD4).

Adherence to antiretroviral medication is essential to the success of the treatment. Hence, prior to initiation of the antiretroviral medication, it is necessary to

prepare the caregivers and children to be ready for the treatment in order to enhance the effectiveness of antiretroviral treatment.

Table 4 Type, Dose, Special Considerations and Side Effects of Antiretroviral Medication (Medecins Sans Frontieres-Belgium cited in Pancharoen, 2002)

DRUG	STRENGHT	DOSE	SPECIAL CONSIDERATIONS	SIDE EFFECTS
NRTI (Nucleoside analogues)				
ZDV Zidovudine	100 mg caps 300 mg caps 10 mg/ml	160 mg/m^2 TID or 240 mg/ m^2 BID	Take with/without food No concurrent use with d4T	Marrow suppression: anemia, neutropenia, GI intolerance, headache, myalgia Fingernail discarnation
3TC Lamivudine	150 mg tab 10 mg/ml	4 mg/kg/dose BID	Take with/ without food Tablets can cut or crushed	Few side effect GI intolerance, headache, pancreatitis Rare: peripheral neuropathy
ddI Didanosine	30 mg (=25 mg) 60 mg (=25 mg) 115 mg (=25 mg) 170 mg (=150 mg)	180-250 mg/ m^2 OD	Administer on empty stomach Don't take with acidic drinks (such as fruit juice) Use separate from other drugs (1-2 hours gap)	Pancreatitis Peripheral neuropathy GI intolerance
d4T Stavudine	15 mg caps 20 mg caps 30 mg caps 40 mg caps	1 mg/kg/dose BID	Take with/ without food Capsules can be opened Do not give in combination with ZDV	Pancreatitis, peripheral neuropathy (more frequent if combined with ddI) Headache, GI intolerance Increase in liver enzymes
ABC Abacavir	300 mg tab 20 mg/ml	8 mg/kg/dose BID	If any suspicion for hypersensitivity: stop and do not restart	Hypersensitivity reaction: fever, rash, dyspnea, fatigue

Table 4 Type, Dose, Special Considerations and Side Effects of Antiretroviral Medication (Continued)

DRUG	STRENGHT	DOSE	SPECIAL CONSIDERATIONS	SIDE EFFECTS
NNRTI (Non- nucleoside reverse transcriptase inhibitors)				
NVP Nevirapine	200 mg tab 50 mg/5 ml	150-200 mg// m^2 /dose BID Initial dosage: half dose for 14 days then increase to full dose	Take with/ without food Start with half dose to prevent rash Stop if severe rash or involvement of mucous membranes. Do not use with rifampicin	Rash (usually between day 7-14) Hepatitis (usually first 12 weeks) Hypersensitivity reaction
EFV Efavirenz	50 mg caps 200 mg caps	10-15 kg: 200mg OD 15-20 kg: 250mg OD 20-25 kg: 300 mg OD 25-32.5 kg: 350mg OD 32.5-40 kg: 400mg OD	Capsules can be opened and mixed with food or water Bedtime-dosing is recommended Do not take fat meal Concurrent use with rifampicin is possible	Skin rash Central nervous system (usually present during first 14 days) Increase in liver enzymes Rare: hepatitis

Table 4 Type, Dose, Special Considerations and Side Effects of Antiretroviral Medication (Continued)

DRUG	STRENGHT	DOSE	SPECIAL CONSIDERATIONS	SIDE EFFECTS
PI (Protease Inhibitors)				
RTV Ritonavir	100 mg caps 80 mg/ml	350-400mg/m^2 /dose BID (start at 200mg/m^2, increase by 50mg/m^2 at 2-3 days interval)	Dose escalation over 14 days to improve GI intolerance Administration with food improves tolerability Store the capsules in the refrigerator if store > 1 month, not the syrup Capsules must not be opened	GI intolerance Increase in liver enzymes Circumoral paresthesia Taste of syrup is difficult to tolerate
IDV Indinavir	200 mg caps 400 mg caps	750 mg/m^2/dose BID	Take on empty stomach with light meal Capsules must not be opened Do not use with rifampicin	Nephrolithiasis: children should drink more than 75 ml/kg/day. Dry mouth and dry skin. GI intolerance
NFV Nelfinavir	250 mg tab	50-55 mg/kg/dose BID	Can be broken in half, crushed and mixed with food or drink. Do not use with rifampicin	Diarrhoea, GI intolerance, Rash
SQV Saquinavir	200 mg SGC 200 mg HGC	50 mg/kg/dose TID	HGC is not recommended except in combination with RTV. Capsules must not be opened. Do not use with rifampicin.	Photosensitive GI intolerance Increase in liver enzymes
Combination Full dose RTV+ SQV-SGC		RTV 400 mg/m^2 + SQV 30 mg/kg BID	Use only as salvage therapy	
Combination Booster RTV+ SQV-SGC		Insufficient data		
Combination Booster RTV+ IDV		Insufficient data		

Characteristics of antiretroviral medication

1. Form. Antiretroviral medications are developed to treat adult patients so most of them are in tablet or capsule form. The medictions in form of liquid for children in Thailand are Zidovudine (ZDV), Lamivudine (3TC), Abacavir (ABC), Nevirapine (RTV), Ritonavir (RTV), and Lopinavir/ ritonavir (LPV/r). Most medications are in powder form such as didanosine (ddI) and nelfinavir (NFV). Various forms of these medications are determinant features which can pose main barriers with respect to administration, thus affecting adherence in children (Belzer et al., 1999; Boni et al., 2000; Temple et al., 2001).

2. Taste. Antiretroviral medications usually have a bad taste. ZDV is the first antiretroviral medication mostly used in the treatment. It has a bitter taste. RTV in liquid form has bad smell and bad taste. ddI is in tablet form and after being grained, it is difficult to dissolve and swallow. It leaves the feeling of sandy in the mouth when taking it.

3. Frequency and time of taking antiretroviral medication. The children need to take antiretroviral medications with punctuality. Taking the medication twice does not mean that a patient can take it at any time in the morning and evening but the interval has to be every 12 hours for the result of decreasing viral load in plasma (Terapong, 2003).

4. Drug interaction. It may happen between antiretroviral medications or between antiretroviral medication and other drugs, especially the drugs used to treat opportunistic infections. Caregivers and children should know the medication names that should not be taken with antiretroviral medication. Rifampicin should not be taken with antiretroviral medications in NNRTIs group such as Nevirapine (NVP) and also those in PI group such as Indinavir (IDV), Nelfinavir (NFV), and Saquinavir (SQV) (see Table 4).

5. Effect of diet on absorption of antiretroviral medication. Caregivers need to know about the effect of diet on absorption of antiretroviral medications. It will help them to properly manage antiretroviral medications so that the medications can be effectively absorb. Those in NRTIs group such as didanosine (ddI) should be taken with empty stomach and should not be taken with fruit juices such as orange juice.

Those in NNRTIs group such as Efavirenz (EFV) should be avoided to take with high fat diet (see Table 4).

Side effects of antiretroviral medication

Although lactic acidosis or hepatic steatosis is not frequently found, its mortality rate is high. Patients often come with tiredness, weight loss, abdominal pain, nausea-vomiting, and breathing difficulty. Most frequently found symptoms are peripheral neuropathy, headache, muscle weakness, anemia, diarrhea, hepatitis and neutropenia. These are side effects of the antiretroviral medication in Nucleoside Reverse Transcriptase Inhibitors (NRTIs) group (Chasombut et al., 2004).

Hypersensitivity is mostly not severe. It is usually found in the first week and can be recovered by itself or with antihistamine without stopping antiretroviral medications. In some cases, they may have severe rash and become Stevens-Johnson syndrome. The rash may relate to fever, oral ulcer, myalgia and joint pain, nightmares, and confusion. These side effects occur because of the NNRTIs particularly Nevirapine (Chasombut et al., 2004).

Lipodystrophy. It can be found about 20-30% of pediatric patients. Major symptom of lipodystrophy is the decreased lipid at cheeks, extremities, and buttock with the accumulated lipid at abdomen and breast. Clinical signs are central obesity and peripheral fat wasting. In addition, they include visceral fat accumulation, buffalo hump, and facial thinning. To diagnose this condition, history taking, physical examination, Dual-energy X-ray Absorptiometry (DXA) and Magnetic Resonance Imaging (MRI) are used to measure lipid levels. At present, there is no definite treatment for this condition but the physician may consider changing antiretroviral medication in Protease Inhibitors group to prevent more complication. (Chasombut et al., 2004).

Hyperlipidemia The patient will have high cholesterol and triglyceride with or without any change of lipid accumulation. It is mostly found with the use of Ritronavir (Chasombut et al., 2004).

Avascular necrosis is defined as having no blood vessel to other parts of the body or death blood vessels. It is mostly found at head of femurs. This side effect is found when the Protease inhibitors (PI) are used (Chasombut et al., 2004).

Educating caregivers about side effects of antiretroviral medications and appropriate treatment when having the side effects are significant to adherence to antiretroviral medications. Hence, prior to beginning the treatment, physicians and nurses have to help the caregivers understand mild and severe side effects of antiretroviral medications. Severe side effects are severe nausea and vomiting, severe diarrhea, severe abdominal pain, jaundice, and skin rash. The patients who have these severe side effects should go to see the physician immediately. Mild side effects are mild nausea and mild abdominal pain, which should be reported to the physician in the next appointment.

Adherence to Antiretroviral Medication

Definition of adherence to antiretroviral medication

Hammami, Nostlinger, Hoeree, Lefevre, Jonckheer, and Kolsteren (2004) defined adherence to antiretroviral medication as the extent to which an individual chooses behaviors that coincide with a clinical prescription achieved through negotiation between the health professional and the patient.

Adherence to antiretroviral medication refers to the percentage of the prescribed dose taking. Belzer et al. (1999) defined good adherence to antiretroviral medication as 90% of the pill prescribed in any regimens. However, the study of Paterson et al. (2000) showed that high level of adherence ≥ 95% was required to achieve virologic suppression. A cut-off point of adherence more than 95% was used to classify good adherence. Adherence to antiretroviral medication < 95% was used to classify poor adherence.

Katko et al. (2001) defined adherence to antiretroviral medication as the proportion of days of medication dispensed to days of medication prescribed, which was converted to a percentage of medication adherence. From a study conducted in adults with HIV infection (Gordillo, Amo, Soriano, & Gonzalez-Lahoz, 1999), the level of adherence to antiretroviral medication > 90% seems necessary to achieve viral suppression.

From the above definitions, adherence to antiretroviral medication means cooperation and willingness to take antiretroviral medication properly, punctually and exactly according to the treatment plan. Since estimates level of adherence to

antiretroviral medication in HIV infection are varied, there is no gold standard measurement of adherence to antiretroviral medication.

Significance of adherence to antiretroviral medication

Antiretroviral medications currently used are widely accepted as the effective treatment. However, prescribing the effective medications to patients does not guarantee the treatment success. The factors influencing the treatment success is adherence to the prescribed medications. Gibb, Giacomet, Livingstone, McGee, Harper, and Formica (1999) studied the level of HIV 1 RNA in 133 children with HIV infection who were receiving antiretroviral medications in 48 weeks of the study. Eighty percent of the subjects reported full adherence (> 95%) had HIV 1 RNA < 400 copies/ml (nondetectable). Watson and Farley (1999) studied the levels of CD4+ count and viral load in children with HIV infection during 400 days of the study. The study findings showed that children with HIV infection who had adherence > 95% had increased CD4+count and viral load < 400 copies/ml (nondetectable). Gordillo et al. (1999) conducted a study on adherence to antiretroviral medications in adults with HIV infection. The findings revealed that the subjects with good adherence (> 95%) had increased CD4+count. The findings of these studies supported significance of adherence to antiretroviral medication because it influenced an increase in immune response and a decrease in viral load in HIV- infected patients.

Adherence to antiretroviral medication is very important in children with HIV infection because they have to take many types of antiretroviral medication continuously throughout their lives. To maintain adherence to antiretroviral medication for very long time is very difficult especially for children.

Evaluation of adherence to antiretroviral medication

There is no standard evaluation of adherence to antiretroviral medication. From the literature review, the evaluation methods are as follows:

1. Medication Event Monitoring System (MEMS). A modern technology is used to innovate this tool that can help recording how many times the lid of medication bottle is opened. The patients have to return the bottle with the electronic chip when they come to see the physician in the next appointment. The electronic chip will be scanned and the data will be interpreted and recorded into the computer. The data can than be analyzed to show the level of medication adherence (Liu et al., 2001).

2. Self-report. Interview and record of the medication taken by a calendar may result in overestimation. Dolezal, Mellins, Brackis-Cott, and Abrams (2003) and Liu et al. (2001) conducted the comparative studies on various instruments used to assess medication adherence in HIV- infected patients. The study findings revealed that different levels of adherence were obtained from the samples in which subjects reported higher levels of adherence to antiretroviral medication than the actual adherence determined by a Medication Event Monitoring System (MEMS).

3. Physician's assessment. Physicians assess adherence to antiretroviral medication by laboratory result, especially viral load and CD4+count (Ammassari et al., 2001). From the literature review, the physician's assessment offers worse results than other methods. Peterson et al. (2000) compared medication adherence evaluated by physicians and Medication Event Monitoring System (MEMS) and found that medication adherence assessed by physician was less than 80% while medication adherence evaluated by Medication Event Monitoring System (MEMS) was higher than 80%. Similarly, Haubrich et al. (1999) compared medication adherence between the patients' self-report and the physician's assessment and found that 45% of the assessment results were different.

4. Laboratory findings. Measurement of drug concentrations in blood of HIV-infected patients taken during visits to their physicians may be effective in some cases. However, this evaluating method may result in error with regard to adherence in cases where the patient took medications just before coming to see the doctor. The test results will surely indicate good adherence although the patient may not actually have good adherence to the medication. The best sensitive method for assessing drug response is to measure viral load. If children with HIV infection had undetectable viral load < 400 copies/ml after the treatment, the opportunistic infection is low and the treatment outcome will sustain more response than in the children who still have a viral infection. Although the patients have incomplete virological response, they may respond well to the treatment both with clinical and immune response. However, there is higher chance of drug resistance that will reduce the duration of effective drug response. The practice guideline of Europe suggested that the clinical and immune responses of the children be used as a major assessment of the treatment response and treatment failure. Monitoring involves evaluating the laboratory results such as CD4

cell count which is a major indicator of the effectiveness of antiretroviral treatment (Chasombut et al., 2004).

5. Pill count. It is an assessment method of adherence that has been used for a long time. However, this method may easily give error results if the patients or caregivers throw away some medications before seeing the physician. It may look like they have taken all prescribed medications.

From the literature review, there is no standard assessment that can measure behaviors in taking antiretroviral medication in children. The methods most commonly used to evaluate adherence to antiretroviral medication include pill count, MEMS, calendar record and interview or self-report by questionnaire (Chesney et al., 2000; Drotar, 2000; Matsui, 2000). However, each method has some limitations and give different results of adherence to medication (Steele et al., 2001).

In studies and clinical practice related to the assessment of adherence to antiretroviral medication in children with HIV infection, the caregivers' recalled self-report were often used. Steele and Grauer (2003) reviewed 15 studies on adherence to antiretroviral medication in children with HIV infection. There were 8 studies that used self-report by the children or their caregivers about the adherence to antiretroviral medication. The findings showed that children whose caregivers reported good adherence to antiretroviral medication had decreased viral load. It means that the report by the caregivers is reliable to evaluate the adherence to antiretroviral medication and can be used in research and clinical practice.

In Thailand, Visual Analog Scale (VAS) was used in the self-report of adherence to antiretroviral medication. Maneesriwongkul and Williams (2004), Tulathong (2004), and Deekong (2004) used VAS to study adherence to antiretroviral medication in the past 30 days and found that adherence to antiretroviral medication was significantly correlated with viral load. In practice, VAS is also used in the clinic by asking caregivers of children with HIV infection to report the adherence to antiretroviral medication. It is found that VAS has validity in assessing adherence to antiretroviral medication in children with HIV infection (Petdachai, 2004).

In this study, the investigator evaluated the adherence to antiretroviral medication in children with HIV infection by interviewing the caregivers about adherence to antiretroviral medication in the past 30 days. They were asked to mark

on the straight line representing 0-100 percent of adherence to antiretroviral medication. They were also asked to give the reasons why the children did not adhere to or missed some doses of antiretroviral medication. The list of these reasons was modified from the Pediatric International Adherence Questionnaire Behavior/ Identification of Pediatric AIDS Clinical Trails Group (PACTG) (1998) that is simple and easy to be used in the clinic. The reasons also reflected behaviors of the caregivers in administering antiretroviral medication.

Factors Influencing Adherence to Antiretroviral Medication in Children with HIV Infection

Child factor

Child's age. Children need less help from others when they get older and can take good care of themselves. Children with HIV infection who are in school age do not need so much physical support but they need more emotional support than infants and toddlers (Caliandro & Hughes, 1998). When children get older, they are more capable to take care of themselves. Arayapitaya (1990) and Ekpho (1991) found that children with thalassemia who were older had more self-care agency than the younger. These study findings were consistent with the self-care concept of Orem (1985) that when the children were older, they would have more development of intelligence, maturity of thoughts, reasons or concrete thinking, ability to evaluate the situation and make decision, and self-responsibility. However, it was not consistent with the findings of Thaiyapirom (1989), Pinsakol (1990), Poomarintra (1992), Jungsomjetpaisan (1994), and Boonyawatanangkool (1998), who reported that children with chronic illness who were older had the same self-care behavior as those who were younger.

For a study in HIV-infected patients who received antiretroviral medication, this is an area of weakness in current literature in which few studies examined the relationship of age to adherence or as predictors of adherence. Belzer et al. (1999) examined the related and predicting factors of adherence to antiretroviral medication in 31 adolescents with HIV infection age 13-24 years. The findings revealed that adolescents who were older perceived the benefits of antiretroviral medication and had good adherence to antiretroviral medication. Therefore, age of children with HIV

infection may have an effect on adherence to antiretroviral medication. Murphy, Durako, Muenz, and Belzer (2001) suggested the need for participants' age to be more effectively incorporated into future models of adherence.

Medication factors

Pill burden. Drug form, dose, and frequency of daily dose are significant to medication adherence in children. In Thailand, we still have to use antiretroviral medication in form of tablet and need to cut it apart or in form of capsule that needs to take the inside medicine out to mix with water for children. Therefore, the form of medication represents an obstacle for administering medication to children. Belzer et. al. (1999), Boni et al. (2000), and Temple et al., (2001) studied medication characteristics and found that medication in tablet form is difficult to swallow and number of tablets are determinant of the problem of medication adherence in children.

Taste. Most children have a hard time in taking antiretroviral medication both in tablet or liquid forms because of bad taste. Since the medications in tablet form have to be ground and mixed with water, they don't completely dissolve and leave a "sandy" feeling in the mouth and throat. These are the obstacles of adherence to antiretroviral medication in children with HIV infection. Goode et al. (2003) found that 44% of children with HIV infection had difficulty in taking antiretroviral medication because of the bad taste of medications. It is consistent with the study of Boni et al. (2000) examining the problems pointed out by parents in administration of antiretroviral medication to 37 children with perinatally acquired HIV infection. The findings revealed that child complains of bad taste was 24%.

Side effect. Each antiretroviral medication may have more or less side effects. The side effects include anemia, neutropenia, muscle weakness, nausea and vomiting, diarrhea, dermatitis, and hepatitis. Although these side effects may be found less in children, they are problems that affect adherence to antiretroviral medication in children with HIV infection (Goode et al., 2003).

Caregivers factors

Social support. Social support represents a significant factor which both directly and indirectly affects health of individuals as well as their behaviors in that the support of others requires interpersonal relationships, thus building a feeling of self-value for personal while motivating them to achieve healthy behavior to maintain

well-being and good health. Social support, therefore, is essential to the health status of individuals. There are several definitions of social support as follows:

Weiss and Longuist (1974) stated that social support referred to social relationship necessary to maintain psychological well-being.

Cobb (1976) defined social support as information leading an individual to believe that he or she is cared for, loved, and esteemed, and is member of a network of mutual obligations.

Kaplan, Cassel, and Gore (1977) noted that person in the network provide relationships. Support provides nourishment to self-esteem, normative affirmation, dependency relatedness, clarification of expectations if needed, and the discharge of disturbing affects.

Kahn (1979) stated that social support is consisted of interpersonal interactions that include the expression of positive affect of one person toward another, the affirmation of another person's behaviors, perception or expressed views, and the giving of symbolic or material aid to another.

Schaefer et al. (1981) defined social support as something that nurtures individuals when they are facing with stress in life.

House (1981) asserted that social support is an interaction among individuals which consists of love, caring, trust, assistance in the form of money or labor, information sharing, and feedback for self-learning and self-assessment.

Thoits (1982) pointed out that social support exists when individuals in a social network receive help in the forms of morale, materials, or information, which enables them to encounter and respond to sickness or stress in a shorter time.

Pender (1987) defined social support as concerning a person's general perception or belief that people in their social network would provide assistance in times of need, or the other hand, received or enacted.

In summary, social support refers to emotional, psychological, material and informational supports that help people live in society.

Types of social support

Weiss and Longuist (1974) categorized social support into 6 types as.

1. Attachment.
2. Social integration.

3. Opportunity for nurturance.

4. Reassurance of worth.

5. A sense of reliable alliance.

6. Obtaining guidance.

Cobb (1976) classified the social support into 3 types as:

1. Emotional support was the information leading an individual to believe that he or she is cared for and loved.

2. Esteem support was the information leading an individual to believe that he or she is esteemed and valued.

3. Social support or network support was the information leading an individual to believe that he or she belongs to a network of communication and mutual obligation.

House (1981) classified social support into 4 types as:

1. Emotional support referred to caring, empathy, love, and trust.

2. Appraisal support referred to affirmation, feedback, and social comparison that created self-confidence.

3. Informational support referred to advice, suggestion, directives, and information that could be used to solve the existing problems.

4. Instrumental support referred to aid in kind of necessary such as finance, labor, time, and services.

Schaefer et al. (1981) categorized social support into 3 types as:

1. Emotional support referred to bonding, warmth, and trust.

2. Informational support was defined as advice on solutions or feedback about behavior or actions of other people.

3. Tangible support referred to the help in the form of materials, money or services.

From these definitions, the investigator applied the social support concepts of Cobb (1976) and Schaefer et al. (1981) that people who received emotional support, informational support, and tangible support would believe that they were loved, cared, honored, and respected. They also felt to be a part of the society that would increase pride of living, good health status and security to be use in the research in which the social support concepts of Cobb (1976) and Schaefer et al. (1981) are used to assist

caregivers for caring children with HIV infection with regard to physical, psychological, emotional and social aspects. Details in each aspect are as follows:

1. Emotional support referred to received of loved, cared for, empathy, praised and encouraged.

2. Esteem support referred to received of respected, and praised in performance.

3. Informational support referred to received of information and advice for problem solving and decision making.

4. Instrumental support referred to received of direct aid in form of materials, finance, and services.

5. Social support or network support referred to received of the sense of being a social member and giving help to each other.

Sources of Social Support

Individuals have an interaction with other people in society all their lives, and the interactions change in accordance with developmental phases or arising situations. These interactions form an interdependent social network which allows individuals to fulfill their daily life duties and face with stress.

Kaplan (1977) identified 3 sources of social support as:

1. Spontaneous or natural supportive system includes direct family members such as grandparents, parents, children, and grandchildren. The latter consists of close person including neighbour, colleagues, and acquaintances.

2. Organized support means group of individuals who gather together to form units, clubs, or associations, which are not those organized by professional healthcare.

3. Professional healthcare workers.

House (1981) categorized groups of people who were the sources of social support into 2 groups according to characteristics of their interaction as follows:

1. Those with no formal relationship refer to individuals who provide help to others who are naturally related, but not related to roles fulfilled in their daily work. These include spouse, relatives or friends.

2. Those with formal relationship refer to individuals who provide help and care to others as required by their line of work or their profession. The help provided is mostly specific such as self-care group support of healthcare team.

Good support from other people in the society such as spouse, relatives, friends, physicians, nurses and other healthcare providers will assist caregivers of children with HIV infection to feel that they are loved, cared, and valued, and that they are a part of family and society. It reduces stress of caregivers and helps them adapt to the existing problems, which can lead to good care for children with HIV infection. There are some studies that support the relationship between social support and caregiver's ability. Patoomwan (1991) studied social support and caregiver's ability in caring for 100 children with lymphoblastic leukemia and found that caregivers with high social support had high ability in caring for the children. Wongchantra (1996) studied about social support and ability of caregivers to provide care for 80 children with brain disorders and found that caregivers who had high social support were able to provide good care for the children. From these research findings, social support may influence ability of caregivers in caring for the dependent.

In summary, social support seems to be a resource that enables caregivers to provide care for the dependent. For children with HIV infection, a significant activity that needs help from caregivers is adherence to antiretroviral medication.

There is no evidence to support a relationship between social support of caregivers and adherence to antiretroviral medication in children with HIV infection. However, there are some studies that indicated that social support of the adults with HIV infection influenced their adherence to antiretroviral medication (Frank, 2002; Gifford et al., 2000; Gordillo et al., 1999; Simoni, Frick, Lockhart, & Liebovitz, 2002). Tulathong (2004) studied the factors influencing adherence to antiretroviral medication in 406 AIDS patients aged 20-28 years. The findings showed that social support had an influence on adherence to antiretroviral medication. Amarapibarn (1993) examined the selective factors related to self-care ability of HIV-infected patients. The sample consisted of 203 HIV- infected patients who were full blown AIDS or had HIV encephalopathy. The research findings revealed that HIV-infected patients who had high social support had high self-care ability. It can be explained that both direct and indirect social supports such as sympathy and advice can affect psychological status of HIV-infected patients and increase their self-esteem, which will motivate them to have better self-care and good adherence to antiretroviral medication.

Knowledge on care of children with HIV infection. Caregiver's knowledge and understanding of use of antiretroviral medication is very important. Before initiation of antiretroviral treatment, caregivers should have knowledge and understanding about AIDS and the use of antiretroviral medication. Avihingsanon (2000) studied problems in using antiretroviral medication in 40 children with HIV infection and found that nonadherence to antiretroviral medication in children was mostly due to caregivers' lack of knowledge about the medications and their benefits. They also forgot to give the medications and did not follow the pharmacists instruction on use of antiretroviral medication.

From the guideline of American Society of Health-System Pharmacists (1997) for preparing and motivating patients and caregivers to follow their pharmacotherapeutic regimens and monitoring plans. The content of education and counseling session may include medication's name, medication's use, expected benefits, medication's route, dosage forms, dosage, administration schedule, action to be taken in case of a missed dose, precautions to be observed during the medication's use, potential common and severe adverse effects that may occur, and action to take if they occur, techniques for self-monitoring of the pharmacotherapy, potential drug-drug or drug-food interactions, instructions for access to a provider, proper storage of the medication, proper disposal of contaminated or discontinued medications.

In Thailand, the guideline of American Society of Health-System Pharmacists (1997) was used in the study of pharmaceutical care service for children with HIV infection who received antiretroviral medication (Avihingsanon, 2000). It was a practice guideline used to educate and counsel 40 caregivers who provided care for children with HIV infection treated with antiretroviral medication. The study findings showed a decrease in problems of children receiving lower dose and not following an advice when using this practice guideline.

From international studies, Berrien et al. (2004) investigated the effect of home-based nursing intervention in caregivers of children with HIV infection. Children with HIV infection and their caregivers can improve medication adherence if they better understand HIV infection and use of antiretroviral medication. It is not consistent with the study of Nicholson, Mellins, Dolzal, Brackis-Cott, and Abrams (2005) who found that higher caregiver's knowledge was not associated with caregiver

reports of medication adherence. It indicated that knowledge of caregivers about HIV infection and the use of antiretroviral medication in children might not assure good adherence to antiretroviral medication.

Ability of caregiver in administering antiretroviral medication. Caregivers of children with HIV infection need to have specific ability in caring and helping the children to adhere to antiretroviral medication. Consequently, managing adherence to antiretroviral medication in children invades private time and disturbs the daily activities of caregivers which may make them feel uncomfortable with administering antiretroviral medication to children in public (Ammassari et al., 2001; Gibb et al., 1999).

Caregivers who are able to solve problems of adherence to antiretroviral medication can help the children to maintain good level of medication adherence. It is consistent with the study of Hammami et al. (2004) by interviewing caregivers regarding their capability in administering antiretroviral medication to children with HIV infection. The findings indicated that children with good adherence to antiretroviral medication were under care of caregivers who had skills in administering antiretroviral medication. Caregivers' ability in managing antiretroviral medication in children is complicated because children are unable to take antiretroviral medication on their own and maintain medication adherence. This responsibility, therefore, must be counted as one of daily activity of both caregivers and children. In the future, these children will learn from the caregiver's behavior and be able to manage antiretroviral medication by themselves.

Ability is human powers depended on various factors such as physical, psychological, emotional, situational, and environmental factors. To provide care for the dependent, caregivers must use the complicated ability to provide necessary dependent-care activities in the face of health defects.

The structure of dependent-care agency is in the process of formalization. Like self-care agency, its broad conceptual structure is formed by capabilities to meet the therapeutic self-care demand of another by specific power component (Orem et al., 2001, p. 285). The structure of the concept was formalized as a three-parts structure (Gast, Denyes, Campbell, Hartweg, Schott-Bear, & Isenberg, 1989).

1. Capabilities for dependent-care operations is an immediate necessary ability for dependent that includes:

1.1 Estimative operations, investigating, conditions, and factors in self and environment that are significant for one's dependent-care.

1.2 Transitional operations, making judgments and decisions about what one can, should, and will do to meet one's dependent care requisites.

1.3 Productive operations, performing measures to meet one's dependent-care requisites.

2. Ten power components: Enabling capabilities for dependent care would be of a nature intermediate between the human functioning and human dispositions as described in the survey list and the estimative, transitional, and production dependent-care operations. Ten power components are:

2.1 Ability to maintain attention and exercise requisite vigilance with respect to self as dependent-care agent and internal and external conditions and factors significant for dependent-care.

2.2 Controlled use of available physical energy that is sufficient for the initiation and continuation of dependent-care operations.

2.3 Ability to control the position of body and its part in the execution of the movements required for the initiation and completion of dependent-care operations.

2.4 Ability to reason within a dependent-care frame of reference.

2.5 Motivation to provide dependent-care. The objectives of dependent-care that are consistent with characters and definitions of reasons, quality and security by caregivers provide constancy of dependent care for prolonged living with their love ones.

2.6 Ability to make decisions about dependent care and to operationalize these decisions.

2.7 Ability to acquire technical knowledge about dependent care from authoritative sources, to retain it, and to operationalize it.

2.8 A repertoire of cognitive, perceptual, manipulative, communication, and interpersonal skills adapted to the performance dependent-care operations.

2.9 Ability to order discrete dependent-care action or action system into relationships with prior and subsequent action toward the final achievement of regulatory goal of dependent-care.

2.10 Ability to consistently perform dependent-care operations, integrating them with relevant aspect of personal, family, and community living.

3. Foundation capabilities and dispositions are necessary ability for specific activity with general deliberate action as:

3.1 Capabilities to perception and action.

3.2 Qualifications or factors influencing to seek for deliberate actions. Foundation capabilities and dispositions include:

3.2.1 Learning and doing capabilities include memory, learned skill to read, write, count, and rational agency.

3.2.2 Sensation and motor neurologic function include touching, visual, hearing, smelling and tasting.

3.2.3 Perception on intrinsic and extrinsic events.

3.2.4 Self-value

3.2.5 Self-habit

3.2.6 Intention

3.2.7 Self-understanding

3.2.8 Self-concern

3.2.9 Self-acceptance

3.2.10 Prioritization and time management

Orem and Taylor (1986) viewed ten power components as a nature intermediate between foundation capabilities and dispositions, and self-care operations. In addition, Gast et al. (1989) analyzed the structure of self-care agency, a key concept in Orem's model of nursing. It means that the foundation capabilities and dispositions will consist of 10 power components. The ten power components will also be a foundation of capabilities for self -care operations (see Figure 2).

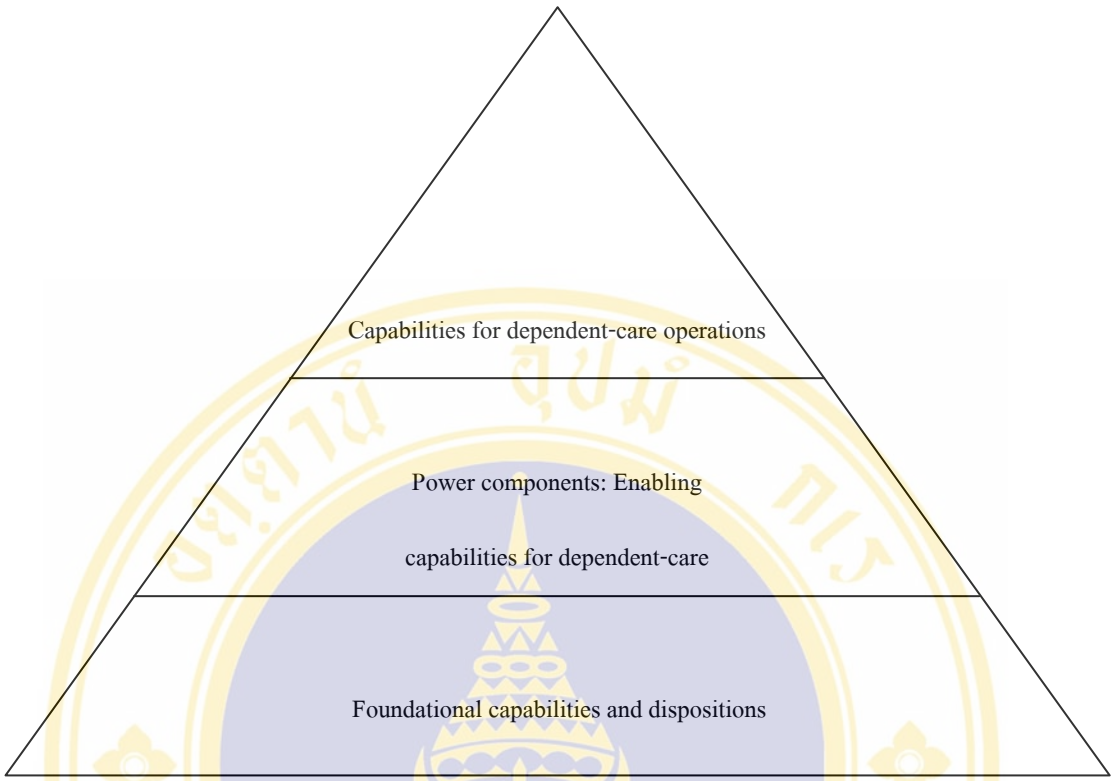


Figure 2 Structure of Self-care Capabilities.
(Gast et al., 1989)

Measurement of capabilities for dependent-care agency

The definitions of capabilities for dependent-care agency are like those of self-care agency. To assess capabilities for dependent-care agency, some researchers applied the concept of capabilities for self-care agency. (Patoomwan, 1991; Puangchan, 1995; Somnarin, 1995; Boonyaleephan et al., 2000; Khueanman, 2002). Measurement of self-care capabilities can be done by two types of instruments as follows:

1. To measure capabilities for self-care operations.

1.1 Two instruments were developed to measure capabilities for self-care operations. Kearny's and Fleischer's instrument, the Exercise of Self-Care Agency represented the first operational measure of self-care agency (Kearny & Fleischer, 1979 cited in Hanucharurnkul, 1993). Another instrument developed by Evers et al., the Appraisal of Self-Care Agency Scale, was the second operational measure of self-care agency (Evers et al., 1985 cited in Hanucharurnkul, 1993).

Keaney and Fleischer (1979 cited in Gast et al., 1989) believed that there may be people who have self-care agency but are incapable of the excise of self-care agency. The concept of excise of self-care agency is somewhat ambiguous. The content of questions aim to evaluating excise of self-care agency but the items considers of foundational capabilities. Riesch and Hauck (1988) stated that after using the instrument, the study findings failed to identify all factors with regard to the analysis of self-care agency.

Evers et al. (1985 cited in Hanucharurnkul, 1993) established the Appraisal of Self-Care Agency Scale: Form A with the objectives to measure self-care operations for serving the self-care needs of regular people, but the form needs to be adjusted to fit sickness and treatment. Orem (1985 cited in Kositthapiwat, 2000) stated that by this instrument, they were able to show the activation of power and the engagement in self-care operations. The answer of each question is to select whether they use the capabilities for self-care or not. This instrument can be used to measure the self-care capabilities because it has no limitation with regard to specific diseases. Hanucharurnkul (1993) translated this scale into Thai version and modified it to suit for cancer patients and then used it with 60 cancer patients who received radiation therapy. The finding showed that the sample had high scores of self-care capability. This instrument has been further modified for use in various groups. Puangchan (1995) modified the appraisal of self-care agency scale of Evers et al. (1985) to study the correlation among basic factors, effects of chronic illness on family, and capability of mothers to take care of children with chronic disease. The sample consisted of 120 mothers of children with chronic disease. The findings revealed that the capability of mothers in caring children with chronic disease was high. The reliability of the questionnaire with Alpha coefficient was 0.66.

2. To measure power of capabilities for self-care agency

2.1 The self-care agency scale in term of measuring capability with the instrument developed by Denyes (1981 cited in Hanucharurnkul, 1993) based on the power component analysis of self-care agency in keeping with the early work of Orem. Denyes compared the components of self-care capability according to his instrument which consisted of 7 capability power components.

Hanson and Bickel (1985 cited in Hanucharurnkul, 1993) developed an instrument to measure self-care agency based on the power components in keeping with the early work of Orem. This scale was tested on healthy adults. However, it was found that this instrument could measure only 8 components of the 10 power components. Weaver (1987 cited in Gast et al., 1989) tested a construction validity of instrument in which it was found that not all the construction of power of capabilities for self-care agency, which were matched with the 8 components of Hanson and Brickle, could be explained. In summary, the instrument has indistinct of construct validity.

In Thailand, Patoomwan (1991) conducted a study in caregivers who provided care for 100 children with acute lymphoplastic leukemia by using the questionnaire on dependent-care agency of Denyes and Fildey that used the Orem's conceptual framework. This study was aimed to study basic factors, social support, and capability of caregivers. The finding showed that caregivers had high dependent-care agency and the reliability of the questionnaire with Alpha coefficient was 0.89.

Somnarin (1995) modified the Denyes and Fildey Dependent-care Agency Instrument to 34 items to measure power of dependent-care agency of 160 caregivers who were taking care of AIDS patients. This study was to determine the relationship between anxiety, basic conditioning factors and dependent-care agency of the caregivers. The findings revealed that the caregivers had high dependent-care agency and the reliability of the questionnaire with Cronbach's Alpha coefficient was 0.90.

Boonyaleephan et al. (2000) developed the questionnaire to measure dependent-care agency in HIV-infected patients based on Orem's self-care deficit theory. The samples in this study were 364 caregivers who provided care for dependent HIV-infected patients. The study findings showed that dependent care agency of caregivers was at high level and the reliability of the questionnaire with Cronbach's Alpha coefficient was 0.85.

Khueanman (2002) developed the Dependent-Care Agency Questionnaire based on Orem's concept of self-care agency. The dependent-dare agency scale consisting of 30 items was used with 72 mothers who cared for autistic children. The research findings revealed that the mothers of children with autistic had high dependent-care agency with the content validity index of the questionnaire (CVI) was

0.87 and the reliability of the questionnaire with Cronbach's Alpha coefficient was 0.84.

For this study, the investigator applied the concept of the dependent-care agency based on 10 power components to develop the Caregiver Ability in Administering Antiretroviral Medication Questionnaire. This questionnaire consisted of 10 power components to motivate caregivers to perform specific activities and a nature intermediate awareness leading to specific action for dependent care.

In conclusion, children with HIV infection have inadequate capability for self-care regarding the management of antiretroviral medications. Therefore, they have to depend on the care of caregivers who may not be their parents or relatives. From the literature review, it can be concluded that effective caregivers receive social supports including emotional support, esteem support, informational support, and instrumental support which will lead to the feeling of being a part of society. All of the above mentioned supports help caregivers to gain understanding and knowledge concerning the care of children with HIV infection. In this way, they can develop their ability and skill to cope with existing problems of medication management such as right doses, right times, and maintain adherence to antiretroviral medication.

CHAPTER III
METHODOLOGY

Research Design

This was a descriptive research that aimed to investigate the factors influencing adherence to antiretroviral medication in children with HIV infection, who received health care services at Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute, Nonthaburi province.

Population and Sampling

Population

The population of this study was caregivers of children with HIV infection aged < 13 years who received antiretroviral medication and health care services at Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute, Nonthaburi province. The caregivers were aware of children's HIV infection and were responsible for administering the antiretroviral medication. They were able to read and understand Thai.

Sample

The sample of this study consisted of 110 primary caregivers of children with HIV infection aged < 13 years who received antiretroviral medication for treatment. Convenience sampling was used to select the sample at Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute, Nonthaburi province with an inclusion criterion that both primary caregivers and children lived in the same house and caregivers were responsible for administering antiretroviral medication for more than 1 month. The children with HIV infection who received antiretroviral medication for prevention of mother-to-child transmission were excluded from the study.

To determine a sample size that was good representative of the population, power analysis for multiple regression (Polit & Beck, 2004) was applied by using α = .05, power = .80 and coefficient of effect size as medium, as follows:

$$N = \frac{L + k + 1}{\gamma}$$

N estimated number of subjects needed

L tabled value for the desired and power analysis (Polit & Beck, 2004: 522). In this study, $\alpha = .05$, power analysis = .80, and L (from the table) = 14.35.

k number of predictors (= 7)

γ estimated effect size between independent variable and dependent variable that can calculate from the following formula:

$$\gamma = \frac{R^2}{1-R^2}$$

R^2 refers to coefficient of effect size that comes from previous studies as the medium coefficient = .13 (Mellins et. al., 2004). The outcome is:

$$= \frac{.13}{1-.13}$$

$$= .15$$

Apply .15 in the formula to compute the sample size as follows:

$$= \frac{14.35}{.15} + 7 + 1$$

$$= 103.60$$

Thus, the estimated sample size was equal to 105 subjects. It was then calculated additionally 10% for possible subjects (R = 0.10) (Udomphanturak, Lerdautkayom, & Santhawat, 2000).

$$\text{n (additionally)} = \frac{n}{(1-R)}$$

$$= \frac{105}{(1-0.10)}$$

$$= 116.60$$

Although the estimated sample size was about 117 subjects, the researcher was able to recruit only 110 subjects who met the inclusion criteria and were willing to participate in the study.

Setting

The setting for this study was Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute, Nonthaburi province. Bamrasnaradura Infectious Disease Institute was a 600-bed specialized hospital that provided health care services and treatment for adults and children with HIV infection including antiretroviral treatment. The service hours of the pediatric infectious clinic were Monday at 13.00-16.00 hours and Wednesday at 08.30-12.00 hours. There were about 202 children with HIV infection who came to the clinic for antiretroviral medication (Bamrasnaradura Infectious Disease Institute, 2005). At this clinic, activities to increase knowledge and skills of caregivers of children with HIV infection included health education, health counseling, and telephone support. In health education session, a nurse counselor provided information about antiretroviral treatment, including significant of medication adherence, how to take antiretroviral medication correctly and regularly, and observation of side effects. At each follow up visit, the nurse counselor also monitored medication adherence by pill counts and asking the caregivers about problem in administering antiretroviral medication. The caregivers could call and ask for help from the nurse counselor at any time if the children had problem with antiretroviral medication. The nurse counselor would call the caregivers if the children lost follow up.

Instruments

The research instruments of this study consisted of 4 interviews and 2 questionnaires that were used with caregivers. They were separated into 6 sections as follows:

Section I: Demographic Characteristics Interview included 2 components:

1. Demographic characteristics of children: sex, present age, age at diagnosis, and immune category.

2. Demographic characteristics of caregivers: sex, age, marital status, occupation, education, relationship with children, duration of caregiving, types of family, number of family members, individual awareness of children's HIV infection, and family income.

Section II: Antiretroviral Treatment Interview comprised age at initiation of antiretroviral treatment, discontinuation of antiretroviral treatment, family assistance with medication administration, pill burden (item 4), taste (item 5) and side effects (item 6).

Total score of pill burden was calculated from the following formula:

1. Pill burden = $(a_1 \times b_1) + (a_2 \times b_2) + \ldots\ldots\ldots\ldots + (a_n \times b_n)$

a_1 = number of tablet/spoon of the 1st medication the child had to take.

b_1 = number of daily dose of the 1st medication the child had to take.

a_2 = number of tablet/spoon of the 2nd medication the child had to take.

b_1 = number of daily dose of the 2nd medication the child had to take.

a_n = number of tablet/spoon of the n medication the child had to take.

b_n = number of daily dose of the n medication the child had to take.

High total score meaned high pill burden.

2. Score of taste was a total score of difficulty or ease in taking all antiretroviral medications by children with HIV infection. The criteria for scoring were as follows:

Easy-taking medication = 0 score X number of medications

Difficult-taking medication = 1 score X number of medications

High total score meaned very bad taste of medications.

3. Score of side effects was a total score of side effects with the following scoring:

No side effect = 0 score

Have side effect = 1 score

High total score meaned having more side effects.

Section III: Adherence to Antiretroviral Medication Interview for caregivers of children with HIV infection. This interview was modified by the investigator from Visual Analog Scale of Maneesriwongkul and Williams (2004) and Pediatric International Adherence Questionnaire Behavior/Identification of Pediatric AIDS Clinical Trials Group (PACTG) (1998). It consisted of 2 components:

1. Percent of adherence to antiretroviral medications was based on caregivers' report. Caregivers were asked to mark on a straight line and indicate how many percentage the children took the antiretroviral medication correctly and regularly

in the past 30 days. Percents of adherence to each antiretroviral medication reported by the caregivers were used to calculate the average percent of adherence which showed the children's overall adherence to the medication. For the purpose of this study, a cut-off point of adherence ≥ 95 % was used to classify good adherence to antiretroviral medication (Parterson et al., 2000).

2. Reasons for nonadherence to antiretroviral medication. Caregivers were asked to check on list of the reasons why the children missed some doses of antiretroviral medication in the past 30 days (21 items).

Section IV: Caregiver Social Support Interview. This interview was modified from the Social Support Interview for mothers with HIV infection, which was developed by Kittithongsopon (1998) based on the concept of social support defined by Cobb (1976) combining with the social support concept of Schaefer et al. (1981). The investigator modified the original items so that they were appropriate to be used with caregivers of children with HIV infection. This interview assessed the social support of caregivers in 5 aspects. The caregivers were asked to indicate how much support they received from other people in the following types of support:

1. Emotional support	Items 1-4
2. Esteem support	Items 5-8
3. Informational support	Items 9-12
4. Instrumental support	Items 13-16
5. Network support	

Items 17-20

All 20 items were positive statements with 5-level rating scale.

Criteria for scoring:

A great deal	=	5 score
Quite a bit	=	4 score
Moderate	=	3 score
A little	=	2 score
Not at all	=	1 score

Score of social support was a total score of all items of the interview, ranging from 20-100 scores. High score meaned receiving more social support.

Section V: Caregiver Ability in Administering Antiretroviral Medication Questionnaire. The investigator developed this questionnaire from the relevant literature and based on the concept of dependent care agency of Orem (2001). The 20-items questionnaire with 5-level rating scale was used to assess the ability of caregivers in 10 aspects as follows:

1. Ability to maintain attention and care for the dependent	Items 1-2
2. Ability to self-controlled use of available physical energy	Items 3-4
3. Ability to control the position of the body	Item 5
4. Ability to reason within a dependent-care frame of reference	Items 6-7
5. Motivation to care for the dependent	Items 8-9
6. Ability to make decisions about care for the dependent and successful implementation	Item 10
7. Ability to acquire technical knowledge about care for the dependent	Items 11-12
8. A repertoire of cognitive, perceptual, manipulative, communication, and interpersonal skill adapted to the performance of dependent-care operation.	Item 13
9. Ability to order discrete dependent-care action.	Items 14-16
10. Ability to consistently perform dependent-care operations, and integrating them with relevant aspects of lifestyle.	Items 17-20

There were 2 types of statements in the questionnaire. Eleven positive statements include items 1, 3, 7, 9, 10, 12, 13, 14, 16, 19, and 20. Nine negative were items 2, 4, 5, 6, 8, 11, 15, 17, and 18.

Criteria for scoring:

Positive statement	Score
Always like me	5
Usually like me	4
Moderately like me	3
Slightly like me	2
Never like me	1

Negative statement

Always like me	1
Usually like me	2
Moderately like me	3
Slightly like me	4
Never like me	5

Score of caregiver ability in administering antiretroviral medication was a total score of all items of the interview, ranging from 20-100 scores. High scores meaned that caregivers had high ability in administering antiretroviral medication.

Section VI: Caregiver Knowledge on Care of Children with HIV Infection Questionnaire. It assessed caregivers' knowledge and understanding of HIV infection in children, and administration and side effects of antiretroviral medication in children. The investigator developed the questionnaire from literature review and the education and counseling guidelines of American Society of Health-System Pharmacists (ASHP) (1997). It contained 20 questions separated into 3 parts:

1. Knowledge on HIV infection in children Questions 1-5
2. Knowledge on antiretroviral medication in children Questions 6-16
3. Knowledge on side effects of antiretroviral medication in children with HIV infection Questions 17-20

There were 13 positive questions that required a correct answer as "Yes". They included questions 1, 2, 5, 6, 7, 8, 9, 12, 13, 16, 17, 19, and 20. The other 7 negative questions that required a correct answer as "No" included questions 3, 4, 10, 11, 14, 15, and 18.

Criteria for scoring:

If the answer is correct, the score is 1.

If the answer is incorrect, the score is 0.

Score of caregiver knowledge on care of children with HIV infection was a total score of all questions of the questionnaire, ranging from 0-20 scores. High scores meaned that caregivers had high knowledge on care of children with HIV infection.

Validity and Reliability

1. Validity. Six validators were asked to assure the content validity of the research instruments, which included: Demographic Characteristics Interview, Antiretroviral Treatment Interview, Adherence to Antiretroviral Medication Interview,

Caregiver Social Support Interview, Caregiver Ability in Administering Antiretroviral Medication Questionnaire, Caregiver Knowledge on Care of Children with HIV infection Questionnaire. The validators also considered the research objectives, appropriate content and language used. Name list of content validators was in Appendix A. They were:

Pediatricians	2 persons
Nursing instructor	1 person
Registered nurse	1 person
Pharmacist	1 person
Psychologist	1 person

After the content validators had reviewed the instruments, the investigator modified items of the questionnaires and the interviews according to their comments and suggestions.

2. Reliability. The investigator used the interviews and questionnaires with 30 caregivers of children with HIV infection who had similar characteristic as those in the study sample. The reliability of both the interviews and questionnaires were calculated as follows:

2.1 Cronbach Alpha coefficient was used for calculation of reliability of Caregiver Ability in Administering Antiretroviral Medication Questionnaire and Caregiver Social Support Interview. The reliabilities were 0.74 and 0.78 respectively.

2.2 Kuder-Richardson formula (Kitpreedaborisood, 2002) was used for calculation of reliability of Caregiver Knowledge on Care of Children with HIV Infection Questionnaire. The reliability was 0.61.

Data Collection

After the proposal of this study was approved by the Committee on Human Rights Related to Human Experimentation, Mahidol University and the Ethical Committee at the Bamrasnaradura Infectious Disease Institute, data were collected by the investigator with the following procedure:

1. A formal letter from Faculty of Graduate Studies, Mahidol University was submitted to the Director of Bamrasnaradura Infectious Disease Institute for a

permission to collect data at the Pediatric Infectious Clinic every Monday at 13.00-16.00 hours and Wednesday at 8.30-12.00 hours.

2. After getting the permission, the investigator met a nurse director of the outpatient department and a head nurse of the Pediatric Infectious Clinic to inform about the research objectives and explain about data collection process.

3. While potential participants were waiting to meet or had already met a physician, the investigator asked a nurse who worked at the clinic to ask caregivers if they were interested in participating in the study. If they are interested in participating, the investigator explained the details of the study and asked for their decision to participate in the study. The investigator acknowledged that the caregivers could stop giving information or withdraw from the study at anytime.

4. After the caregivers signed a consent form, they were invited into a private area. The investigator interviewed them using Demographic Characteristics Interview, Antiretroviral Treatment Interview, Adherence to Antiretroviral Medication Interview, and Caregiver Social Support Interview. The investigator read each question and asked the caregivers to give their response and then recorded it.

5. The investigator explained how to answer the questionnaire and asked the caregivers to respond to all questions by themselves. Caregiver Ability in Administering Antiretroviral Medication Questionnaire was first distributed. For caregivers who had difficulty in answering the questionnaire, the investigator would read it and asked the caregivers to respond to each item until completion. The answers were recorded on the questionnaire.

6. The next questionnaire to be distributed was the Caregiver Knowledge on Care of Children with HIV Infection Questionnaire. The caregivers were also asked to answer all questions by themselves. For caregivers who had difficulty in answering the questionnaire, the investigator would read it and asked the caregivers to respond to each item until completion. The answers were recorded on the questionnaire.

7. The investigator checked to see if the data collected from all interviews and questionnaires were completed.

8. The investigator might explain and give some information to the caregivers if they had any inaccurate information or misunderstanding about care of children with HIV infection.

9. The investigator collected information about the latest laboratory finding of CD4 and lymphocyte from the children's medical record.

10. All data from the interviews and questionnaires were analyzed by computer with appropriate software.

Protection of Human Subjects

1. The study proposal was submitted to the Committee on Human Rights Related to Human Experimentation, Mahidol University and revised according to the committee's comments and suggestions.

2. The study proposal was submitted to the Ethical Committee at the Bamrasnaradura Infectious Disease Institute and revised according to the committee's comments and suggestions.

3. After receiving the permission to collect data, the investigator started to recruit the sample by explaining the details of this study and rights of the participants. Caregivers were invited to join the study by giving freedom to make their decision. They were assured that the collected data would be kept confidential and reported as a group. There is no identification of the participant in the data. The participants have rights to withdraw from the study at any time without any impact on the treatment, care, and services their children were receiving. They could also ask any questions that they had.

4. After the participants read the information sheet (Appendix C) and decided to participate in the study, they were asked to sign the consent form (Appendix C).

Data Analysis

Personal computer (PC) and software were used for data analysis with the statistic level of significance at .05. The steps of analysis were as follows:

1. Descriptive statistics including frequency, percentage, mean and standard deviation were used to analyze demographic data of caregivers and children, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, caregiver ability in administering antiretroviral medication, and adherence to antiretroviral medication.

2. Testing assumptions of multiple regression analysis. The assumptions that were tested included normal distribution, homoscedasticity, and multicollinearity.

2.1 Normal distribution. One-Sample Kolmogorov-Smirnov Test indicated that pill burden, taste, side effects, and adherence to antiretroviral medication were not normally distributed. Histogram (Appendix E) also showed that dependent variable, adherence to antiretroviral medication, was not normally distributed and outlier (1 case) was identified as distinctly different from other observations (see details in Appendix E). This outlier was excluded from multiple regression analysis.

2.2 Homoscedasticity. Scatter plot (Appendix E) showed that the constancy of the residuals across values of the independent variables were spread at zero area, which indicated homoscedasticity in the multivariate case.

2.3 Multicollinearity. The pearson's product moment correlation was performed to examine the relationships among independent variables. The result of the analysis revealed that the highest correlation coefficient among the independent variables was 0.40. In addition, collinearity statistics showed that tolerance was nearly 1 (0.77 to 0.95, Appendix E). Multicollinearity was not a problem in this study.

3. Pearson's product moment correlation coefficient was used to generate correlation coefficient among 8 variables, which included child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, caregiver ability in administering antiretroviral medication, and adherence to antiretroviral medication.

4. Multiple Regression Analysis (Hierarchical method) was used with regard to the study conceptual framework to investigate which independent variables were able to predict adherence to antiretroviral medication in children with HIV infection. The independent variables were entered into the analysis as follows:

Step 1 Child's age.

Step 2 Pill burden, taste, side effects.

Step 3 Caregiver social support.
Caregiver knowledge on care of children with HIV infection.
Caregiver ability in administering antiretroviral medication.

CHAPTER IV
RESULTS

This study was conducted to examine the factors influencing adherence to antiretroviral medication in children with HIV infection. The sample was 110 caregivers of children with HIV infection who came for a follow up visit at the Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute. Data were collected from November 2005 to February 2006. The study findings were presented in 6 parts as follows:

Part 1. Demographic characteristics

1.1 Demographic characteristics of caregivers

1.2 Demographic characteristics of children with HIV infection

Part 2. Treatment and medication characteristics

2.1 Treatment characteristics

2.2 Pill burden, taste, side effects

Part 3. Caregiver factors

Part 4. Adherence to antiretroviral medication in children with HIV infection

Part 5. Correlation between child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, caregiver ability in administering antiretroviral medication

Part 6. Hierarchical multiple regression analysis predicting adherence to antiretroviral medication in children with HIV infection

Part 1. Demographic characteristics

1.1 Demographic characteristics of caregivers

Table 5 Demographic Characteristics of Caregivers (N = 110)

Caregivers' characteristics	Number	Percentage
Age (years)		
20-40	65	59.10
41-60	34	30.90
61- 77	11	10 .00
(Range = 20 -77, Mean = 42.14, SD = 12.92)		
Sex		
Male	25	22.70
Female	85	77.30
Marital status		
Single	15	13.60
Married	55	50.00
Widowed/ divorced/ separated	40	36.40
Education		
No	4	3.60
Primary	53	48.20
Secondary	25	22.70
Diploma/ vocational	18	16.40
Bachelor's degree and higher	10	9.10

Table 5 Demographic Characteristics of Caregivers (N = 110) (Continued)

Caregiver's characteristics	Number	Percentage
Occupation		
Civil service/ State enterprise	7	6.40
Employee	41	37.30
Agriculturist	3	2.70
Merchants and private business	31	28.20
Housewife/ No work	28	25.40
Family income (bahts /month)		
500 - 10,000	79	71.90
10,001-50,000	27	24.50
50,001-100,000	2	1.80
100,000 -150,000	2	1.80
(Range = 500- 150,000, Mean = 12,899.32, SD = 23,711.51)		
Type of family		
Nuclear	55	50.00
Extended	55	50.00
Caregiver-child relationship		
Parents	55	50.00
Grandparents	27	24.60
Relatives	24	21.80
Other	4	3.60

Table 5 Demographic Characteristics of Caregivers (N = 110) (Continued)

Caregiver's characteristics	**Number**	**Percentage**
Duration of caregiving (years)		
1- 6	47	42.70
7- 13	63	57.30
(Range = 1-13, Mean = 7.18, SD = 2.81)		

Table 5 showed that most of the caregivers were 20-40 years old (59.10 %), were female (77.30 %), had family income ≤ 10,000 bahts/month (71.90 %), and took care of the children for 7 to13 years (57.30%). About half of the sample were married (50%), had primary education (48.20%), lived in nuclear family (50%), and were parents of the children (50%). About 37.30% of the sample were employees.

1.2 Demographic characteristics of children with HIV infection

Table 6 Demographic Characteristics of Children (N = 110)

Children's characteristics	**Number**	**Percentage**
Age (years)		
2 - 6	21	19.10
7 - 13	89	80.90
(Range = 2-13, Mean = 8.79, SD = 2.74)		
Sex		
Male	61	55.50
Female	49	44.50
Immune category (CD4 percentage)		
No suppression (≥ 25%)	38	34.50
Moderate suppression (15-24%)	40	36.40
Severe suppression (< 15%)	32	29.10

Table 6 showed that most of the children were 7-13 years old (80.90 %), were male (55.50%), and had moderate immune suppression (36.40%).

Part 2. Treatment and medication characteristics

2.1 Treatment characteristics

Table 7 Treatment Characteristics (N = 110)

Characteristics	Number	Percentage
Duration of antiretroviral treatment (years)		
≤ 5	58	52.70
6-12	52	47.30
(Range = 1 month – 12 years, Mean = 4.88, SD = 2.90)		
Discontinuation of antiretroviral treatment		
No	97	88.20
Yes	13	11.80
Family assistance with medication administration		
No	40	36.40
Yes	70	63.60
Medication form		
Only pill	86	78.20
Only liquid	9	8.20
Both	15	13.60
Taste		
No difficulty	99	90.00
Difficulty with one medication	6	5.50
Difficulty with two medications	3	2.70
Difficulty with three medications	2	1.80

Table 7 Treatment Characteristics (N = 110) (Continued)

Characteristics	Number	Percentage
Side effects		
0	79	71.80
1	18	16.40
2-5	13	11.80

Table 7 showed that most of the children received antiretroviral treatment less than or about 5 years (52.70%). Most of the caregivers reported that the children never discontinued antiretroviral treatment (88.20%), whereas 11.80% of the children discontinued antiretroviral treatment which caregivers reported that duration of discontinuation of antiretroviral treatment ranged from 1 week to 6 years and the reasons for discontinuation were due to lack of family assistance with medication administration, lack of money, child's illness, child's refusal to take medicine, and child's moving to another country. Most of the caregivers received family assistance in administering antiretroviral medication (63.60%). Most of the children received only pill of antiretroviral medication (78.20%), had no difficulty in taking antiretroviral medication (90%), and had no side effects (71.80%).

2.2 Pill burden, taste, side effects

Table 8 Range, Mean, and Standard Deviation of Pill burden, Taste, and Side effects Scores (N=110)

Variable	Range	M	SD
Pill burden	0.5- 13	5.20	3.10
Taste	0-3	0.16	0.55
Side effects	0-5	0.48	0.95

Table 8 showed that scores of pill burden reported by the caregivers ranged from 0.5-13 with a mean score of 5.20 (SD = 3.10), which indicated that pill burden was low. Scores of taste reported by the caregivers ranged from 0-3 with a mean score of 0.16 (SD = 0.55), which indicated that antiretroviral medication was easy to take. Scores of side effects reported by the caregivers ranged from 0-5 with a mean score of 0.48 (SD = 0.95), which indicated that the children had less side effects.

Part 3. Caregiver factors

Table 9 Range, Mean, and Standard Deviation of Caregiver Social Support, Caregiver Knowledge on Care of Children with HIV Infection, and Caregiver Ability in Administering Antiretroviral Medication (N=110)

Variable	Possible range	Actual range	M	SD
Caregiver social support				
Emotional support	4-20	4-20	14.87	3.67
Esteem support	4-20	8-20	16.25	2.94
Informational support	4-20	8-20	16.57	2.80
Instrumental support	4-20	4-20	11.57	4.22
Network support	4-20	4-20	12.75	3.47
Overall social support	**20-100**	**44-98**	**72.03**	**11.69**
Caregiver knowledge on care of children with HIV infection	**0-20**	**7-20**	**15.92**	**2.86**
Caregiver ability in administering antiretroviral medication	**20-100**	**59-100**	**87.85**	**7.92**

Table 9 showed that overall mean of caregiver social support was high (Mean = 72.03, SD = 11.69). When considering each subscale, mean score of informational support was the highest (Mean = 16.57, SD = 2.80), while mean score of instrumental support was the lowest (Mean = 11.57, SD= 4.22). Scores of caregiver knowledge on care of children with HIV infection ranged from 7 to 20 with a mean of 15.92 (SD= 2.86), which indicated that caregivers had good knowledge on care of children with HIV infection. Caregiver ability in administering antiretroviral

medication ranged from 59 to 100 with a mean score of 87.85 (SD= 7.92), which indicated that caregivers had high ability in administering antiretroviral medication.

Part 4 Adherence to antiretroviral medication in children with HIV Infection

Table 10 Frequency and Percentage of Children Classified by Level of Adherence to Antiretroviral Medication in Children with HIV Infection (N=110)

Medication adherence	**N**	**%**
≥ 95% (Good)	85	77.30
< 95% (Poor)	25	22.70
(Range= 0-100, Mean = 94.92, SD= 12.51)		

Table 10 showed that scores of children's medication adherence reported by the caregivers ranged from 0 to 100 with a mean score of 94.92 (SD= 12.51). The majority of the children (77.30%) had good adherence to antiretroviral medication (≥ 95%).

Part 5. Correlations Between Child's age, Pill burden, Taste, Side effects, Caregiver Social Support, Caregiver Knowledge on Care of Children with HIV Infection, and Caregiver Ability in Administering Antiretroviral Medication

Table 11 Intercorrelations, Means, and Standard Deviations for Studied Variables with Adherence to Antiretroviral Medication in Children with HIV Infection (Correlation matrix) (N=109)

Variable	1	2	3	4	5	6	7
1. Child's age	1.00						
2. Pill burden	.18	1.00					
3. Taste	.03	.18	1.00				
4. Side effects	.09	.23*	.08	1.00			
5. Social support	-.01	- .02	- .16	-.20*	1.00		
6. Knowledge	.07	.01	.08	.33**	- .06	1.00	
7. Ability	-.07	-.02	- .40**	.09	.12	.21*	1.00
Y Adherence to ARV	**.01**	**- .08**	**- . 37****	**.04**	**.02**	**.08**	**.24***
M	**8.79**	**5.20**	**.16**	**. 48**	**72.03**	**15.92**	**87.85**
SD	**2.74**	**3.10**	**. 55**	**. 95**	**11.69**	**2.86**	**7.92**

* p< .05 ** p< .01

Correlations between independent variables and adherence to antiretroviral medication in children with HIV infection were tested prior to multiple regression analysis. It was revealed in a bivariate analysis that taste was negatively and mildly correlated with adherence to antiretroviral medication in children with HIV infection (r = - 0.37, p< .01), which indicated that when children had no difficulty in taking antiretroviral medication, adherence to antiretroviral medication was good. Caregiver ability in administering antiretroviral medication was positively and mildly correlated

with adherence to antiretroviral medication in children with HIV infection ($r = 0.24$, $p < .05$), which indicated that when caregiver of children with HIV infection had high ability in administering antiretroviral medication, adherence to antiretroviral medication was good. Results in table 11 showed that these correlations among all independent factors were mild (ranged from 0.01 to -0.40). All independent variables were entered in the hierachical multiple regression analysis based on the conceptual framework of the study.

Part 6. Hierarchical Multiple Regression Analysis Predicting Adherence to Antiretroviral Medication in Children with HIV Infection

Table 12 Hierarchical Multiple Regression Analysis Predicting Adherence to Antiretroviral Medication in Children with HIV Infection (N = 109)

Model and Predictor variable	R^2	R^2 change	F change	F overall	Beta
Model 1.	.00	.00	.00	.00	
Child's age					.01
Model 2.	.14	.14	5.82	4.37**	
Child's age					.02
Pill burden					-.04
Taste					-.37**
Side effects					.08
Model 3.	.16	.02	.59	2.72*	
Child's age					.02
Pill burden					-.04
Taste					-.35**
Side effects					.06
Social support					-.05
Knowledge					.06
Ability					.09

* $p < .05$ ** $p < .01$

From hierarchical multiple regression analysis, only two models were able to predict adherence to antiretroviral medication in children with HIV infection. In the first step, child's age was entered and could not predict adherence to antiretroviral medication in children with HIV infection. Medication factors including pill burden, taste, and side effects were entered in the second step. They could explain 14 percent of variance in adherence to antiretroviral medication in children with HIV infection. In particular, taste could significantly predict adherence to antiretroviral medication in children with HIV infection ($p<.01$). In the last step, caregiver factors including caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication were added. All independent variables could jointly explain 16 percent of variance in adherence to antiretroviral medication in children with HIV infection (Overall $F_{(7,101)} = 2.72$, $p< .05$). Taste was still the only significant predictor of adherence to antiretroviral medication in children. To obtain the predictive equation, multiple regression analysis was then conducted again by using raw score and standard score with predictive ability about 14% of variance in adherence to antiretroviral medication in children with HIV infection (Table 13).

1. Raw score regression equation to predict adherence to antiretroviral medication.

adherence to antiretroviral medication = 96.74 – 5.76 taste

2. Standard score regression equation to predict adherence to antiretroviral medication.

Z adherence to antiretroviral medication = – .37 Z taste

Table 13 Prediction of Adherence to Antiretroviral Medication in Children with HIV Infection by Taste Using Multiple Regression Analysis (N = 109)

Variable	B	SEB	Beta
Constant	96.74	.80	
Taste	- 5.76	1.40	-. 37**

$R^2 = .14$ adj $R^2 = .13$

Overall $F_{(7,101)} = 17.03$

** $p < .01$

CHAPTER V
DISCUSSION

This descriptive study was aimed to investigate the factors influencing adherence to antiretroviral medication in children with HIV infection. The objectives of the study were to 1. examine adherence to antiretroviral medication in children with HIV infection, and 2. investigate predicting power of child factor (child's age), medication factors (pill burden, taste, side effects), and caregiver factors (caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication) on adherence to antiretroviral medication in children with HIV infection. The study findings were discussed as follows:

Objective 1. To examine adherence to antiretroviral medication in children with HIV infection.

This study found that the majority of the sample (77.30%, Table 10) had good adherence to antiretroviral medication (≥ 95%), whereas 22.70% of the sample had poor adherence to antiretroviral medication (< 95%). When considering child factor, it can be explained that the majority of the sample consisted of school-age children between 7 to 13 years old (80.90%, Table 6) who had increased self-care ability and were able to take antiretroviral medication. Furthermore, the children received antiretroviral treatment for about 4-5 years. (Mean = 4.88, Table 7), and the majority of the sample (88.20%, Table 7) had never discontinued antiretroviral treatment. Moreover, most of the caregivers (63.60%, Table 7) reported that they received family assistance in administering antiretroviral medication which might help increase the level of adherence to antiretroviral medication in children with HIV infection.

When examining the medication factors, it was found that the majority of the sample (78.20%, Table 7) received antiretroviral medication only in pill form which 90% of the caregivers reported that children had no difficulty in taking the medication

(Table 7). Furthermore, the majority of children (71.80%, Table 7) had no side effects. The findings of the study indicated that medication factors did not constitute barriers for adherence to antiretroviral medication in children with HIV infection.

When considering caregiver factors, it was found that the majority of the caregivers were female (77.30%, Table 5). Fifty percent of the caregivers were parents of the children (Table 5) with duration of caregiving averaging from 7-8 years (mean = 7.18, Table 5). It can be explained that parental caregivers may offer love and sensitive care to their children, especially when they are ill. Furthermore, most of them were females who offered particularly gentle care for their children. The long duration of care offered by the caregivers further aided the administration of antiretroviral medication to become a part of their daily life and developed their ability in administering antiretroviral medication.

In contrast, twenty-five caregivers whose children (22.70%, Table 10) had poor adherence to antiretroviral medication (< 95%) reported that reasons of poor adherence were due to forgetfulness of the caregivers who did not take the medication with them when their children were away from home, the caregivers' preoccupation with other things, and the children's getting up late.

The study findings were consistent with the findings of Watson and Farley (1999) who investigated adherence to antiretroviral medication among 72 children aged 3 months to12 years old. They found that about half (52%) of the children on therapy for HIV infection maintained adherence greater than 75% based on pharmacy records of the medication. Feingold, Rutstein, Meislich, Brown, and Rudy (2000) also studied adherence to antiretroviral treatment among 70 children with HIV infection and found that 54% of the participants reported good adherence (missed less than 2 doses per week), while another 17% reported fair adherence (missed between 2 and 4 doses per week), and 29% of the sample reported poor adherence (missed more than 4 doses per week).

In Thailand, the findings of this study were consistent with the findings of Deekong (2004) who used VAS to assess adherence to antiretroviral medication in the past 30 days in HIV-infected patients. It was found that about 86.10% of the subjects had good medication adherence (≥ 95%), whereas 13.90% had poor medication adherence (<95%). Tulathong (2004) also used VAS to assess adherence to

antiretroviral medication in the past 30 days in HIV-infected patients and found that about 79.80% of the subjects achieved good medication adherence (≥ 95%), whereas 20.20% had poor medication adherence (<95%). For the purposes of this study, a cut-off point of adherence ≥ 95 % was used to classify good adherence to antiretroviral medication as suggested by Parterson et al. (2000) who showed that very high levels of adherence to antiretroviral medication (≥ 95 %) was required to achieve virologic suppression.

Objective 2. To investigate predicting power of child factor (child's age), medication factors (pill burden, taste, side effects), and caregiver factors (caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication) on adherence to antiretroviral medication in children with HIV infection.

From the hierachical regression analysis, it was found that child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication could jointly explain 16% of variance in adherence to antiretroviral medication in children with HIV infection. Among these independent variables, taste was a significant predictor in the third model (Overall $F_{(7,101)} = 2.72$, $p < .05$). However, table 8 showed that antiretroviral medication was easy to take (range 0-3, mean = 0.16) and table 7 showed that 90% of the children had no difficulty in taking antiretroviral medication. This finding could be explained that taste may be confounded with caregiver ability in administering antiretroviral medication. Table 11 showed that taste was negatively correlated with caregiver ability in administering antiretroviral medication ($r = -.40$, $p < .01$), which indicated that when the children had difficulty in taking antiretroviral medication, caregivers had low ability in administering antiretroviral medication. Table 11 also showed that caregiver ability in administering antiretroviral medication positively correlated with adherence to antiretroviral medication in children with HIV infection ($r = .24$, $p < .05$), which indicated that when the caregivers had low ability in administering antiretroviral medication, adherence to antiretroviral medication was poor.

The findings of this study were similar to those of other studies. Reddington et al. (2000) found that caregivers of HIV- infected children reported that poor adherence to antiretroviral medication was due to difficulty in swallowing pill or foul-tasting medication in which 81% of the caregivers responded “very helpful” for better tasting medications. Boni et al. (2000) studied the problems pointed out by caregivers in administration of antiretroviral medication in 37 children with HIV infection in which the mean age was 8.2 years old. The findings revealed that the main problems were difficulty in swallowing pill and children resisting, refusing, and spitting out drugs because of bad taste (32%).

From the hierachical regression analysis, it was found that child’s age, pill burden, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication were not significant predictors of adherence to antiretroviral medication in children with HIV infection.

Children with chronic illness are required to undergo long-term treatment. Thus, caregivers of these children must strictly follow medication regimens (Lamchang & Akachinores, 1998). One possible reason for explaining variance in adherence to antiretroviral medication may be due to cultural differences. In Thai culture, caregivers closely supervise children’s activities and half of the primary caregivers in this study were parents (50%, Table 1) who provided love, gentle care, and close supervision for their children on a daily basis, regardless of their children’s age. The caregivers offered the best care especially administration of several antiretroviral medications for the remainder of the children’s lives. These daily activities must be performed by the caregivers for children who are unable to engage in self-care.

The study findings further supported the results of the studies of Singh, Squier, Wagener, Nguyen, and Yu (1996) and Haubrich et al. (1999) who found that child’s age was not associated with adherence to antiretroviral medication. In contrast the findings of this study were inconsistent with those of another study. Gordillo et al. (1999) found younger age to be associated with nonadherence and suggested the need for participant’s age to be more effectively incorporated into future models of adherence. Similarly, Mellins et al. (2004) found that child’s age was associated with

adherence to antiretroviral medication in that older children were likely to have higher nonadherence to antiretroviral medication. Adherence concerns intensify as children approach adolescence because of premature responsibility in taking medication, increased complexity of medication regimens, and developmental and social challenges.

Medication factors including pill burden and side effects were not significant predictors of adherence to antiretroviral medication in children with HIV infection. In this study, the sample reported pill burden at a low level (range 0.5-13, mean = 5.20, SD = 3.10, Table 8). This finding was similar to that of other studies. Mellins et al. (2004) studied adherence to antiretroviral medication in 75 children ages ranged from 3 to 13 years and found that pill burden was low, and suggested that adherence was not associated with the complexity or burden of medication regimens. Chesney (2003) and Brackis-Cott et al. (2003) also found that adherence was not associated with complexity and pill burden of medication regimens. Other two studies also failed to document an association between the number of pill taken per day and adherence (Reddington et al., 2000; Mellins et al., 2003). In contrast, this study finding was inconsistent with that of Belzer et al. (1999) who studied 31 HIV-positive adolescents aged 13-24 years and found that “Too many pills” and “Side effect” were the most common reasons youth reported missing medication (43% and 29% respectively).

From these findings, the investigator still believed that medication factors including pill burden and side effects may influence adherence to antiretroviral medication. However, the findings of this study were unable to explain variance in adherence to antiretroviral medication in children with HIV infection which may be explained by the fact that data from the study sample were not normally distributed as testing assumptions of multiple regression analysis showed that pill burden and side effects were not normally distributed.

Caregiver factors including caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication were not significant predictors of adherence to antiretroviral medication in children with HIV infection. These findings were similar to those of other studies. Murphy et al. (2001) found that neither size of social network nor perceived quality of social support predicted adherence. Deekong (2004) found that

caregiver knowledge about HIV/AIDS was not significantly related to medication adherence among adult patients receiving antiretroviral medication. Nicholson et al. (2005) found that caregiver's knowledge about HIV treatment in HIV-infected children was not associated with caregiver's report of medication adherence.

In contrast, the findings of this study contradicted with those of other studies. Deekong (2004) found that caregiver social support was a significant predictor of medication adherence among adult patients receiving antiretroviral medication ($p < .027$). Furthermore, Mellins et al. (2004) found family support resources as ways to promote child adherence. Berrien et al. (2004) suggested that caretakers of children with HIV infection can improve adherence if they better understand HIV infection and antiretroviral medications. Although there is no existing studies on caregiver ability in administering antiretroviral medication, some studies suggested that informational support including knowledge about disease and treatment and motivation to adhere to difficult treatment will develop greater self-care agency (Wortman, 1984). Orem (1985) postulated that the presence of a social support system as an environmental resource may facilitate self-care or dependent-care.

With the above conflicting findings, the investigator still believed that caregiver factors including caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication may influence adherence to antiretroviral medication in children with HIV infection. However, the findings of this study showed that these factors were unable to predict adherence to antiretroviral medication, which can be possibly explained by the fact that the majority of the caregivers had high level of social support (range 44-98, mean = 72.03, SD = 11.69, Table 9), high level of knowledge on care of children with HIV infection (range 7-20, mean = 15.92, SD = 2.86, Table 9), and high level of ability in administering antiretroviral medication (range 59-100, mean = 87.85, SD = 7.92, Table 9). This finding may be explained by the fact that data from the study sample were homogeneous. It may be due to the fact that health care providers of this setting had prepared caregivers prior to initiation of antiretroviral treatment and gave informational support to them during antiretroviral treatment. Prasitsuebsai et al. (2006, 18-21 April) developed a two-day "kids camp" experience for 19 HIV-infected children aged 5-15 years old and their caregivers. This study found that caregivers'

HIV knowledge scores at the beginning and the end of the camp were moderately high and suggested that educational activities may have impact on adherence to antiretroviral medication and self-care of the children.

In conclusion, this study showed that factors included child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication were incorporated to explain 16% of variance in adherence to antiretroviral medication in children with HIV infection. Furthermore, taste was a significant predictor of adherence to antiretroviral medication in children with HIV infection (Overall $F_{(7,101)} = 2.72$, $p < .05$).

CHAPTER VI
CONCLUSION

Summary of the Study

This descriptive study was aimed to examine the factors influencing adherence to antiretroviral medication in children with HIV infection. The sample was 110 caregivers of children with HIV infection who came for a follow up visit at the Pediatric Infectious Clinic of Bamrasnaradura Infectious Disease Institute. Data were collected from November 2005 to February 2006 by using Demographic Characteristics Interview, Antiretroviral Treatment Interview, Adherence to Antiretroviral Medication Interview, Caregiver Social Support Interview, Caregiver Knowledge on Care of Children with HIV Infection Questionnaire, and Caregiver Ability in Administering Antiretroviral Medication Questionnaire. Data were then analyzed using Hierachical Multiple Regression Analysis.

Findings of the study can be summarized as follows:

1. About 77.30 % of children had good medication adherence (≥95%), whereas 22.70% had poor medication adherence (<95%).

2. Taste was negatively and mildly correlated with adherence to antiretroviral medication in children with HIV infection ($r = -.37$, $p < .01$), and caregiver ability in administering antiretroviral medication was positively and mildly correlated with adherence to antiretroviral medication in children with HIV infection ($r = .24$, $p < .05$).

3. Independent variables including child's age, pill burden, taste, side effects, caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication could jointly explain 16 % of variance in adherence to antiretroviral medication in children with HIV infection. Among these independent variables, taste was a significant predictor of adherence to antiretroviral medication in children with HIV infection (Overall $F_{(7,101)} = 2.72$, $p<.05$), with predictive ability about 14% of variance in adherence to

antiretroviral medication in children with HIV infection (Overall $F_{(7,101)} = 17.03$, $p<.01$).

Implications and Recommendations

Implications for nursing practice

1. With the results of this study, nurses should plan and develop intervention models to enhance medication adherence in children living with HIV disease by developing caregiver's ability in administering antiretroviral medication.

2. Nurses should take work collaboratively with physicians and pharmacists to help improve characteristics and taste of antiretroviral medications given to the children, which would help increase medication adherence.

Implications for future study

1. The study sample had homogeneous characteristics such as caregiver social support, caregiver knowledge on care of children with HIV infection, and caregiver ability in administering antiretroviral medication, so further studies should be conducted in a sample with heterogeneous characteristics.

2. In this study, taste was indirectly measured by asking the caregivers to report their observation. In further studies, taste should be assessed directly by asking the children to report their perception of each medication.

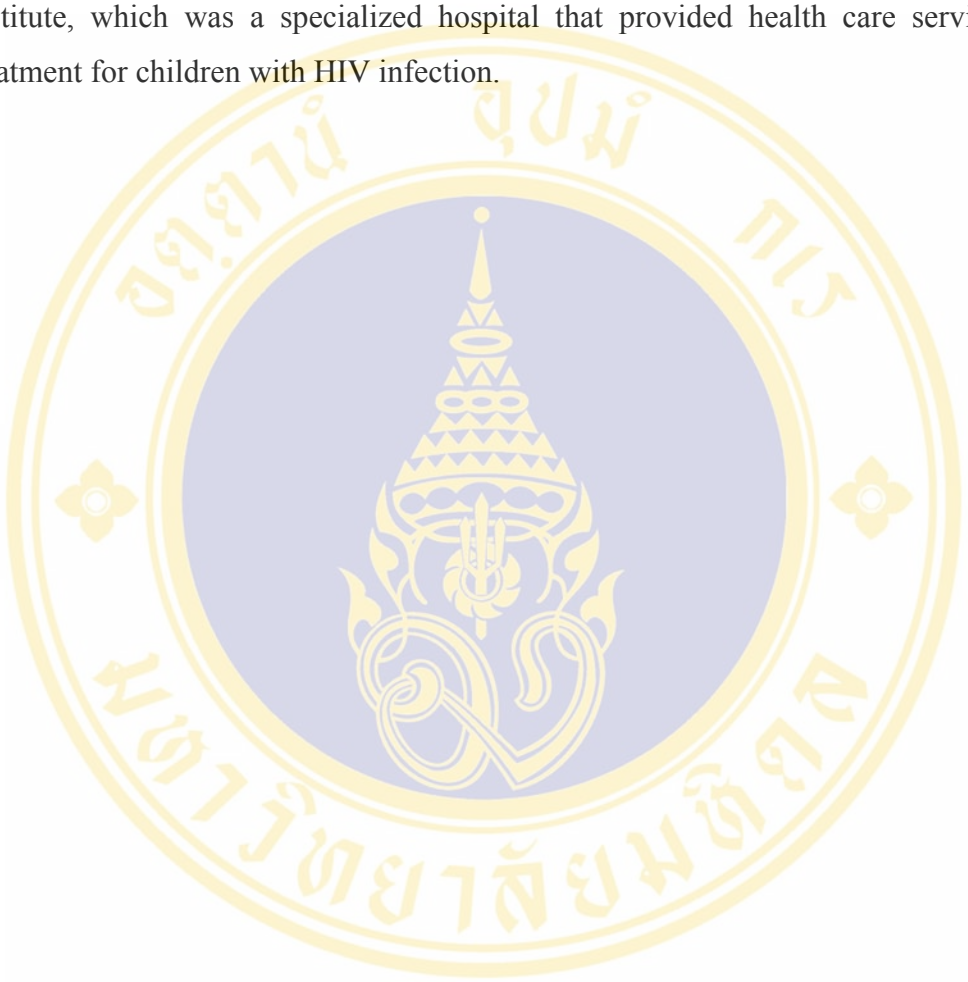
3. The reliabilities of Caregiver Social Support Interview, Caregiver Knowledge on Care of Children with HIV Infection Questionnaire, and Caregiver Ability in Administering Antiretroviral Medication Questionnaire were 0.78, 0.61, and 0.74 respectively. In the next studies, these instruments should be improved to investigate the factors influencing adherence to antiretroviral medication in children with HIV infection.

4. Future study should examine other factors that may influence adherence to antiretroviral medication in children with HIV infection such as immune categories, disclosure of HIV status to the child, and caregiver-child relationship.

Limitations of the Study

1. There were several limitations of this study including its cross-sectional design and the use of self-reported adherence measure that may underestimate or overestimate the actual prevalence of nonadherence.

2. The results of this study may not represent medication adherence of children with HIV infection in other settings in Thailand because the study sample size was small and the participants of this study were caregivers of children who came to the clinic for antiretroviral medication at the Bamrasnaradura Infectious Disease Institute, which was a specialized hospital that provided health care services and treatment for children with HIV infection.



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APPENDIX

APPENDIX A

List of Content Validators

The content validity of the interviews and questionnaires used in this study were assured by six content validators. Name list of content validators was as follows:

1. Assoc. Prof. Kulkanya Chokephaibulkit, M.D.,
   Dip. Amer. Board of Pediatrics, Dip. Amer. Board of Pediatrics Infectious Diseases.
   Department of Pediatrics, Faculty of Medicine, Siriraj Hospital
   Mahidol University.
2. Rujanee Sunthornkachit, M.D.
   Bamrasnaradura Infectious Diseases Institute,
   Ministry of Public Health
3. Prof. Dr. Veena Jirapaet, RN, D.N.Sc. (Clinical Research Methodology)
   Department of Nursing,
   Faculty of Nursing, Chulalongkorn University.
4. Miss Chantana Sakarnkul, RN, M.S.W. (Medical Social Work)
   Bamrasnaradura Infectious Diseases Institute,
   Ministry of Public Health
5. Miss Wimon Anansakunwat, Pharmacist, B.Pharm, M.A.
   Department of Pharmacy, Faculty of Medicine, Siriraj Hospital
   Mahidol University.
6. Miss Uraporn Kottapat, Clinical Psychologist, B.Ed., M.S.
   Department of Pediatrics, Faculty of Medicine, Siriraj Hospital,
   Mahidol University

APPENDIX B

Documentary Proof of Ethical Clearance

Documentary Proof of Ethical Clearance from the Committee on Human Rights Related to Human Experimentation, Mahidol University

No. 134/2005

Documentary Proof of Ethical Clearance
The Committee on Human Rights Related to
Human Experimentation
Mahidol University, Bangkok

Title of Project: Factors Influencing Adherence to Antiretroviral Medication in Children with HIV Infection
(Thesis for Master Degree)

Principle Investigator: Miss Saowanee Songprakon

Name of Institution: Faculty of Nursing

Approved by the Committee on Human Rights Related to Human Experimentation

Signature of Chairman: .....
(Professor Dr.Srisin Khusmith)

Signature of Head of the Institute: .....
(Professor Dr.Pornchai Matangkasombut)

Date of Approval: 10 OCT 2005

Date of Expiration: - 9 OCT 2006

Documentary Proof of Approval from the Ethical Committee of Bamrasnaradura Infectious Disease Institute

FM – REC – 06 – 01

แบบสรุปผลการพิจารณาโครงการวิจัยสถาบันบำราศนราดูร

เลขที่งานวิจัย ว BIR-30-05 วันที่ 28 กันยายน 2548

เรื่อง การสรุปการพิจารณาโครงการวิจัย

เรียน ผู้อำนวยการสถาบันบำราศนราดูร

จากการพิจารณาโครงการวิจัยเรื่อง ปัจจัยที่มีผลต่อการรับประทานยาต้านไวรัสของ ผู้ป่วยติดเชื้อเอชไอวี

ผู้วิจัย นพ. เสาวนีย์ ทรงประโคน

มีผลการพิจารณาของคณะกรรมการมีดังนี้

☑ คณะกรรมการพิจารณาโครงร่างการวิจัย ☑ ผ่านการพิจารณา ☐ ไม่ผ่านการพิจารณา

☐ คณะกรรมการพิจารณาผลประโยชน์งานวิจัย ☐ ผ่านการพิจารณา ☐ ไม่ผ่านการพิจารณา

☐ กลุ่มงานที่เกี่ยวข้อง ☐ ผ่านการพิจารณา ☐ ไม่ผ่านการพิจารณา

☐ สรุปความคิดเห็นอื่นๆ

จึงเรียนมาเพื่อโปรดพิจารณา

(แพทย์หญิงรุจนี สุนทรชิต)

ประธานคณะกรรรมการพิจารณาโครงการวิจัย

☑ ทราบ

☐ อนุมัติ ☐ ไม่อนุมัติ

☐ อื่น ๆ

(แพทย์หญิงสิริวรรณ สิริถวิน)

รองผู้อำนวยการสถาบันบำราศนราดูร

ที่ปรึกษาคณะกรรมการพิจารณาโครงการวิจัย

30 / ก.ย. / 48

☑ อนุมัติ ☐ ไม่อนุมัติ

☐ อื่น ๆ

(แพทย์หญิงอัจฉรา เชาวะวณิช)

ผู้อำนวยการสถาบันบำราศนราดูร

3 / ต.ค. / 48

APPENDIX C

Information Sheet and Informed Consent Form

คำอธิบายโครงการวิจัย

(Information Sheet)

ชื่อโครงการ ปัจจัยที่มีอิทธิพลต่อการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี

วัตถุประสงค์

วัตถุประสงค์ของการวิจัยครั้งนี้เพื่อศึกษาปัจจัยที่มีผลต่อการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี

วิธีการวิจัย/ระยะเวลาที่เข้าร่วมการวิจัย

เมื่อท่านยินดีเข้าร่วมในการวิจัย ผู้วิจัยจะให้ท่านเซ็นชื่อในแบบฟอร์มใบยินยอมให้ทำการวิจัยโดยได้รับการบอกกล่าวและเต็มใจ หลังจากนั้นผู้วิจัยจะขอพูดคุยสัมภาษณ์ และขอให้ท่านตอบแบบสอบถาม ทั้งหมด 6 ชุด คือ

ชุดที่ 1 แบบสัมภาษณ์ข้อมูลส่วนบุคคล มีข้อคำถาม 11 ข้อ

ชุดที่ 2 แบบสัมภาษณ์ข้อมูลด้านการรักษา มีข้อคำถาม 6 ข้อ

ชุดที่ 3 แบบสัมภาษณ์เกี่ยวกับการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี มีคำถาม 2 ข้อ

ชุดที่ 4 แบบสัมภาษณ์การสนับสนุนทางสังคมของผู้ดูแล มีข้อคำถาม 20 ข้อ

ชุดที่ 5 แบบสอบถามความสามารถของผู้ดูแลในการจัดการให้เด็กรับประทานยาต้านไวรัสเอดส์ มีข้อคำถาม 20 ข้อ

ชุดที่ 6 แบบสอบถามความรู้ของผู้ดูแลในการดูแลเด็กที่ติดเชื้อเอชไอวี มีข้อคำถาม 20 ข้อ

โดยคาดว่าจะใช้เวลาประมาณ 1 ชั่วโมง ในการพูดคุยสัมภาษณ์และตอบแบบสอบถาม ในกรณีที่ท่านไม่เข้าใจข้อคำถาม ท่านสามารถซักถามผู้วิจัยได้ตลอดเวลา ถ้าท่านมีปัญหาในการอ่านผู้วิจัยจะอ่านข้อคำถามให้ท่านฟังทีละข้อ และช่วยเหลือท่านในระหว่างการตอบแบบสอบถามทั้งหมด

เหตุผลที่เชิญชวนให้ผู้ยินยอมตนให้เข้าร่วมโครงการวิจัย

ผู้วิจัยต้องการศึกษาเกี่ยวกับการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอของเด็กที่ติดเชื้อเอชไอวี ซึ่งส่วนใหญ่จะยังไม่สามารถรับผิดชอบการรับประทานยาเองได้ ในฐานะที่ท่านเป็นผู้ดูแลหลักที่รับผิดชอบดูแลให้เด็กรับประทานยาตามแผนการรักษาของแพทย์ ข้อมูลที่ได้จากท่านจึงมีความสำคัญและจำเป็นอย่างยิ่งในการวิจัยครั้งนี้

ประโยชน์ และความเสี่ยงที่คาดว่าจะเกิดกับผู้ยินยอมตนให้ทำการวิจัย

ท่านอาจไม่ได้รับประโยชน์โดยตรงจากการเข้าร่วมการวิจัยครั้งนี้ แต่ข้อมูลที่ได้จากท่านจะช่วยให้พยาบาลและบุคลากรที่ดูแลเด็กที่ติดเชื้อเอชไอวี สามารถให้คำแนะนำและช่วยเหลือท่านและผู้ดูแลคนอื่นๆได้ดียิ่งขึ้น

การพูดคุยสัมภาษณ์และตอบแบบสอบถามจะไม่ก่อให้เกิดผลเสียใดๆต่อท่านและเด็กในความดูแลของท่าน อย่างไรก็ตาม ท่านอาจเสียเวลาบ้างในการพูดคุยและตอบแบบสอบถาม คำถามบางคำถามอาจทำให้ท่านรู้สึกไม่สบายใจ ท่านสามารถปฏิเสธที่จะตอบคำถามใดๆที่ท่านไม่ต้องการที่จะตอบได้

การเก็บรักษาข้อมูลเป็นความลับ

ผู้วิจัยจะเก็บรักษาข้อมูลที่ได้รับไว้เป็นความลับ โดยจะนำเสนอผลการวิจัยในภาพรวม ไม่มีการระบุชื่อและนามสกุลของท่านและเด็ก โดยจะใช้ตัวเลขแทนชื่อของผู้ร่วมการวิจัยแต่ละคน และการเปิดเผยข้อมูลเกี่ยวกับท่านต่อหน่วยงานต่างๆที่เกี่ยวข้อง จะกระทำเฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

สิทธิผู้ยินยอมตนให้ทำการวิจัย

การเข้าร่วมการวิจัยครั้งนี้ขึ้นอยู่กับความสมัครใจของท่านและจะไม่มีค่าตอบแทนใดๆ ท่านมีสิทธิ์ที่จะปฏิเสธการพูดคุยสัมภาษณ์และตอบแบบสอบถามครั้งนี้ หรือยุติการให้ข้อมูลทันทีที่ท่านต้องการ โดยไม่มีผลกระทบต่อการดูแลรักษาที่เด็กในความดูแลของท่านจะได้รับตามปกติใดๆทั้งสิ้น

ในระหว่างการเข้าร่วมการวิจัย หากท่านมีข้อสงสัยประการใด ท่านสามารถติดต่อผู้วิจัย หรืออาจารย์ที่ปรึกษาได้ตลอด 24 ชั่วโมง โดยติดต่อได้ที่

ผู้วิจัย นางสาวเสาวนีย์ ทรงประโคน

ตำแหน่ง พยาบาลวิชาชีพ ระดับ 5

ที่ทำงาน โรงพยาบาลตระการพืชผล อำเภอตระการพืชผล จังหวัดอุบลราชธานี 34130

อาจารย์ที่ปรึกษา อ. ดร. วัลยา ธรรมพนิชวัฒน์

ตำแหน่ง อาจารย์ ระดับ 7

ที่ทำงาน ภาควิชาการพยาบาลกุมารเวชศาสตร์ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล

แบบฟอร์มใบยินยอมให้ทำการวิจัยโดยได้รับการบอกกล่าวและเต็มใจ
(Informed Consent Form)

การวิจัยเรื่อง ปัจจัยที่มีอิทธิพลต่อการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี

วันให้คำยินยอม วันที่..... เดือน..... พ. ศ. .....

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีวิจัย รวมทั้งประโยชน์ที่เกิดขึ้นจากการวิจัยอย่างละเอียด และมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจ ไม่ปิดบัง ซ่อนเร้น จนข้าพเจ้าพอใจ

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลต่อการรักษาโรคที่เด็กในความดูแลของข้าพเจ้าพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้า และเด็กในความดูแลของข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นการสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น ผู้วิจัยรับรองว่าหากมีข้อมูลเพิ่มเติมที่ส่งผลกระทบต่อการวิจัย ข้าพเจ้าจะได้รับการแจ้งให้ทราบโดยไม่ปิดบัง ซ่อนเร้น

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ และได้ลงนามในใบยินยอมด้วยความเต็มใจ

ลงนาม ..... ผู้ยินยอม

ลงนาม ..... พยาน

ลงนาม ..... พยาน

ในกรณีที่ผู้ยินยอมให้ทำการวิจัยไม่สามารถอ่าน และเขียนหนังสือได้ จะต้องได้รับการยินยอมในขณะที่ยังมีสติสัมปชัญญะ และระบุข้อความไว้ตามนี้

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

ลงนาม ..... ผู้ยินยอม
(หรือประทับลายนิ้วหัวแม่มือ)
ลงนาม ..... พยาน
ลงนาม ..... พยาน

ในกรณีที่ผู้ยินยอมตนให้ทำการวิจัยยังไม่บรรลุนิติภาวะ จะต้องได้รับการยินยอมจากผู้ปกครอง หรือผู้อุปการะโดยชอบด้วยกฎหมาย

ลงนาม ..... ผู้ปกครอง/
ผู้อุปการะโดยชอบด้วยกฎหมาย
ลงนาม ..... พยาน
ลงนาม ..... พยาน

ในกรณีที่ผู้ยินยอมตนให้ทำการวิจัยไม่สามารถตัดสินใจเองได้ ให้ผู้แทนโดยชอบด้วยกฎหมาย หรือผู้ปกครอง หรือญาติที่ใกล้ชิดที่สุดเป็นผู้ลงนามยินยอม

ลงนาม ..... ผู้แทน/
ผู้ปกครอง/ญาติ
ลงนาม ..... พยาน
ลงนาม ..... พยาน

APPENDIX D

The Instruments

ส่วนที่ 1 **ID .....**

HN .....

วันที่ .....

แบบสัมภาษณ์ข้อมูลส่วนบุคคล

คำชี้แจง แบบสัมภาษณ์ชุดนี้ มีวัตถุประสงค์ เพื่อสอบถามข้อมูลส่วนตัวของท่านและเด็ก ที่อยู่ในความดูแลของท่าน เพื่อนำข้อมูลที่ได้มาใช้ในประกอบการศึกษาวิจัยครั้งนี้ | สำหรับผู้วิจัย

ข้อมูลของ เด็ก

1. เพศ [ ] 1. ชาย [ ] 2. หญิง ☐ V001

2. อายุของเด็ก..... ปี ..... เดือน ☐ V002

3. เด็กตรวจพบว่าติดเชื้อเอชไอวีเมื่ออายุ..... ปี ..... เดือน ☐ V003

4. ระดับภูมิต้านทาน โดยพิจารณาจากระดับของCD4+ count (ผู้วิจัยเก็บข้อมูลผลการตรวจครั้งล่าสุดจากแฟ้มประวัติของผู้ป่วย) ..... cell/ mm^3 ☐ V004

[ ] 1. ไม่มีการกดภูมิต้านทาน (.....%)

[ ] 2. มีการกดภูมิต้านทานปานกลาง (.....%)

[ ] 3. มีการกดภูมิต้านทานรุนแรง (.....%)

ข้อมูลของผู้ดูแล

1. เพศ [ ] 1. ชาย [ ] 2. หญิง ☐ V005

2. อายุ ..... ปี ☐ V006

3. สถานภาพสมรส

[ ] 1. โสด [ ] 2. คู่ ☐ V007

[ ] 3. หย่า/ หม้าย/ แยก

4. อาชีพ ☐ V008

[ ] 1. แม่บ้าน/พ่อบ้าน [ ] 2. รับราชการ/รัฐวิสาหกิจ

[ ] 3. เกษตรกร [ ] 4. รับจ้าง

[ ] 5. ค้าขาย [ ] 6. อื่นๆ ระบุ .....

5. การศึกษา

[ ] 1. ไม่ได้เรียนหนังสือ [ ] 2. ประถมศึกษา V009

[ ] 3. มัธยมศึกษาตอนต้น [ ] 4. มัธยมศึกษาตอนปลาย

[ ] 5. อนุปริญญา /ประกาศนียบัตร [ ] 6. ปริญญาตรีหรือสูงกว่า

6. ผู้ดูแลเกี่ยวข้องเป็นอะไรกับเด็ก V010

[ ] 1. บิดา [ ] 2. มารดา

[ ] 3. ญาติฝ่ายบิดา ระบุ ..... [ ] 4. ญาติฝ่ายมารดา ระบุ.....

[ ] 5. ไม่ใช่ญาติ ระบุ .....

7. ระยะเวลาในการดูแลเด็กรายนี้ ..... ปี V011

8. ลักษณะของครอบครัว V012

[ ] 1. ครอบครัวเดี่ยว

[ ] 2. ครอบครัวขยาย

9. จำนวนสมาชิกที่อาศัยอยู่บ้านเดียวกัน ..... คน V013

10. มีใครบ้างที่ทราบการติดเชื้อเอชไอวีของเด็ก V014

( ) สามี/ภรรยา ( ) เพื่อนร่วมงาน

( ) สมาชิกในครอบครัว ( ) พยาบาล

ระบุ..... ( ) แพทย์

( ) ญาติพี่น้อง ( ) อื่นๆ

ระบุ..... ระบุ.....

( ) เพื่อนสนิท

( ) เพื่อนบ้าน

11.รายได้เฉลี่ยของครอบครัว ต่อเดือน ..... บาท V015

ส่วนที่ 2

แบบสัมภาษณ์ข้อมูลด้านการรักษา

V016

1. เด็กเริ่มรักษาด้วยยาต้านไวรัสเมื่ออายุ ..... ปี .....เดือน

V017

2. เด็กเคยหยุดใช้ยาต้านไวรัสไประยะหนึ่งหรือไม่
   [ ] 1. ไม่เคย
   [ ] 2. เคย นานเท่าใด.....
   เพราะอะไร ระบุ.....

V018

3. มีสมาชิกคนอื่นในครอบครัวที่ช่วยดูแลเด็กให้รับประทานยาต้านไวรัสหรือไม่
   [ ] 1. ไม่มี
   [ ] 2. มี ระบุ .....

V019

4. รูปแบบยาต้านไวรัสที่เด็กได้รับในปัจจุบัน
   [ ] 1. ยาเม็ด..... ตัว
   ยาเม็ดตัวที่ 1 จำนวน..... เม็ด/ ครั้ง รับประทานวันละ..... เวลา
   ยาเม็ดตัวที่ 2 จำนวน..... เม็ด/ ครั้ง รับประทานวันละ..... เวลา
   ยาเม็ดตัวที่ 3 จำนวน..... เม็ด/ ครั้ง รับประทานวันละ..... เวลา
   ยาเม็ดตัวที่ 4 จำนวน..... เม็ด/ ครั้ง รับประทานวันละ..... เวลา
   [ ] 2. ยาน้ำ..... ตัว
   ยาน้ำตัวที่ 1 จำนวน..... ช้อน/ ครั้ง รับประทานวันละ..... เวลา
   ยาน้ำตัวที่ 2 จำนวน..... ช้อน/ ครั้ง รับประทานวันละ..... เวลา
   ยาน้ำตัวที่ 3 จำนวน..... ช้อน/ ครั้ง รับประทานวันละ..... เวลา
   ยาน้ำตัวที่ 4 จำนวน..... ช้อน/ ครั้ง รับประทานวันละ..... เวลา

V020

5. รสชาติของยาต้านไวรัสที่เด็กรับประทานอยู่เป็นอย่างไร
   [ ] 1. ยาที่เด็กรับประทานได้ง่าย ..... ตัว
   [ ] 2. ยาที่เด็กรับประทานได้ยาก ..... ตัว

6. ยาต้านไวรัสที่เด็กได้รับในปัจจุบัน มีผลข้างเคียงต่อไปนี้หรือไม่
(เลือกได้ มากกว่า 1 ข้อ) ☐ V021

[ ] 1. ไม่มี
[ ] 2. ผื่นแดงตามร่างกาย
[ ] 3. คลื่นไส้ / อาเจียน
[ ] 4. ปวดศีรษะ/ เวียนศีรษะ
[ ] 5. ปวดท้อง/ ท้องเสีย
[ ] 6.ชาปลายมือปลายเท้า
[ ] 7. ปวดเมื่อยตามตัว
[ ] 8. ตาตัวเหลือง/ ตับอักเสบ
[ ] 9. นอนไม่หลับ
[ ] 10. ซีด
[ ] 11. อื่นๆ ระบุ.....

ส่วนที่ 3 แบบสัมภาษณ์ผู้ดูแลเกี่ยวกับการรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี

คำชี้แจง ให้ทำเครื่องหมาย X บนเส้น และเขียนจำนวนเปอร์เซ็นต์การรับประทานยาต้านไวรัสเอดส์อย่างต่อเนื่องสม่ำเสมอในเด็กที่ติดเชื้อเอชไอวี

1. ใน 30 วันที่ผ่านมา เด็กในความดูแลของท่านรับประทานยาต้านไวรัสเอดส์แต่ละตัวครบทุกเม็ดทุกมื้อตามเวลาที่กำหนด คิดเป็นกี่เปอร์เซ็นต์ (เช่น จำนวนมื้อทั้งหมด 60 มื้อ ถ้าเด็กรับประทานยาครบทุกมื้อภายใน 30 วัน จะคิดเป็น 100 เปอร์เซ็นต์)

ชื่อยา .....

ลักษณะยา ☐ เม็ด/ แคปซูล ☐ น้ำ

สียา ระบุ .....

0 100

ไม่ต่อเนื่องสม่ำเสมอเลย (ไม่รับประทานยาเลย)

ต่อเนื่องสม่ำเสมอมากที่สุด (ไม่เคยขาดแม้แต่ครั้งเดียว)

2. เหตุผลที่ทำให้เด็กไม่ได้รับประทานยาต้านไวรัส

คำชี้แจง ให้ทำเครื่องหมาย (/) ลงในช่อง " ใช่ " ที่ระบุเหตุผลที่ทำให้เด็กไม่ได้รับประทานยาต้านไวรัส (เลือกได้มากกว่า 1 ข้อ)

เหตุผล	ใช่
1. ยาหมด/ ไม่ได้มาตรวจตามแพทย์นัด	
2. ยามีรสชาติไม่ดี	
3. ท่านลืม	
4. ท่านกังวลเกี่ยวกับอาการข้างเคียงของยา	
5. กิจวัตรประจำวันเปลี่ยนแปลงไป	
6. ท่านยุ่งกับการดูแลเด็ก	
7. เด็กไม่ยอมรับประทานยา/ บ้วนยาทิ้ง	
8. มีคนดูแลเด็กหลายคน และท่านมักไม่ได้อยู่กับเด็ก เมื่อถึงเวลาที่เด็กต้องรับประทานยา	
9. ท่านไม่ต้องการให้คนอื่นสังเกตเห็น เมื่อเด็กรับประทานยา	
10. เด็กไม่สบาย	
11. ไม่คิดว่าเด็กต้องรับประทานยาต่อไปอีก	
12. มีคนอื่นบอกว่าไม่ต้องให้เด็กรับประทานยาต่อ	
13. ท่านไม่สบาย	
14. ท่านรู้สึกว่ายาอาจมีอันตรายต่อเด็ก	
15. เด็กไม่ได้อาศัยอยู่ที่บ้านที่เก็บยาไว้	
16. ท่านรู้สึกซึมเศร้า	
17. เด็กสุขภาพแข็งแรงดี	
18. มียาหลายชนิดที่ต้องให้เด็กรับประทาน	
19. ท่านไม่อยู่บ้าน	
20. ท่านยุ่งกับกิจกรรมอื่น	
21. อื่นๆ..... (โปรดระบุ)	

ส่วนที่ 4

แบบสัมภาษณ์การสนับสนุนทางสังคมของผู้ดูแล

คำชี้แจง แบบสัมภาษณ์นี้มีวัตถุประสงค์ เพื่อต้องการทราบว่า ท่านซึ่งเป็นผู้ดูแลเด็กที่ติดเชื้อเอชไอวี ได้รับการสนับสนุนและช่วยเหลือมากน้อยเพียงใดและได้รับจากใครบ้าง แบบสัมภาษณ์ชุดนี้จะมีข้อคำถามให้ท่านตอบ จำนวน 20 ข้อ ผู้วิจัยจะอ่านข้อคำถามให้ฟังทีละข้อและขอให้ท่านพิจารณาว่า

1. ข้อคำถามนั้นตรงกับความรู้สึกหรือความเป็นจริงที่เกิดขึ้นกับท่านมากน้อยเพียงใด และเลือกคำตอบที่ตรงกับความรู้สึก หรือความเป็นจริงที่เกิดขึ้นกับท่านมากที่สุดเพียงคำตอบเดียว โดยผู้วิจัยจะเป็นผู้ทำเครื่องหมาย [/] ลงในช่องคำตอบ ในแต่ละข้อมีคำตอบให้เลือกดังนี้

มากที่สุด	หมายถึง ข้อความนั้นตรงกับความรู้สึกหรือตรงกับความเป็นจริงที่ท่านได้รับมากที่สุด
เป็นส่วนมาก	หมายถึง ข้อความนั้นตรงกับความรู้สึกหรือตรงกับความเป็นจริงที่ท่านได้รับเป็นส่วนมาก
ปานกลาง	หมายถึง ข้อความนั้นตรงกับความรู้สึกหรือตรงกับความเป็นจริงที่ท่านได้รับปานกลาง
เล็กน้อย	หมายถึง ข้อความนั้นตรงกับความรู้สึกหรือตรงกับความเป็นจริงที่ท่านได้รับเล็กน้อย
ไม่ได้รับเลย	หมายถึง ข้อความนั้นไม่ตรงกับความรู้สึกหรือไม่ตรงกับความเป็นจริงที่ท่านได้รับเลย

2. การสนับสนุนที่ท่านได้รับในเรื่องต่างๆ ตามข้อคำถามแต่ละด้าน ท่านได้รับจากบุคคลใดบ้าง ขอให้ท่านเลือกบุคคลที่ท่านเห็นว่าให้การสนับสนุนท่านตามความเป็นจริงมากที่สุด โดยท่านสามารถเลือกได้มากกว่าหนึ่งกลุ่ม และให้ท่านระบุว่าท่านได้รับจากบุคคลใดมากเป็นอันดับที่ 1 และอันดับที่ 2

ในกรณีที่ท่านเลือกกลุ่มบุคคลในข้อสมาชิกคนอื่นๆ ในครอบครัว ญาติ พี่น้อง และอื่นๆ ให้ท่านระบุความสัมพันธ์ของท่านกับบุคคลที่ให้การสนับสนุนด้วย ซึ่งผู้วิจัยจะเป็นผู้เขียนตัวเลขลงในช่องคำตอบให้ท่าน

ข้อความ	มากที่สุด	เป็นส่วนมาก	ปานกลาง	เล็กน้อย	ไม่ได้รับเลย
การสนับสนุนด้านอารมณ์ 1. ท่านได้รับความรักและความห่วงใยในฐานะที่ดูแลเด็กที่ติดเชื้อเอชไอวีมากน้อยเพียงใด					
2. ท่าน					
3. ท่าน					
4.ท่าน					

ผู้ให้การสนับสนุนด้านอารมณ์

การสนับสนุนที่ท่านได้รับในเรื่องต่างๆดังกล่าวข้างต้น ท่านได้รับจากบุคคลใดบ้าง

( ) สามี/ภรรยา

( ) สมาชิกในครอบครัว

ระบุ.....

( ) ญาติพี่น้อง

ระบุ.....

( ) เพื่อนสนิท

( ) เพื่อนบ้าน

( ) เพื่อนร่วมงาน

( ) พยาบาล

( ) แพทย์

( ) อื่นๆ

ระบุ.....

ข้อความ	มากที่สุด	เป็นส่วนมาก	ปานกลาง	เล็กน้อย	ไม่ได้รับเลย
การสนับสนุนด้านการเห็นคุณค่าในตนเอง 5. ท่านได้รับการยอมรับนับถือในบทบาทของผู้ดูแลเด็กที่ติดเชื้อเอชไอวี มากน้อยเพียงใด					
6. ท่าน.....					
7. ท่าน.....					
8. ท่าน.....					

ผู้ให้การสนับสนุนด้านการเห็นคุณค่าในตนเอง

การสนับสนุนที่ท่านได้รับในเรื่องต่างๆดังกล่าวข้างต้น ท่านได้รับจากบุคคลใดบ้าง

( ) สามี/ภรรยา

( ) สมาชิกในครอบครัว

ระบุ.....

( ) ญาติพี่น้อง

ระบุ.....

( ) เพื่อนสนิท

( ) เพื่อนบ้าน

( ) เพื่อนร่วมงาน

( ) พยาบาล

( ) แพทย์

( ) อื่นๆ

ระบุ.....

ข้อความ	มากที่สุด	เป็นส่วนมาก	ปานกลาง	เล็กน้อย	ไม่ได้รับเลย
การสนับสนุนด้านข้อมูลข่าวสาร 9. ท่านได้รับความรู้ ข้อมูลที่เป็นประโยชน์ต่อการดูแลสุขภาพของท่าน มากน้อยเพียงใด					
10. ท่าน.....					
11. เมื่อท่าน					
12. เมื่อท่าน.....					

ผู้ให้การสนับสนุนด้านข้อมูลข่าวสาร

การสนับสนุนที่ท่านได้รับในเรื่องต่างๆดังกล่าวข้างต้น ท่านได้รับจากบุคคลใดบ้าง

( ) สามี/ภรรยา

( ) สมาชิกในครอบครัว

ระบุ.....

( ) ญาติพี่น้อง

ระบุ.....

( ) เพื่อนสนิท

( ) เพื่อนบ้าน

( ) เพื่อนร่วมงาน

( ) พยาบาล

( ) แพทย์

( ) อื่นๆ

ระบุ.....

ข้อความ	มากที่สุด	เป็นส่วนมาก	ปานกลาง	เล็กน้อย	ไม่ได้รับเลย
การสนับสนุนทางด้านวัสดุ สิ่งของ เงินทอง และแรงงาน 13. เมื่อท่านต้องการพักผ่อน มีผู้ช่วยเหลือทำงานบ้านและดูแลเด็กแทนท่าน มากน้อยเพียงใด					
14. เมื่อท่าน.....					
15. เมื่อท่าน					
16. เมื่อท่าน					

ผู้ให้การสนับสนุนด้านวัสดุ สิ่งของ เงินทอง และแรงงาน

การสนับสนุนที่ท่านได้รับในเรื่องต่างๆดังกล่าวข้างต้น ท่านได้รับจากบุคคลใดบ้าง

( ) สามี/ภรรยา

( ) สมาชิกในครอบครัว

ระบุ.....

( ) ญาติพี่น้อง

ระบุ.....

( ) เพื่อนสนิท

( ) เพื่อนบ้าน

( ) เพื่อนร่วมงาน

( ) พยาบาล

( ) แพทย์

( ) อื่นๆ

ระบุ.....

ข้อความ	มากที่สุด	เป็นส่วนมาก	ปานกลาง	เล็กน้อย	ไม่ได้รับเลย
การสนับสนุนด้านการเป็นส่วนหนึ่งของสังคม 17. แม้ท่านจะให้การดูแลเด็กที่ติดเชื้อเอชไอวี ท่านยังได้รับการพูดคุยและไปมาหาสู่เหมือนเดิม มากน้อยเพียงใด					
18. ในระหว่างที่					
19. ในระหว่างที่					
20. ท่านได้รับเชิญ					

ผู้ให้การสนับสนุนด้านการเป็นส่วนหนึ่งของสังคม

การสนับสนุนที่ท่านได้รับในเรื่องต่างๆดังกล่าวข้างต้น ท่านได้รับจากบุคคลใดบ้าง

( ) สามี/ภรรยา

( ) สมาชิกในครอบครัว

ระบุ.....

( ) ญาติพี่น้อง

ระบุ.....

( ) เพื่อนสนิท

( ) เพื่อนบ้าน

( ) เพื่อนร่วมงาน

( ) พยาบาล

( ) แพทย์

( ) อื่นๆ

ระบุ.....

ส่วนที่ 5

แบบสอบถามความสามารถของผู้ดูแลในการจัดการให้เด็กรับประทานยาต้านไวรัสเอดส์

คำชี้แจง แบบสอบถามนี้ มีวัตถุประสงค์เพื่อสอบถามการกระทำ ความรู้สึก หรือลักษณะของท่านเกี่ยวกับการดูแลเด็กติดเชื้อเอชไอวีให้รับประทานยาต้านไวรัสเอดส์ แบบสอบถามชุดนี้จะมีข้อคำถามให้ท่านตอบ จำนวน 20 ข้อ กรุณาอ่านข้อความทางด้านซ้ายมืออย่างรอบคอบ และเลือกคำตอบที่ตรงกับท่านมากที่สุดเพียงคำตอบเดียว โดยทำเครื่องหมาย [/] ลงในช่องคำตอบ ในแต่ละข้อมีคำตอบให้เลือกดังนี้

ตรงกับตัวท่านมากที่สุด	หมายถึง	ข้อความนั้นตรงกับการกระทำ ความรู้สึกหรือลักษณะของท่านมากที่สุด
ตรงกับตัวท่านมากพอควร	หมายถึง	ข้อความนั้นตรงกับการกระทำ ความรู้สึกหรือลักษณะของท่านมากพอควร
ตรงกับตัวท่านปานกลาง	หมายถึง	ข้อความนั้นตรงกับการกระทำ ความรู้สึกหรือลักษณะของท่านปานกลาง
ตรงกับตัวท่านเล็กน้อย	หมายถึง	ข้อความนั้นตรงกับการกระทำ ความรู้สึกหรือ ลักษณะของท่านเล็กน้อย
ไม่ตรงกับตัวท่านเลย	หมายถึง	ข้อความนั้นไม่ตรงกับการกระทำ ความรู้สึกหรือลักษณะของท่าน

ข้อความ	ตรงกับตัวท่านมากที่สุด	ตรงกับตัวท่านมากพอควร	ตรงกับตัวท่านปานกลาง	ตรงกับตัวท่านเล็กน้อย	ไม่ตรงกับตัวท่านเลย
1. ท่านดูแลให้เด็กรับประทานยาต้านไวรัส ด้วยตนเอง เพื่อให้แน่ใจว่าเด็กได้รับประทานยามื้อนั้นแล้ว					
2. ท่านยุ่งกับการทำงาน จนบางครั้งลืมให้เด็กรับประทานยาต้านไวรัส					
3.					
....					
....					
19. การดูแลให้เด็กรับประทานยาต้านไวรัส เป็นส่วนหนึ่งของกิจวัตรประจำวันที่ท่านปฏิบัติเสมอ					
20. ท่านฝึกให้เด็กรับประทานยาต้านไวรัสตรงเวลาโดยใช้สิ่งเตือนเวลาในชีวิตประจำวัน เช่น นาฬิกาปลุก, เพลงชาติ, รายการโทรทัศน์ เป็นต้น					

ส่วนที่ 6

แบบสอบถามความรู้ของผู้ดูแลในการดูแลเด็กที่ติดเชื้อเอชไอวี

คำชี้แจง โปรดทำเครื่องหมาย [/] ลงในช่องที่ตรงกับความคิดเห็นของท่านมากที่สุด

ข้อความ	ใช่	ไม่ใช่
ความรู้เกี่ยวกับการติดเชื้อเอชไอวีในเด็ก 1. เด็กที่ติดเชื้อเอดส์ จะมีภูมิคุ้มกันบกพร่อง		
2.		
3.		
4.		
5. ไม่ควรให้เด็กที่ติดเชื้อเอดส์อยู่ใกล้ชิดกับผู้ป่วยวัณโรค		
ความรู้เกี่ยวกับการใช้ยาต้านไวรัสในเด็ก 6. ยาต้านไวรัส ช่วยให้เด็กที่ติดเชื้อเอดส์แข็งแรงและมีอายุยืนยาว		
7.		
....		
16. การรับประทานยาบางชนิดร่วมด้วย ทำให้ยาต้านไวรัสดูดซึม และออกฤทธิ์ไม่ดี		
ความรู้เกี่ยวกับผลข้างเคียงของยาต้านไวรัสในเด็ก 17.เด็กที่ติดเชื้อเอดส์ และได้รับยาต้านไวรัส อาจมีอาการข้างเคียงจากการรับประทานยาต้านไวรัสได้		
....		
20. ยาต้านไวรัสอาจทำให้เกิดผลข้างเคียงในระยะยาวได้ เช่น ทำให้เด็กมีรูปร่างเปลี่ยนแปลง แก้มตอบ แขนขาลีบ และมีไขมันสะสมที่หน้าท้องและหน้าอก		

APPENDIX E

Testing Assumptions of Multiple Regression Analysis

The assumptions that were tested before using multiple regression analysis included normal distribution, homoscedasticity, and multicollinearity. The results for each assumptions were presented as follows:

1. Normal distribution was assessed by using histogram of standardized residuals. The dependent variable was shown as not normally distributed and outlier (1 case) was identified as distinctly different from other observations (Figure 3). The standardized residuals were then plotted. The plotted values did not fall close to the line of normal probability (Figure 4).

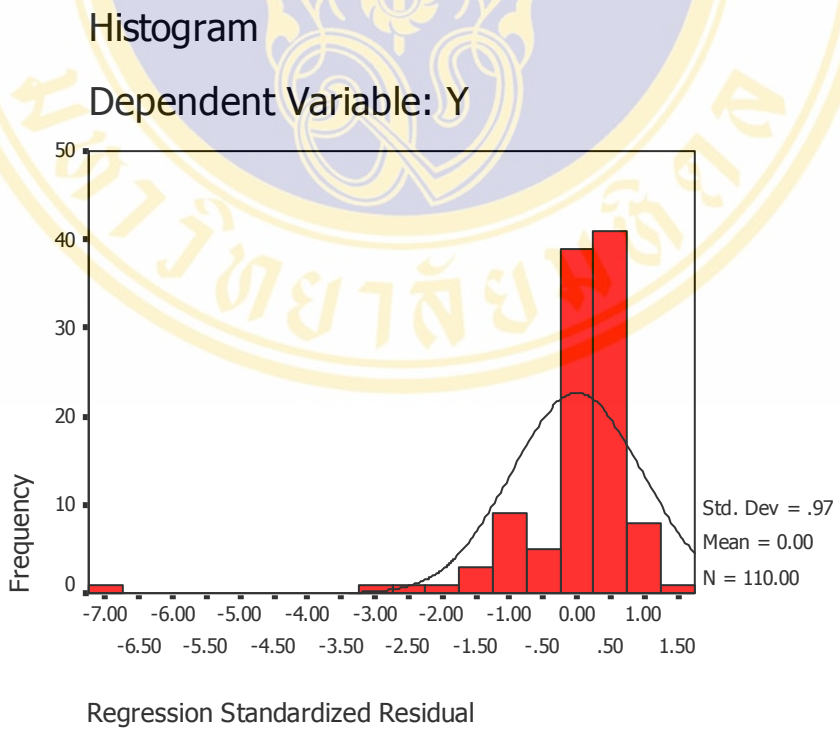

Figure 3 Histogram of Standardized Residuals

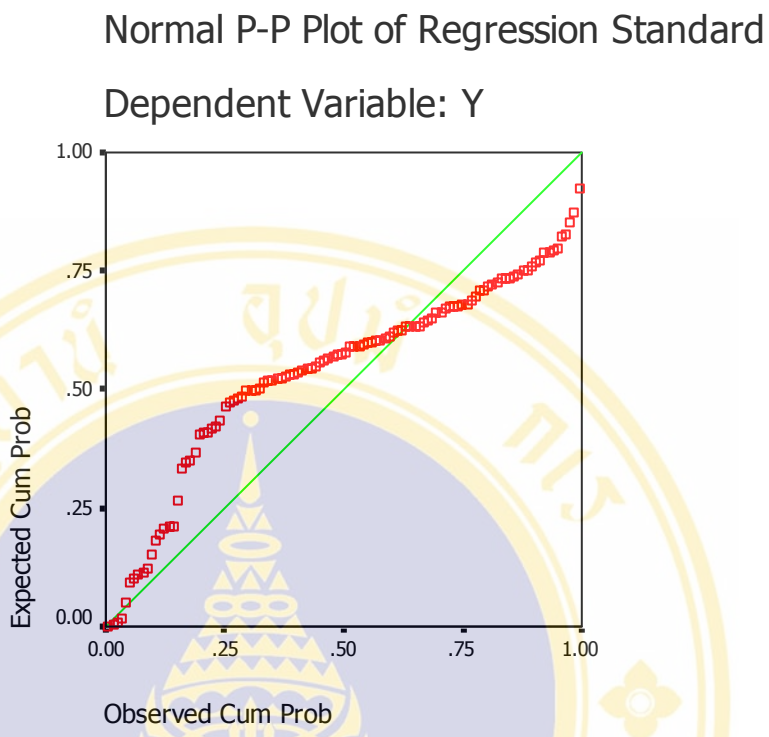

Figure 4 Normal P-P Plot of Regression Standardized Residual

One outlier case was identified in this study, with 0% of adherence to antiretroviral medication. The child was 6 years old and had moderate level of immune suppression. The child was on antiretroviral treatment for 6 years and discontinued the treatment for 2 years.

The caregiver was a mother who was a drug addict. She reported the reasons why the child discontinued antiretroviral treatment as due to lacked of money and family assistance with medication administration. This caregiver reported low social support (score = 54, mean = 72.03), and had poor knowledge on care of children with HIV infection (score = 8, mean = 15.92), but reported had high ability in administering antiretroviral medication (score = 92, mean = 87.85).

One-Sample Kolmogorov-Smirnov test showed that pill burden, taste, side effects, and adherence to antiretroviral medication were not normally distributed (Table 14).

Table 14 One- Sample Kolmogorov- Smirnov Test (N = 110)

		Child's age	Pill burden	Taste	Side effects	Social Sup port	Know ledge	Ability	Adher ence
N		110	110	110	110	110	110	110	110
Normal Parameters	Mean	8.79	5.20	.16	.48	72.03	15.92	87.85	94.92
	SD	2.74	3.10	.55	.95	11.69	2.86	7.92	12.51
Most Extreme	Absolute	.13	.15	.52	.41	.09	.12	.10	.34
Differences	Positive	.08	.15	.52	.41	.04	.10	.06	.34
	Negative	-.13	-.12	-.38	-.31	-.09	-.12	-.10	-.32
Kolmogorov-Smirnov Z		1.32	1.56	5.42	4.33	.96	1.27	1.05	3.59
Asymp. Sig. (2-tailed)		.06	.02	.00	.00	.32	.08	.22	.00

2. Homoscedasticity

This assumption was tested by scatter plot (Figure 5). It showed that the constancy of the residuals across values of the independent variables were spread at zero area, which indicated homoscedasticity in the multivariate case.

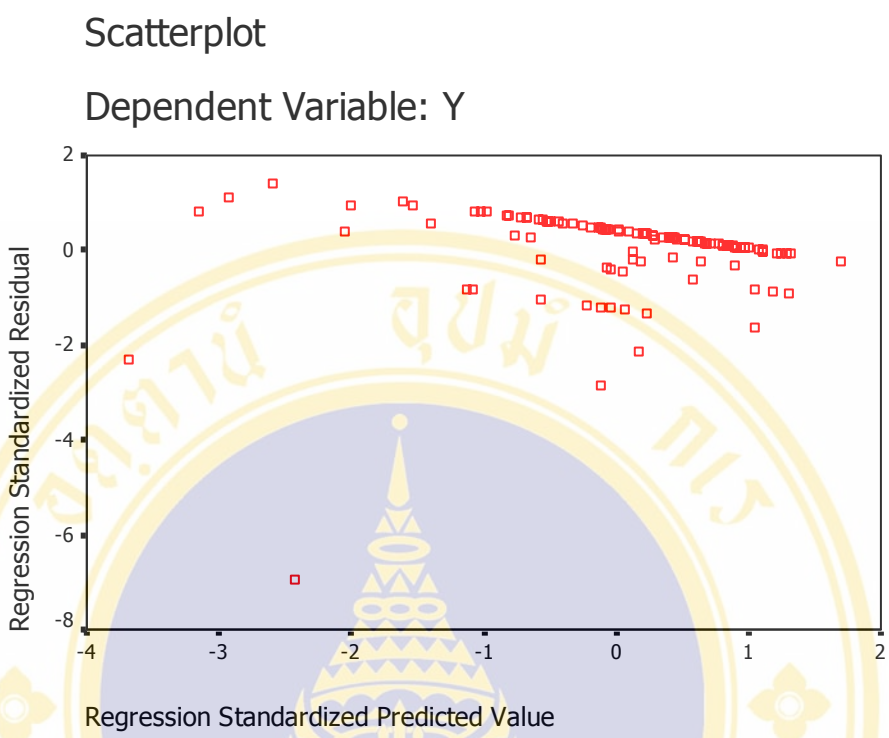

Figure 5 Scatter Plot between Regression Residuals and Regression Predicted Value

3. Multicollinearity

The Pearson's Product Moment Correlation was performed to examine the relationships among independent variables. The results revealed that the highest correlation coefficient among the variables was .40 (Table 11). In addition, the tolerance of a variable was used as a measure of collinearity. The tolerance values were .77 to .95 (Table 15). Therefore, the multicollinearity was not a problem in this study.

Table 15 Unstandardized Coefficients, Standardized Coefficients, t- value, and Collinearity Statistics of Independent Variables, and Constant (N = 110)

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
	B	Std. Error	Beta			Tolerance	VIF
1(Constant)	91.89	4.03		22.81	.00		
Child's age	.35	.44	.08	.79	.43	1.00	1.00
2(Constant)	92.67	4.17		22.22	.00		
Child's age	.37	.44	.08	.85	.40	.97	1.04
Pill burden	-.13	.40	-.03	-.33	.75	.90	1.12
Taste	-5.35	2.18	-.24	-2.46	.02	.97	1.04
Side effects	1.10	1.29	.08	.86	.39	.94	1.06
3(Constant)	71.52	16.96		4.22	.00		
Child's age	.27	.43	.06	.62	.54	.95	1.05
Pill burden	8.76E-03	.40	-.00	-.02	.98	.88	1.13
Taste	-5.74	2.38	-.25	-2.41	.02	.77	1.30
Side effects	-.36	1.37	-.03	-.27	.79	.79	1.26
Social support	.10	.10	.10	1.01	.31	.92	1.09
Knowledge	1.21	.44	.28	2.73	.01	.83	1.21
Ability	-5.11E-02	.17	-.03	-.31	.76	.78	1.28

APPENDIX F

Reasons for Nonadherence

Table 16 Reasons for Nonadherence to Antiretroviral Medication (N= 25)

Item	Frequency
1. I ran out of medicine; didn't come for medicine	3
2. The medicine tasted bad	1
3. I just forgot	4
4. I was worried about the side effects	-
5. There was a change in daily routine	4
6. Too busy with the child	6
7. My child refused to take medicine or spat it out	3
8. There are lots of people looking after the child and I am not away with him/her at the right time	2
9. I did not want others to notice me giving the medicine	1
10. My child was ill	2
11. Don't think child needs it anymore	-
12. Family said someone told them not to give the medicine	-
13. I was ill	-
14. I felt medicine might be harmful to my child	-
15. The child was not staying in the house where the medicine was kept	-
16. I felt depressed	-
17. My child was well	-
18. There was too much medicine to give	2
19. I was away from home	5
20. I was busy with other things	7
21. Other, specify - Child wake up late - Child is out of home - Child's attention to play - Child's complains of large pill	 6 8 2 1

BIOGRAPHY

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