DEVELOPMENT OF QUALITY OF LIFE INSTRUMENT FOR PATIENTS WITH CONTINUOUS MEDICATION

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วรรณา ตั้งภักดีรัตน์ : การพัฒนาเครื่องมือประเมินคุณภาพชีวิตสำหรับผู้ป่วยใช้ยาต่อเนื่อง. (DEVELOPMENT OF QUALITY OF LIFE INSTRUMENT FOR PATIENTS WITH CONTINUOUS MEDICATION) อ.ที่ปรึกษาวิทยานิพนธ์หลัก : ผศ.ภญ.ดร.รุ่งเพ็ชร สกุลบำรุงศิลป์, 151 หน้า.

การวิจัยครั้งนี้มีวัตถุประสงค์เพื่อพัฒนาและทดสอบเครื่องมือวัดคุณภาพชีวิตของผู้ป่วยไทยที่ใช้ยาต่อเนื่อง โครงสร้างของคุณภาพชีวิตเริ่มต้นประกอบด้วยสิบด้านได้จากการศึกษาเชิงคุณภาพของผู้ป่วยที่ใช้ยาต่อเนื่องในโรคเรื้อรัง 24 ท่าน ข้อคำถาม 42 ข้อถูกพัฒนาขึ้น การตรวจสอบ ความตรงเชิงเนื้อหา โดยผู้เชี่ยวชาญ 9 ท่านจากหลายสาขาวิชา เครื่องมือนี้ปรับตามคำแนะนำของผู้เชี่ยวชาญเหลือ 30 ข้อ ได้นำไปทดสอบขั้นต้นในกลุ่มตัวอย่าง 30 ราย ผลทดสอบความเที่ยงมีค่าสัมประสิทธิ์ ครอนบาชแอลฟ่า เท่ากับ 0.783-0.924 ต่อมานำไปทดสอบจริง เก็บจากผู้ป่วย โรคเรื้อรังที่ใช้ยาต่อเนื่องอย่างน้อยหกเดือน จำนวน 530 คน จากโรงพยาบาล 2 แห่งในกรุงเทพเป็นโรงพยาบาลเอกชนและรัฐบาล ใช้แบบสอบถามภาษาไทย 3 ฉบับ คือ แบบวัดคุณภาพชีวิตผู้ป่วยใช้ยาต่อเนื่อง 30 ข้อ แบบวัดสุขภาพเอส เอฟ 36 ฉบับ 2 และแบบวัดคุณภาพชีวิตของ EQ5D3L การตรวจสอบคุณสมบัติการวัดทางจิตวิทยาใช้วิธีการวิเคราะห์องค์ประกอบเชิงสำรวจในการตรวจสอบความตรงเชิงโครงสร้าง รวมถึงทดสอบความเที่ยงของเครื่องมือและความตรงเชิงเหมือน ผลการวิจัยได้เครื่องมือวัดคุณภาพชีวิตผู้ป่วยใช้ยาต่อเนื่องเหลือ 27 ข้อแต่ละข้อมีลักษณะตัวเลือกแบบลิเคิร์ต 5 ระดับประกอบด้วย 6 ด้าน ได้แก่ ด้านรบกวนกิจกรรมประจำวัน ด้านจิตใจ ด้านกิจกรรมทางสังคม ด้านการสนับสนุนจากครอบครัว ด้านผลข้างเคียงจากยา และด้านผลเชิงบวกจากยา ค่าความเที่ยงมีค่าสัมประสิทธิ์ ครอนบาชแอลฟ่า เท่ากับ 0.782-0.912 ความเที่ยงตรงตามสภาพ และคว ามตรงเชิงสอดคล้องเมื่อเทียบกับเครื่องมือวัดคุณภาพชีวิตใช้ยาต่อเนื่องพบว่ามีความสัมพันธ์เชิงบวกกับเครื่องมือวัดคุณภาพชีวิตที่เป็นที่ยอมรับ ได้แก่ แบบวัดสุขภาพเอส เอฟ 36 ฉบับ 2 เครื่องมือวัดคุณภาพชีวิตของ EQ-5D3L และแบบวัดสุขภาพ SF-6D และความสัมพันธ์เชิงบวกกับแบบวัดความร่วมมือในการใช้ยา ผลการวิเคราะห์นี้มีหลักฐานเพียงพอในการสนับสนุนความตรงและความเที่ยงในเบื้องต้นของเครื่องมือวัดคุณภาพชีวิตผู้ป่วยใช้ยาต่อเนื่อง ดังนั้นเครื่องมือวัดคุณภาพชีวิตผู้ป่วยใช้ยาต่อเนื่องเป็นเครื่องมือที่เป็นประโยชน์สำหรับการเปรียบเทียบในกลุ่มผู้ป่วยหลายโรคที่มีการใช้ยาต่อเนื่องในอนาคตได้

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The purposes of this study were to develop a quality of life instrument in Thai patients with continuous medications use (CM-QOL) and to test the psychometric properties of the instrument. Construction of the CM-QOL was initiated using qualitative methodology involving 24 patients with chronic medications use, resulting in tentative 10 domains and an initial pool of 42 items. Content validity was evaluated by 9 experts from various disciplines. After revision based on the comments from the experts, 30 items were included in this instrument. The instrument was piloted in 30 participants, resulting in a Cronbach's alpha coefficient of range 0.783-0.924. Later, 30-item CM-QOL and two well-established instruments: Short Form-36 version 2 (SF-36v2) and EuroQol (EQ5D3L) in Thai were tested concurrent validity in 530 patients with chronic medications use at least six months from two hospitals in Bangkok, one private and one government hospital. Psychometric testing, exploratory factor analysis (EFA) was analyzed the construct validity. Scale reliability, internal consistency, and convergent validity were explored. It was found that 27-item CM-QOL with 5 levels on a Likert scale consisted of 6 domains: daily activity disturbance, mental, social activity, family support, adverse drug reaction, and positive consequence. The overall coefficient alpha of this instrument was in range 0.782-0.912. Concurrent and convergent validity were supported by positive correlations with established instruments (SF-36v2, EQ-5D, SF-6D) and medication adherence scale. These analyses provide preliminary evidence support for the validity and reliability of the CM-QOL for patients with continuous medications use. Therefore, CM-QOL can be a useful instrument for comparison across multiple diseases in patients with continuous medications use in the future.

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

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

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LIST OF ABBREVIATIONS

CM-QOL	Continuous Medication Use- Quality of Life
COPD	Chronic Obstructive Pulmonary Disease
EFA	Exploratory Factor Analysis
EQ5D3L	EuroQol 5 domains 3 levels
HRQoL	Health-Related Quality of Life
NPH	Nottingham Health Profile
OA	Osteoarthritis
QoL	Quality of Life
OTC	Over –The- Counter
QWB	Quality of Well-Being
SF-36	Medical Outcome Study Short Form 36
SF-6D	Medical Outcome Study Short Form 6 Domains
SIP	Sickness Impact Profile

CHAPTER I

INTRODUCTION

Background and rationale

With the growth of urban life, many people have the inappropriate lifestyles such as poor eating habits (fast food and fatty foods), less rest, lack of exercise, and lack of time for self-care that are a major cause of the increasing trend of chronic illnesses like hypertension, stroke, arthritis, diabetes, dyslipidemia, and heart disease. Patients with chronic diseases can be controlled their stages of diseases but are commonly not cured. About 80% of chronic disease deaths take place in low and middle income countries (WHO, 2011). Mortality rates from chronic diseases have increased dramatically in Thailand and also according to report by the 2006 Health and Welfare Survey of the Population and Social Statistics Group, Thailand National Statistics Office, represents 16% of the total Thai population has some form of chronic disease and 35.6% among those aged 45 and over (Kaufman, Chasombat, Tanomsingh, Rajataramya, & Potempa, 2011). Three-fifths of Thai adults have at least one risk factor of cardiovascular problems. Most of them have also comorbidities along with hypertension, diabetes and hyperlipidaemia (Wanitkun, Batterham, Vichathai, Leetongin, & Osborne, 2011). Currently, chronic diseases are the main causes of mortality and disability in population that need long term therapy. Treating with medication is necessary to patients with chronic diseases who could not be treated only with lifestyle modifications because these drugs are the helpful effects such as the treatment, prevent complications, or relieving symptoms of chronic diseases. On average, 50% of all people on chronically used drugs are not taking their medications as prescribed properly (Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). Numerous studies have shown that appropriate chronic medications can reduce symptoms and prevent or delay the onset of complications and also resulting in improved health-related quality of life and workplace productivity (Goldfarb et al., 2004a).

Most chronic patients take on multiple medications for these conditions. Some need less and some need more items. Some use once, some use shorter and some use longer period. Due to more expectation from the used medications, some patients visit multiple physicians resulting known as polymedicine and some consult many pharmacists on prescriptions and buy over-the-

counter (OTC) medications called as polypharmacy that may affect patients' quality of life (Pippalla, Chinburapa, Duval, & Akula, 1997). Patients with long term or continuous medications may be suffered from multiple barriers such as medication regimens complexity, their own side effects, cognitive impairement, poor health literacy and lack of financial support. These barriers can impact adherence rates (P. S. Odegard & K. Capocciak, 2007). Patients with nonadherence can occur underuse, overuse, or misuse chronic drugs. The most common factors on therapeutic non-compliance can be classified to patient-centered factors (forgetfulness, physical difficulties), therapy-related factors (treatment complexity, duration of the therapy, drug side effects), social and economic factors (cost of therapy, family support), healthcare system factors, and disease factors (absence of symptoms). (Jin, Sklar, Min Sen Oh, & Chuen Li, 2008). Moreover, the difficulties in managing varied chronic drug regimens still cause poor adherence. (Jin, Sklar, Min Sen Oh, et al., 2008; P. S. Odegard & K. Capocciak, 2007). With chronic disease management, most patients have still medication-related problems. Some make their own decisions by evaluating between the risks and beneficial effects of medicines use without necessarily counseling their doctors. For instant, antihypertensive medications are associated with side effect as dizziness, lethargy, headache on awakening, diurnal polyuria. Those patients accept the possible adverse reaction but some patients decide to stop taking medications. (K. Gordon, F. Smith, & S. Dhillon, 2007). In such a case, the patients with undesired effects may lead to the principal cause of drug therapy problems.

In today's society, health care systems have recognized that pharmacists need to take responsibility for drug therapy outcomes (Hepler & Strand, 1990). This indicates that opportunities exist for pharmacists to provide pharmaceutical care services that would be valued for patients who taking long-term medication. To effectively function, pharmacists have to be sensitive to patients' need and thus require an adequate tool to assess patients as well as detect patient's problems including therapeutic outcomes. Health related quality of life is a commonly used instrument for monitoring outcomes of medication use. Currently, there are many quality of life instruments that can be evaluated by patients' perspectives of their disease and treatment.

The term "health-related quality of life (HRQoL)" is understood to be the value assigned to the duration of life, modified by social opportunity, perceptions, functional status and disability

caused by disease, accident, treatment or other event (Guyatt, Feeny, & Patrick, 1993). Although there are differences between the definitions of HRQoL, QoL, and health status, the terms are frequently interchanged. Nowadays, HRQoL involves domains (aspects) that can be shown to affect health. HRQoL defines as a multidimensional concept, a patient-reported outcome, that includes domains related to the functioning and perceived well-being in the physical, mental and social domains of daily life (Nichol & Harada, 1999). There is still no universally agreed definition of health-related quality of life and then it is a broad constructs. HRQol instruments can be evaluated in both objective measures of functioning or health status such as physical functioning, daily role and subjective perceptions on health such as spiritual aspects, mental domains (Testa & Simonson, 1996). The development of standardized and validated questionnaires has made it possible to utilize HRQoL measures systematically, with a reliability and validity comparable to the laboratory values or clinical observations (P.M. Fayers & Machin, 2000). The HRQoL instruments are classified as either generic or specific (P.M. Fayers & Machin, 2000; Guyatt, et al., 1993). An instrument for measuring quality of life usually consists of a series of questions or items grouped within domains of related attributes.

Nowaday, there are numerous validated generic questionnaires such as the Medical Outcome Study Short Form (SF-36, SF-12), Nottingham Health Profile (NPH), Sickness Impact Profile (SIP), the Quality of Well-Being (QWB) Scale, the EuroQol instrument (EQ-5D), and so on. Two major types of these instruments are named generic instruments and disease or specific instruments. Generic instruments are applicable to general conditions, so the investigators can use compare among patients with different illnesses and health statuses. Although specific quality of life questionnaires are more sensitive than generic tools on the same conditions they could not explore the difference of quality of life in vary patients. Health care professionals widely use specific questionnaires to monitor the effect of drug therapy at different times(P.M. Fayers & Machin, 2000; Guyatt, et al., 1993). Some researchers apply both generic and specific instruments in their study because there is no one questionnaire that can test every condition.

Before using the quality of life questionnaire, the validity and reliability test still need to analyze further in target population. Designing the study should be concerned if there are many items in questionnaire resulting in both validity and reliability, too.

Several studies have shown that health care team including physicians, pharmacists, nurses and other healthcare professionals in collaboration drug therapy management can help increase adherence to medications for patients with chronic diseases and also improve patients' quality of life (Isetts et al., 2006; Tunpichart, Sakulbumrungsil, Somrongthong, & Hongsamoot, 2012; Winkeljohn, 2010). The treatment outcome in patients with chronic disease cannot be cure, but improve the patients' well-being. The pharmacist's role needs to detect direct patient's outcome of medication treatment using the quality of life instruments.

Previously, most measuring HRQoL in patients do not focus more on medication use aspects. Generally, these instruments assess a measure of the impact of patients with chronic diseases on their quality of life. From the previous literature, it has been shown that depression increased the risk of disabling disease and daily role functioning and was the most commonly affected HRQoL domain in patients with eight chronic conditions (hypertension, diabetes, heart disease, stroke, OA knee, other joints, asthma/COPD, and depression) by using a generic instrument, known as COOP/WONCA charts (Lam & Lauder, 2000). This questionnaire is simple and self reported in six scales including physical fitness, feelings, daily activities, social activities and overall health.

The pharmacotherapy aspect in the HRQoL instrument has not been given much attention. For instance, a systematic review about HRQoL of women with polycystic ovary syndrome found that there were nine studies used a standardized instrument as follows: 12 (63.2%) papers used generic quality of life instruments and 8 (42%) used the disease-specific polycystic ovary syndrome tools. In addition to few studies may not be adequate for using specific tool in the outcomes assessment of treatment for this disease (Jones, Hall, Balen, & Ledger, 2008). Several generic and disease-specific instruments have been used in measuring HRQoL associated with endometriosis and its treatment. Generic HRQoL instruments commonly cited are the SF-36 and SF-12. The utility measure, EQ-5D, has also been used. In addition to an endometriosis-specific questionnaire developed by a group of clinicians, the Endometriosis Health Profile-30 (EHP-30) and the Endometriosis Health Profile-5 (EHP-5), a brief version of the EHP-30, are recently available for the assessment of HRQoL in patients with endometriosis. The instrument used for endometriosis which has also evaluated the context of pharmacologic

treatment on HRQoL was developed by Zhao and colleagues but was not validated (Gao et al., 2006).

Medication therapy can increase patients' HRQoL level because long-term medication uses can improve symptoms e.g., improvement dyspnea with theophylline use (Mahler, 2000), pharmacological treatments for endometriosis improve psychological functioning, pain, vitality, physical functioning, and general health (Gao, et al., 2006). The chronic liver disease has been performed in many studies by using both generic quality of life tools (SF-36, Nottingham Health Profile; NHP) and disease quality of life tools (the Hepatitis Quality of Life Questionnaire (HQLQ),the Chronic Liver Disease Questionnaire (CLDQ), the Liver Disease Quality Of Life Questionnaire (LDQOL), and the Liver Disease Symptom Index 2.0 (LDSI 2.0)). There is still lack of therapy related domains of patients with chronic liver disease (Gutteling, de Man, Busschbach, & Darlington, 2007).

The pharmaceutical therapy-related quality of life (PTRQoL) concept has been developed to represent the negative biophysiological or psychosocial effects from patients' experience towards using pharmaceuticals and/or receiving pharmaceutical services. Pharmacists need to have an instrument that can measure sensitive to change than the traditional HRQoL instruments such as pharmacy intervention (Murawski & Bentley, 2001). However, the PTRQoL is a useful tool for drug use, some difficulties concerning the continuous use of medication are not of its interest.

To learn about the impact of a particular medication regimen or a particular pattern of pharmacotherapy specific to each disease, one can use the disease specific QoL instrument. Many different instruments have included the pharmacotherapy aspect as a measure for quality of life in patients (Gao, et al., 2006; Mahler, 2000; Nichol & Harada, 1999). However, most of them are focused on aspects specific to the disease being studied, thus comparison across different health conditions or different diseases would not be appropriate and there will be no value when used these pharmaceutical related questions in separation of the disease specific QoL measure that they are a part of. Some of them have some limitations, like Zhao's study. The HRQoL associated with medication therapy has not been validated and might be too broad. Measuring quality of life in patients with continuous medications should take into consideration the aspects of impact on

medication use. However, systematic validation of a single generic QoL instrument covering a set of domains that are thought to be relevant to quality of life of patients taking continuous medication is needed for studying how it has impacts on patients. Developing a generic instrument with the focus on continuous medication will provide a tool for pharmacists to monitor the effect of drug factors on patients' quality of life and can make comparison across different health conditions as well as different medication regimens. It is possible that Health-Related Quality of Life (HRQoL) instruments has become as a principal indicator of the effectiveness of medication treatment especially in case of lifelong therapy or chronic disease.

Patients taking continuous medications have been indicated as having a significant impact on health-related quality of life. The effect of continuous medication use on well-being view is the main issue for planning healthcare intervention and provides valuable information for policy maker in decision-making process. Therefore, it is important that outcome measures for medication use not only measure adherence rate, but also evaluate patients' perception of their condition and associated impacts. The quality of life instrument for continuous medication use, has been few widely used. In addition, the instrument which intended to measure perception of lifelong medication use it have published slightly validity and reliability test (Debavalya et al., 2008; MacKeigan & Pathak, 1992). As mentioned, both aspects and the instrument are in need of validation. One problem that is difficult progress in this area is the lack of conceptual models that specify how different things of patient outcome measures interrelate. Because there was no instrument designed specific to measuring HRQoL in patients with continuous medications directly.

This research was designed the development of a new instrument for measuring quality of life in Thai patients with continuous drug use. The new instrument was intended to develop as the quality of life with continuous medication use (CM-QOL) instrument, so these scales can be measured and generalized across different diseases with the same sensitivity as a condition (specific) instrument.

Research questions

1. What are the quality of life domains for continuous medication use?
2. What are the items of each domain?

Purposes of the study

1. To identify quality of life domains for continuous medication use
2. To develop quality of life items for patients with continuous medications
3. To test the psychometric properties of the new instrument in patients with regular medication use including:

    3.1 Construct validity of the new quality of life instrument in patients with continuous medication use

    3.2 Internal consistency reliability of each domain of the new quality of life instrument in patients with continuous medication use

    3.3 Criterion-related validity of the new quality of life instrument in patients with continuous medication use by comparing this new instrument with SF-36V2 in Thai, EQ-5D3L in Thai, SF6D and Adherence score

Expected Benefits:

1. Health care providers can use information based on the patients' perspective in order to make decision in the management of individual patients and guide the treatment plans.

2. The developed instrument will be beneficial to measure outcomes of pharmaceutical care process/intervention for monitoring the outcome in routinely used treatment.

3. The effective instrument can assess therapy effectiveness across populations both directly and indirectly.

Operational definitions

Continuous medication use is referred to an ongoing incident of taking a medication during the period of at least six months by a patient.

Quality of life of continuous medication use is defined as the patient's sense of his own well-being, satisfaction of life through the process of perception and self assessment regarding continuous medication use.

Reliability is defined as internal consistency reliability that gives an estimate of the equivalence of sets of items from the same test (e.g., a set of questions aimed at assessing quality of life or adverse drug reaction). Cronbach's alpha is the coefficient commonly used to estimate the reliability of instruments based on internal consistency (P.M. Fayers & Machin, 2000; Kimberlin & Winterstein, 2008).

Validity is defined as the extent to which an item or measure accurately assesses what it is intended to measure (P.M. Fayers & Machin, 2000; S. S. Sen, G. V. Gupchup, & J. Thomas, III., 1999).

Construct Validity is referred to the extent to which an item or measure accurately represents the proposed construct (P.M. Fayers & Machin, 2000; S.S. Sen, et al., 1999).

Content Validity Index (CVI) is defined as a quantitative assessment of the degree to which the item or measure is content valid by an evaluation of a panel of experts (J.S. Grant & L.L. Davis, 1997).

Criterion-related validity is referred as an item or scale is required only to have an empirical association with some criterion or gold standard (P. M. Fayers & Machin, 2007).

Scope of the study

This research was designed as a cross-sectional study. Regarding developing the new quality of life questionnaire was conducted in chronic patients with continuous medication use. The setting of the study was conducted in Bangkok, selected one private hospital and one government hospital outpatient clinic which represented the population of Thai patients with continuous drug use.

CHAPTER II

LITERATURE REVIEW

To study about developing quality of life questionnaire in patients with continuous medication, this chapter is comprised of 3 main parts that are continuous medication use and the effect on the patient's life, conceptual model of pharmaceutical therapy-related quality of life, and guideline development and testing of the quality of life instrument. The theoretical and conceptual framework of this study is also described.

Part I: Continuous Medication Use and Health-Related Quality of Life

Because of continuously improving medical treatment, today many serious diseases have become lifelong illnesses. Chronic diseases or chronic conditions are an emerging health problem throughout the world today. Increasing incidences and prevalence of chronic diseases, especially diabetes, heart disease, cancer, obesity and hypertension, are evident in many countries. In case of Thailand, there are many changes in the way people live, which include work, relaxation, family and housing and food regarding eating habits which lead to chronic diseases. Older age groups more often reported chronic diseases especially diabetes and hypertension (Tanvatanakul, Saowakontha, Amado, & Vicente, 2007). According to screening assessment of the elderly in rural Thailand by a mobile unit, about 58% of hypertensive persons and 75% of those with diabetes were first detected during the survey (Swaddiwudhipong et al., 1996).

As any asymptomatic chronic disease, adherence or compliance to medical therapy tends to decrease when using with long term period. In addition, non-compliance can reduce the benefits of treatment. Adherence rates to long-term treatments for chronic diseases vary with an estimated average adherence of 50% (Varmeire, Hearnshaw, Van Royen, & Denekens, 2001).

Adherence barriers to diabetes medication use list the patient-, medication-, and provider-related barriers to medication taking, which are frequently discussed in the literature as follows (P.S. Odegard & K. Capocciak, 2007).

Patient factor (S. S. Sen, G. V. Gupchup, & J. Thomas, 3rd)

- Fears: disease worsening, hypoglycemia, needles, social stigma, weight gain
- Knowledge and skill: education
- Self-efficacy
- Health beliefs
- Depression
- Lack of confidence in immediate or future benefits of the mediation
- Remembering doses and refills

Medication factor

- Complexity of regimen (e.g., more than 1 DM, splitting tablets, drawing up insulin)
- Frequency of dosing (2 or more times daily results in poorer adherence)
- Cost
- Adverse effects

Provider or system factor

- Fear that patient will not be able to use therapy
- Knowledge: medications, use of insulin, monitoring, diabetes treatment
- Skill: able to demonstrate proper use of devices
- Inadequate educational support
- Inadequate follow-up resources

Disadvantages of non- adherence in patients with chronic illness are suffering patients' disease, decreased quality of life, and loss of health care resources (Goldfarb et al., 2004b).

Continuous medication use and the effect on the patient's life

In case of the prevalence and character of medication-related symptoms in primary care, the researchers found that 37% of symptoms occurred with every dose, and 93% persisted for 1 month or more. The most frequently identified side effects were gastrointestinal problems, fatigue, dizziness and problems with balance, and rash or itching. Doctors changed medication treatment when patients complained regarding muscular pain, insomnia, abdominal pain, and urticaria or itching (Weingart et al., 2005).

The study regarding medication-related problems from the perspective of patients with a chronic condition was found that under-use of medicines was commonly associated with the use of diuretics. Patients who taking diuretics complained frequent urination resulting an inconvenience, which could be a barrier to their activities. Patients perceived a need of these drugs, then they intended to use continuously. Lifelong diuretics use could relieve symptoms of disease e.g., swelling of the feet, breathing difficulties, etc. (Karen Gordon, Felicity Smith, & Soraya Dhillon, 2007)

Confusion over multiple medications, complex medication regimens and poor counseling by medical personnels can lead to non-adherence such as depression, confusion or difficulty in swallowing medications. Limited a person's ability was the obstacle of continuation to access supply. Moreover, failing eyesight reduced the ability to read instructions, hearing loss limited ability to hear directions or willingness to ask questions. Patients may stop medications because of no financial support and psychological factors: fears of dependence or fears of long-term effects (such as some patients in Malaysia believed long term use of 'Western' drug was harmful) or side-effects (Jin, Sklar, Sen Oh, & Li, 2008).

The World Health Organization (WHO) defines health as "a state of complete physical, mental, and social well-being". The humanistic outcome of therapy that is evaluated by the patient's perspective about perception of feeling. Valuable information can be a guideline in order to improve patient's well-being. Conceptual health-related quality of life (HRQoL) instruments is still broad health aspect. This is consisted of physical, mental, and social well-being domain.

Some studies gather difficulty daily activities, social burden and role functioning in health-related quality of life concept. (Bryant, Schunemann, Brozek, Jaeschke, & Guyatt, 2007).

The importance of HRQoL measurement has been found that the instrument selected measures the health dimensions relevant to that particular set of patients (Wilson & Cleary, 1995). QoL information is most valuable in the assessment of drug treatment under the following circumstances (MacKeigan & Pathak, 1992).

1. When the primary objective of a drug is palliative rather than curative, as is often the case in chronic disease. For example, a randomized clinical trial of auranofin therapy and QoL in patients with rheumatoid arthritis demonstrated that, by the fourth month of treatment, patients receiving auranofin plus conventional therapy had a QoL (as assessed by the Quality of Well-Being Scale) that was superior to the QoL of those receiving conventional treatment alone.
2. When a drug is somewhat effective but is also fairly toxic. The question to be answered here is, Do the present QoL benefits of the therapy outweigh the QoL losses induced by adverse effects? This question is one with which cancer patients fight when decided whether to undergo chemotherapy.
3. When lifelong therapy is administered to prevent complications of a relatively asymptomatic disease (such as when anticholesterolemic drugs are administered to reduce atherosclerosis and so prevent myocardial infarction and stroke). The patient may ask whether the present impairment in your QoL (caused by the drug therapy) is worth the abstract reduction in risk that has been promised.
4. When there are several equally effective therapies for a specific condition but the adverse effect profiles differ. In case of, QoL data help to answer the question, Which treatment impairs QoL the least? A treatment decision for soft-tissue sarcoma illustrates this issue and also demonstrates the fallacy of assuming that QoL can be assessed intuitively. The two treatment options were limb amputation or local surgical excision followed by adjuvant radiotherapy. It was assumed that a treatment that spared the limb would produce a better QoL than amputation; however, this was not the case. Radiotherapy was found to disrupt both mobility and sexual functioning to the extent that patients' QoL was worse than if the limb had been amputated. As a

result, oncologists developed modified limb-sparing procedures (consisting of a combination of surgery, radiotherapy, and physical therapy) that improved patients' QoL.

QoL and pharmaceutical care

Helper and Strand provided their popular definition of pharmaceutical care, which described it as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life " (Hepler & Strand, 1990). This definition, which placed QoL in the core of the pharmaceutical care philosophy, was subsequently adopted worldwide. QoL analysis is useful for investigating the social, emotional, and physical effects of treatments on daily living from the perspective of the patient. Many studies that showing clinical pharmacy services, such as asthma management, hypertension, have a positive impact on HRQoL benefit (Pickard & Hung, 2006). Recently, the professional of pharmacy has been presented with the opportunity and challenge of ensuring that drugs are used to 'optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug reactions' through medication therapy management (MTM) services described in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003("Summary of the Executive Sessions on Medication Therapy Management Programs: Bethesda, Maryland, June 14 and August 18,2004," 2005).

The study (Debavalya, et al., 2008) regarding the impact of home care pharmacy services in Thai diabetic patients found that quality of life of the intervention group (received medication counseling and home visit monthly for 3 months by a pharmacist) was higher than the control group ($p=0.014$). Adherence to treatment of the intervention group also increased and patient's satisfaction was good. HRQoL instrument was developed from questionnaires of Diabetes Control and Complication Trial (DCCT). There were 3 domains as follows: activities about diabetic disease satisfaction, sense of diabetic condition, and worry issues.

HRQoL as a patient-reported health outcome is generally considered a multidimensional construct that includes physical, mental, and social functioning, as well as perceptions of general

well-being. There are two main types of HRQoL instruments: generic and disease-specific questionnaires (P.M. Fayers & Machin, 2000; Guyatt, et al., 1993).

1. Generic instruments (SF36, Nottingham Health Profile, Sickness Impact Profile) are designed to assess the many dimensions of health-related issues and are used for health policy research. EuroQol (EQ5-D) is another general purpose instrument, using as both simplicity and the multi-country aspects. Table 1 lists some examples of each type of questionnaire, with their applications, strengths and weakness (Kheir, Foppe van Mil, Shaw, & Sheridan, 2004).

2. Specific instruments (domain/disease-specific, population-specific, function-specific, symptom- specific or *ad-hoc* scale pertinent to one study only) measure only a specific area of quality of life, rather than assessing quality of life globally. For instance, some of the commonly used FACT-G (Functional Assessment of Cancer Therapy-General), FLIC (Functional Living Index: Cancer) and EORTC-QLQ-C30 (European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire-Core 30).

Table 1: Examples of quality of life measurements

Measure	Example	Application	Strengths	Weakness
Generic	Short Form (SF-36), The EuroQOL, Nottingham Health Profile, The Sickness Impact Profile (SIP)	Wide variety of populations	- usually a single instrument - established reliability and validity - allow comparison between conditions or interventions	- Do not focus on area of interest - May not be responsive
Disease-specific	The Asthma Quality of Life Questionnaire, Arthritis Impact Measurement Scale, Inflammatory Bowel Disease Questionnaire	Focus on problems associated with specific diseases, patient groups or areas of function	- clinically sensible - may be more responsive than generic instruments	- Do not allow comparison between conditions - Limited in terms of populations and conditions

The choice of HRQoL instrument depends on the type of study being conducted. The optimum properties of a HRQoL scale are determined by the purpose for which it is put. There is no such thing as a "best tool" in an absolute sense, only tool best suited to a particular purpose. If no scale is suited for a particular purpose, then researchers design new tool according to requirements of the study including the desirable criterion of an ideal and gold standard HRQoL tool (P.M. Fayers & Machin, 2000).

HRQoL concerns those attributes valued by patients. There are attributes regarding sense of well-being, physical, emotional, and intellectual function. Moreover, the degree to which individuals ability to participate in activities within the family, in workplace, and in the community are also aspects. Many literatures have been studied as follows:

Research on health-related quality of life in patients with chronic condition

The study about the impact of eight chronic diseases (hypertension, diabetes, heart disease, stroke, OA knee, other joints, asthma/COPD, depression) on the HRQoL of Chinese patients was used data analysis with the COOP/WONCA charts. These charts consisted of one chart each on physical fitness, feelings, limitation in daily activities, limitation in social activities, overall health and change in health. The scores of each of the five COOP/WONCA charts were grouped into two categories (optimal and sub-optimal) for analysis. The optimal category consisted of scores 1 and 2 and the sub-optimal category consisted of scores 3, 4 and 5 for charts on physical fitness, feelings, daily activities and activities. Scores 1, 2 and 3 were grouped into the optimal category, while scores 4 and 5 were grouped into the sub-optimal category for overall health chart. The results showed that the difference in the feelings scores and social activities scores were statistically significant for depression. Increased risk of limitations on daily activities was associated with stroke (OR = 1.8771), OA (OR = 1.5867), disease of joints other than the knees (OR = 2.0187) and asthma/COPD (OR = 2.1679). OA also increased the risk of sub-optimal overall health (OR = 1.7927). The study concluded that depression was the most disabling disease, and OA had more impact on the HRQoL than many other chronic diseases(Lam & Lauder, 2000).

Systematic literature review of the health-related quality of life (HRQoL) burden of endometriosis in adults and adolescents was revealed that generic instruments (SF-36, SF-12) most commonly used. The EQ-5D was also studied to measure utilities. The Endometriosis Health Profile-30 (EHP-30) and its subset, the EHP-5, have been recently developed for use in endometriosis studies. In addition, the study revealed that drug and surgical treatments for endometriosis improved patients in aspects of physical functioning, psychological functioning, vitality, pain level, and general health. Few studies used disease specific instruments to characterize the HRQoL burden of endometriosis, addressed the HRQoL impact of endometriosis-related infertility, and examined endometriosis in adolescents. Lack of validity test of disease specific tool needed to explore further such as Zhao and colleagues developed their own endometriosis-related HRQoL instrument which has been evaluated in the context of pharmacologic treatment on HRQoL (Gao, et al., 2006).

Part II: Conceptual model of pharmaceutical therapy-related quality of life

Pharmaceutical Care is a patient-centered, medication management therapy outcomes needs the pharmacist to collaborate with healthcare personnels monitoring and plaining patients. The responsible managements are to promote health, to prevent disease, and to monitor. Moreover, reconciliation of medication use ensures that patients are safe and effective. The goal of Pharmaceutical Care is to optimize the patient's health-related quality of life, and achieve positive clinical outcomes, within realistic economic expenditures (Helper & Strand, 1990). Today, Health-related quality of life (HRQoL) is increasingly utilized as an evaluative outcome in medical treatment. HRQoL has become an indicator for evaluating drug therapy especially palliative drugs use with lifelong therapy or chronic disease (MacKeigan & Pathak, 1992).

Health-related quality of life represents the effects of a disease and its treatment as perceived by patients. Treatment effectiveness study was included in the concept of quality of life dramatically. A primary outcome evaluation valued the subjective aspects of health (Hickey, Barker, McGee, & O'Boyle, 2005). Medication-taking does influence a patient's quality of life, so measures of HRQoL should detect the effect. Unfortunately, available instruments may not be adequately responsive to medication use effects, in addition to being influenced by non-pharmaceutical factors. The evolution of Pharmaceutical Therapy-Related Quality of Life (PTRQoL), a new conceptual construct, is developed by Murawski and Bentley (2001). Underlying assumption that as a consequence of the experience of the disease (chronic illness), the patient's HRQoL decreases (post-disease, pre-treatment HRQoL). (Figure 1) Thus, before being a disease, HRQoL exists prior to the onset of disease (pre-disease HRQoL). As a consequence of the event of the disease, as known as disease effect, the patient's quality of life will decrease (post-disease, pre-treatment HRQoL). If the pharmaceutical therapy provided constituted perfect therapy, e.g., the drug was absolutely curative and the only effects produced were positive and free of burden, then patient HRQoL would be restored to the pre-disease level (theoretically maximal obtainable post-treatment HRQoL). But treatments are rarely, if ever, perfect. Especially for chronic conditions, restoration of the original, pre-disease levels of patient quality of life may not be feasible. Thus, post-treatment HRQoL improves to some level less than the original, pre-disease state. But observed post-treatment HRQoL is expected to lie at some point below this theoretically maximal obtainable post-treatment HRQoL due to side effects, adverse drug reactions, mental or emotional costs, or other sequellae of medication-taking. There is the discrepancy between the theoretically maximal obtainable post-treatment HRQoL determined by a pharmaceutical's therapeutic efficacy (positive effect) and observed post-treatment HRQoL (positive effect less negative consequences of use) that establishes in conceptualization of PTRQoL (Gap = Inherent burden = PTRQoL).

This construct, PTRQoL, is thought to be composed of 2 general dimensions: (1) negative consequences due to medication structure and biophysiological actions (familiar side effects and adverse drug reactions) and (2) psychosocial consequences of medication use and the experience and memory of medication use.

Negative consequences due to medication structure and biophysiological actions may reduce patient well being and limit the benefits of therapy such as nausea, hair loss, impotence, or sedation. Psychosocial consequences dimension can have an impact on the patient's quality of life. In the process of taking a medication, patients may have many worries (e.g., stress, fear, anxiety with the consumption of drugs) that may influence their social and psychological well being. The wide gap will demonstrate that the pharmaceutical therapy is more harmful. Thus, the total treatment effect, e.g., the actions and effects of medications or pharmaceutical services, may be decomposed into two major components: the therapeutic effect and the inherent burden, or PTRQoL. To obtain the optimal therapy outcome, we should minimize the disadvantage of medication use (as well as minimize inherent burden) (Murawski & Bentley, 2001).

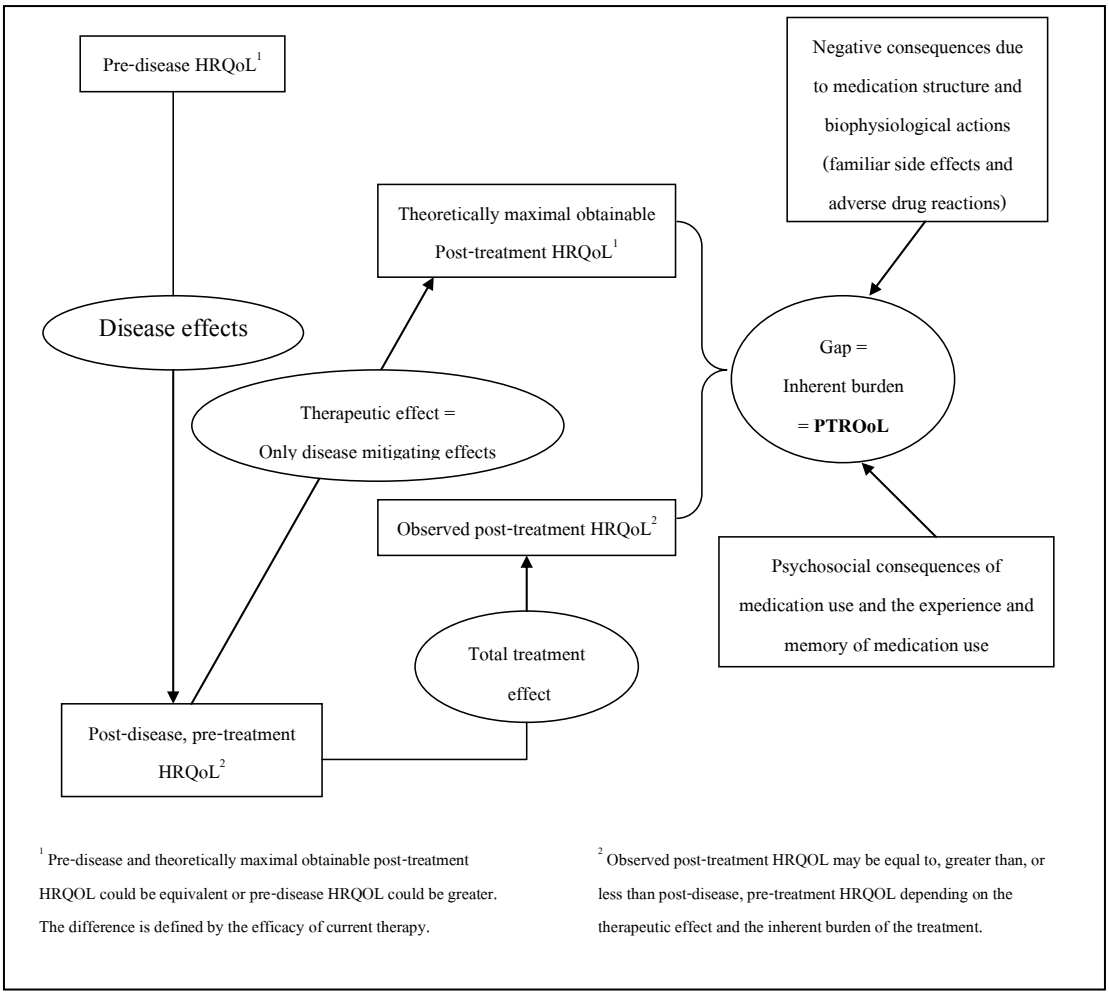


Figure 1: Negative and psychosocial consequences of medication use constitute the "inherent burden" = PTRQoL

To better characterize what health-related QoL instruments measure, Wilson and Cleary developed a model that identifies the conceptual approaches used by various instruments (Wilson & Cleary, 1995). This conceptualization shows that a model of patient outcomes, linking clinical variables to QoL. The arrows indicate the dominant causal associations. The main components are the five boxes in the middle of the figure. The first box, biological and physiological variables, focuses on the function of cells, organ, and organ systems (Figure 2). Examples include the following: diagnosis such as pulmonary tuberculosis; laboratory values such as serum creatinine; measures of physiological function such as pulmonary function tests. The second box is symptom status, which refers to physical, cognitive, and emotional symptoms perceived by the patient. The third component is functional status, which includes functioning in psychologic and

social domains, as well as physical functioning. Measures of function assess the ability of the individual to perform particular defined tasks. The next box, general health perceptions, refers to the integration of all the health concepts that precede it, as perceived by the patient. The final box, overall QoL, refers to patients' own evaluation of their QoL, such as how happy or satisfied they are with life as a whole. This would include measures of life satisfaction and global QoL. The outcomes are linked causally and the model further propose that characteristics of the individual and characteristics of the environment can influence the components of the model.

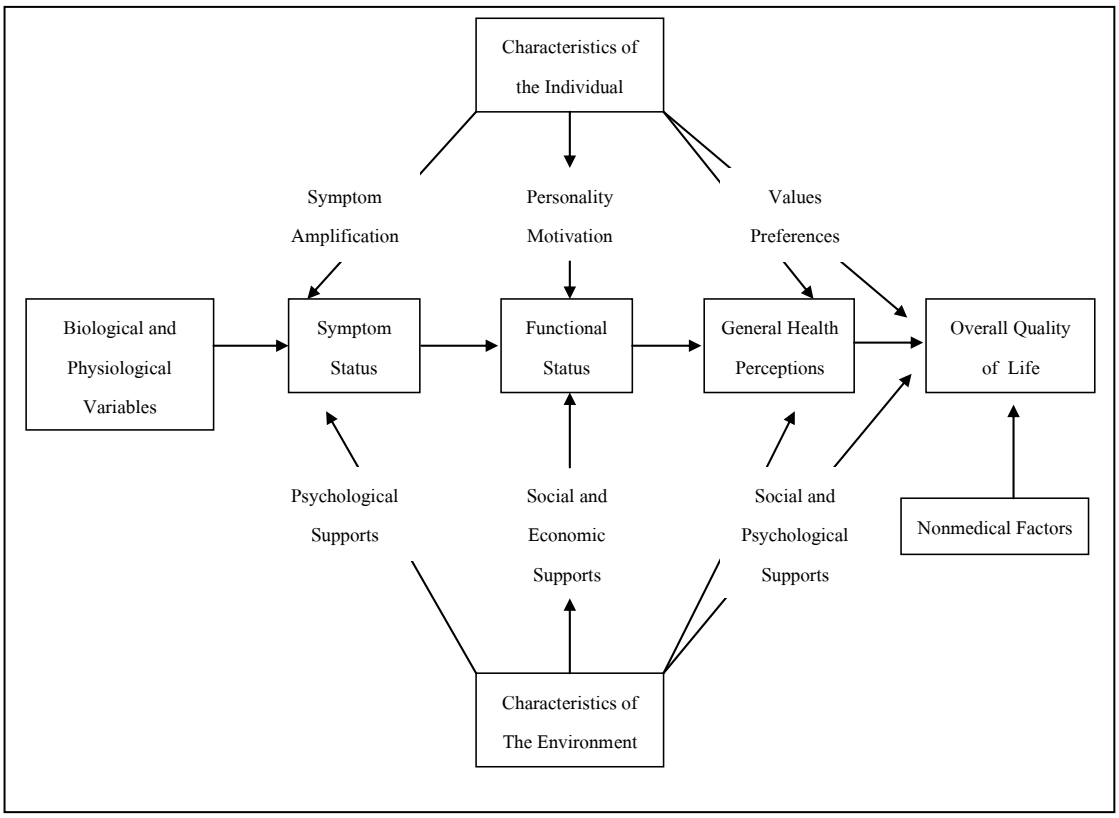


Figure 2: Relationships among measures of patient outcome in a health-related quality of life conceptual model.

Part III: Development and testing of the quality of life instrument

This section will be described methods for developing and testing new QoL instruments (P.M. Fayers & Machin, 2000; Juniper, Guyatt, & Jaeschke, 1996; Leurmarnkul, 2000).

I. Instrument development

1. Construct definition HRQoL
2. Specifying measurement goals
3. Identification of subscales
4. Item generation
5. Item reduction
6. Instrument format and response choices

II. Instrument testing

7. Pretesting
8. Reliability
9. Validity
10. Responsiveness

Instrument development

1. Construct definition HRQoL

Before the development of any new instrument, the investigator should define clearly meaning HRQoL. It must be taken as to what is included in the domain of the construct and what is excluded from this domain.

2. Specifying measurement goals

The investigator should consider at least the following criteria.

1) Defining the target population: A detailed definition might include age, literacy level, language ability, and presence of other illness that might have impact on HRQoL.

The investigator may be thinking of a particular study in which the instrument is to be used, but constructing an instrument for too specific a population or function may limit its subsequent use. One can usually choose a patient population that is narrow enough to allow focus on important impairments in that disease or function but broad enough to be valid for use in other studies.

2) Primary purpose: The researcher needs to determine the main objective of the instrument as evaluative, discriminative, or predictive instrument. It is difficult to achieve maximum efficiency in all three objectives in one instrument (Juniper, et al., 1996). The investigator needs to make a suitable judgement. Primary purposes of each type of instrument were below:

A. Evaluative instrument: It will be used to measure changes in the quality of life of an individual or a group over time. Evaluative instruments are used to quantify the benefit of a treatment during a clinical trial or the benefit of a community intervention (Juniper, et al., 1996; S.S. Sen, et al., 1999).

B. Discriminative instrument: This instrument distinguishes among individuals or groups on the basis of some underlying dimension at one point in time. Discriminative instruments can be used in surveys to distinguish among communities according to their health status (Juniper, et al., 1996; S.S. Sen, et al., 1999).

C. Predictive instrument: Scales may also be designed to predict future outcomes for patients(P.M. Fayers & Machin, 2000). Predictive instruments are used to classify individuals into a set of predefined measurement categories when a "gold standard" is available, either concurrently or prospectively, to determine whether individuals have been classified correctly. Predictive HRQoL instruments are generally used as screening or diagnostic tests to identify which individuals have or will develop a specific condition or outcome (Leurmarnkul, 2000; S.S. Sen, et al., 1999).

3) Other considerations: The researcher should also consider on the format of the instrument. There were designed as interviewer and/or self-administered. Some researchers used by the telephone interviews. In addition, the investigator should weigh up the numbers of items in the developed questionnaire.

3. Identification of subscales

This well thought through theory starts with construct conceptualization/definition based on a review of the literature (P.M. Fayers & Machin, 2000). This process will help investigator to know the construct as domains/dimensions/subscales/factors.

4. Item generation

The first phase of developing a QoL instrument is to generate a large pool list of all QoL issues that are relevant to the domains of interest, using literature searches, interviews with healthcare workers, and discussions with patients. After identifying all of the relevant topics, the first task is to create a pool of all potentially relevant items. There is no rule for the size of the initial item pool. From this pool, the researcher will later select items for inclusion in the final questionnaire. Mostly used methods of item generation are interviews with patients, focus group discussions, a review of the quality of life instrument literature, interview with health care professionals, and a review of generic HRQoL instruments (Juniper, et al., 1996).

5. Item reduction

Perfectly, an instrument should be brief, should cover all relevant issues, and should explore in detail those issues that are considered of particular interest to the study (P.M. Fayers & Machin, 2000). Generally, there are two methods for item reduction as follows:

1) Reducing items in the basis of their frequency and importance (clinical impact)

This method is to take into account the opinions and values of patients. One approach to item reduction is to ask patients to identify those items that they have experienced as a result of their illness. For each positively identified item, they rate the importance using a 5-point Likert type scale(“extremely important” to “not important”). Results are expressed as *frequency* (the proportion of patients experiencing a particular item), *importance* (the mean importance score attached to each item), and the *impact*, which is the product of frequency and importance (Juniper, et al., 1996).

2) Factor analysis

Some investigators use mathematical modeling (factor analysis) to determine which items should be included in HRQoL instruments. In factor analysis, items that have high correlations with one another are grouped together. Items that are not strongly associated with one of the domains or factors that emerge from the factor analysis are excluded from the final questionnaire. The disadvantage of using factor analysis for item reduction is that the "orphan" items that are excluded from the factor analysis model may be important to patients. Thus investigators should consider the issue that the relative importance one puts on the impact of an item and its relationship with other items.

6. Instrument format and response choices

The researcher should also consider about the format of the questions:

1) Selection of response options

Response options refer to the categories or scales that are available to patients for answering each questionnaire item. Discriminative instruments should have short sets of response options that facilitate uniform interpretation. Kirshner and Guyatt suggested that a simpler scale is better. The simplest scale, a dichotomous scale (e.g., yes-or-no response options), is appropriate. It is also very easy to use for telephone interviews. In the case of evaluative instruments, individual items must be responsive (sensitive to change). Scores on individual items must change when clinically or humanistically important improvement or deterioration occurs. Items with five, seven, or nine response options or visual-analogue scales may be used in an evaluative instrument. To ensure and enhance this measurement property, investigators usually choose scales with a number of options, such as a 7-point scale where responses may range from 1 = no impairment to 7 = total impairment or continuous scale such as a 10-cm Visual Analog Scale (VAS) (Juniper, et al., 1996; S.S. Sen, et al., 1999).

2) Time specification

Patients should be asked how they been feeling over a well-defined period of time. Juniper et.al., use 2 weeks in most of their instruments on the basis of their our intuitive

impression that this time frame is near the upper limit of what patients can accurately recall. Time period can be modified according to the research. Furthermore, it may consider regarding population's memory (Juniper, et al., 1996).

3) Questionnaire administration

In the traditional pattern to questionnaire administration, patients are not permitted to see the responses they gave on previous occasions. Some investigators have found that showing patients their previous responses improves the validity of the questionnaire without adversely affecting the responsiveness (Juniper, et al., 1996).

4) Language suitable for translation

Very rarely will an instrument be used only in the country and culture in which it was developed. To make adaptation for use easier, it should be to avoid jargon, idioms, or metaphors in a new instrument. Even within the English-speaking world, there are words and terms that are not common to all cultures and countries. For instance, crook, down-in-the-dumps, and pooped are used in some geographic areas and not in others. Therefore, it is best to use words that apply to the widest range of cultures and geographic areas (Juniper, et al., 1996). There should be avoided double negatives meaning. In case of, a question such as "I don't feel less interest in sex (Yes/No)" is ill-advised (P.M. Fayers & Machin, 2000).

Instrument testing

7. Pretesting

The new QoL questionnaires need extensively to test on groups of patients before being released for general use. This testing is mainly conducted in two stages: pilot or pre-test, and large scale testing. The purpose of this pre-test is to identify and solve potential problems. These might include ambiguity or difficult phrasing of the questions and responses, or might relate to the layout and flow of the questions. The pilot study will usually involve between 10 and 30 patients, selected as representing the range of patients in the target population. These should not be the same patients as those who were used when identifying the issues to be addressed. In case of, Juniper et.al., administer the new questionnaire to approximately five patients, selected to represent as wide a spectrum as possible (disease severity, educational background, age, and gender). After an uninterrupted administration of the questionnaire, the investigators ask patients to explain in their own words exactly how they understand each item. The investigators note consistent problems in wording and understanding, make the necessary changes, and administer the revised instrument to another group of five patients. This process is repeated until no more changes are needed. It is advisable to avoid the potentially embarrassing items that may affect on missing data (P.M. Fayers & Machin, 2000; Juniper, et al., 1996).

Large scale testing phase, the field study, aims to provide quantitative data for validation purpose, reliability, and in order to decide the appropriate sample sizes. The field study should be designed with a sufficiently large sample size to be able to detect major differences in responses according to gender, age group or culture (P.M. Fayers & Machin, 2000).

8. Reliability testing

Reliability is the accuracy or precision of an instrument, or the degree to which the instrument minimizes random error (S.S. Sen, et al., 1999). Different techniques to measure the reliability of an instrument include test-retest, inter-rater and internal consistency reliability. Reliability coefficients range from 0.00 to 1.00, with higher coefficients indicating higher levels or reliability (P.M. Fayers & Machin, 2000; Kimberlin & Winterstein, 2008).

Test-retest reliability, or stability of measurement, is determined by administering a test at two different points in time to the same individuals and determining the correlation or strength of association of the two sets of scores. This is usually assessed using a test-retest study, with patients who are thought to have stable disease who are not expected to experience changes due to treatment effects or toxicity. The time of the second administration is critical when tests are administered repeatedly. Ideally, the interval between administrations should be long enough that values obtained from the second administration will not be affected by the previous measurement (e.g., a subject's memory of responses to the first administration of a knowledge tests, the clinical response to an invasive test procedure) but not so distant that learning or a change in health status could alter the way subjects respond during the second administration (Kimberlin & Winterstein, 2008).

Inter-rater reliability (also called interobserver agreement) is a measure of the magnitude of the agreement between ratings given by different observers administering the same instrument in a population with a stable health condition. For categorical variables, Cohen's kappa is commonly used to determine the coefficient of agreement. Kappa (κ) is used when two raters or observers classify events or observations into categories based on rating criteria (Kimberlin & Winterstein, 2008). Interpretation of κ is subjective, but the guideline values in Table 2 are commonly used (P.M. Fayers & Machin, 2000).

Table 2: Guideline values of κ to indicate the strength of agreement

κ	Agreement
<0.20	Poor
0.21-0.40	Slight
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1.00	Very high

The value of κ is equal to 1 if there is perfect agreement, and equals 0 if the agreement is no better than chance.

Internal consistency reliability assesses the homogeneity of the items that make up the instrument. Internal consistency gives an estimate of the equivalence of sets of items from the same test (e.g., a set of questions aimed at assessing quality of life or disease severity). The most widely used method for estimating internal consistency reliability is Cronbach's alpha ($\alpha_{Cronbach}$). Cronbach's alpha is a function of the average intercorrelations of items and the number of items in the scale (P.M. Fayers & Machin, 2000; S.S. Sen, et al., 1999). Coefficients above 0.7 are generally regarded as acceptable for psychometric scales, although it is often recommended that values should be above 0.8 (good) or even 0.9 (excellent). For individual patient assessment, it is recommended that values should be above 0.9. The α coefficient ranges from 0 to 1: values greater than 0.70 are generally considered acceptable for group comparisons, and 0.90 for person-level comparisons (Nunnally, 1978).

In order to estimate the reliability of the instrument under optimum conditions, then it is important to keep all other factors to a minimum, such as ensuring that the patient's health status is stable, using only one interviewer, making sure the environment is quiet and free from interruptions or distractions, and interviewing the patient at the same time of day and, if possible, the same day of the week (Juniper, et al., 1996).

9. Validity testing

An assessment of the validity of a new instrument is an evaluation of the extent to which an item or measure accurately assesses what it is intended to measure (Kimberlin & Winterstein, 2008). Validity has been given three major meanings: (1) construct validity--- measuring psychological attributes, (2) criterion-related validity--- establishing a statistical relationship with a particular criterion, and (3) content validity--- sampling from a pool of required content.

Construct validity

Construct validity is the extent to which scores on a particular instrument relate to other measures in a manner that is theoretically consistent (such as the measure behaves as expected) (S.S. Sen, et al., 1999). Mainly, assessment of construct validity makes use of correlations, changes over time, and differences between groups of patients. There are building and testing

conceptual models that express the postulated relationships between the hypothetical domains of QoL and the scales that are being developed to measures these domains. There are four methods for testing construct validity as follows (P.M. Fayers & Machin, 2000):

1) Known-groups validation: Known-groups validity is tested by comparing scale scores, adjusted for age and sex, across groups known to differ. This method is one of the simpler forms of construct validation (P.M. Fayers & Machin, 2000).

2) Convergent validity: This method examines the degree to which interpretations of scores on the instrument being tested are similar to the interpretation of scores on other instruments that theoretically measure similar constructs. In case of, a new emotional functional measure should correlate highly to an existing measure of emotional functional. Convergent validity is usually considered together with discriminant validity.

3) Multitrait-multimethod analysis (MTMM): This correlation matrix is a method for examining convergent and discriminant validity. The principle of this technique is that two or more “methods”, such as different instruments, are each used to assess the same “traits”, for example QoL aspects, items or subscales. Discriminant validity, or divergent validity, this method is the absence of correlation between measures of unrelated constructs.

4) Exploratory factor analysis: This method can be a useful aid to identify clusters that were not hypothesized in advance, because it summarizes the intercorrelations among items in terms of underlying dimensions or factors. Items that correlate more highly with one another than with other items will tend to load together on the same factor. There are two main components of exploratory factor analysis: 1) estimating the number of underlying dimensions; and 2) rotating the number of factors to identify which items cluster together on the same factor.

Criterion validity

Criterion validity is concerned with the degree to which a score obtained from the HRQoL instrument correlates with a gold standard (a criterion measure designed to assess the same thing) (S.S. Sen, et al., 1999). The instrument is said to be valid if its scores correlate highly with scores on the criterion. A correlation coefficient is computed between scores on the instrument and the criterion. The magnitude of the coefficient is a direct estimate of how valid the instrument is, according to this validation method. Criterion validity can be divided into concurrent validity and predictive validity (P.M. Fayers & Machin, 2000).

1) Concurrent validity refers to the agreement with the true value. Currently, a "gold standard" is not available for QoL instruments because they measure postulated constructs that are experimental and subjective. Therefore the most common approach involves comparing new questionnaires against one or more well-established instruments.

2) Predictive validity refers to the ability of the instrument to predict future health status, future events, or future test results.

Content validity

Content validity refers to the extent to which items form measure are sampled from a particular content area or domain. Because there is no statistical test to determine whether a measure adequately covers a content area or adequately represents a construct, content validity usually depends on the judgment of experts in the field (Kimberlin & Winterstein, 2008).

There are no true gold standard HRQoL instruments. Hence, HRQoL instrument is really largely based on content and construct validity assessment.

10. Responsiveness

Responsiveness is the ability of an instrument to detect small but significant changes in outcomes over time. Responsiveness sometimes is called sensitivity to change. There are a number of approaches to testing responsiveness. Three strategies address the following questions: In patients who truly change their health status, can the investigators measure this change (using a

paired *t*-test to compare baseline and follow-up scores)? Is the instrument able to distinguish between those patients who change and those who stay stable (using an unpaired *t*-test to determine if the magnitude of change in instrument score differ between stable subjects and those whose HRQoL has changed). What is the magnitude of the instrument's responsiveness index? This index is calculated from the minimal important difference (Juniper, et al., 1996).

Conceptual framework

Health-related quality of life instrument is increasingly used as a measurable outcome in clinical trials. Currently, available HRQoL measuring instruments were generic or disease specific. Because there are no instruments designed with intention of measuring HRQoL in patients with continuous medications directly. The researcher cannot directly measure desire or consideration, the researcher needed to construct measures that the researcher hope will capture them. Adapted from Murawski and Bentley 's framework, the quality of life for patients using continuous medications in this study was studied only continuous medication use. This study chooses to assess the continuous medications use effects rather than other component.

Conceptual framework for this study was displayed in Figure 3 (Murawski & Bentley, 2001). PTRQoL is limited to those aspects or portions of HRQoL influenced by pharmacotherapy. It has been noted that pharmacotherapy that reduces the number or severity of symptoms can improve a patient's HRQoL. Oftentimes, levels of HRQoL is not achieved, even when the therapy is perfectly efficacious because of the inherent burden association with drug therapy (PTRQoL). This construct, pharmaceutical therapy-related quality of life (PTRQoL), will be made up two general dimensions: (1) the negative consequences attributable to medication's structure and biophysiological actions (e.g., side effects and/or adverse drug reactions) and (2) the psychosocial consequences of medication use and the experiences and memory of medication use. Relationship of PTRQoL to quality of life based on the Wilson and Cleary (1995) conceptual model was described as the following:

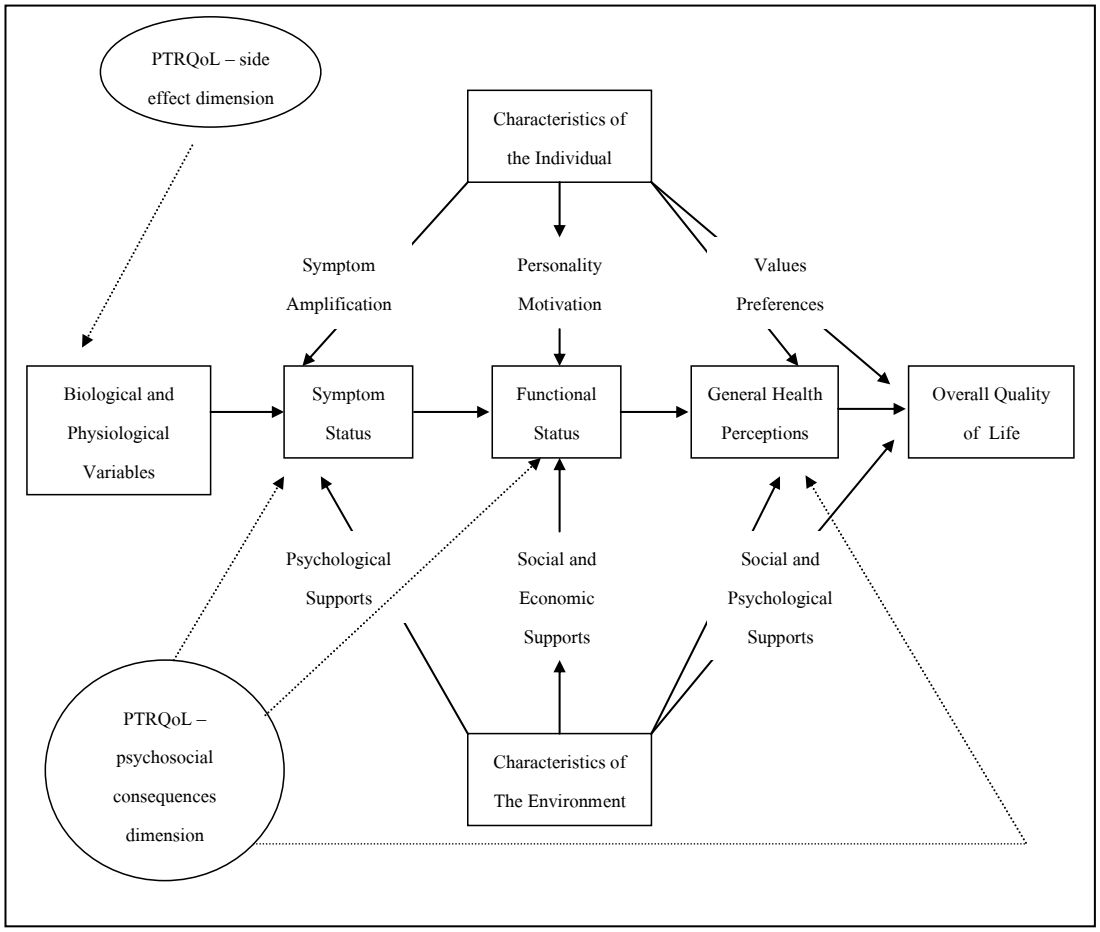


Figure 3: Relationship of PTRQoL to quality of life based on the Wilson and Cleary (1995) conceptual model

The Wilson-Cleary model defines five levels of patient outcomes: (1) biologic and physiologic variables, (2) patient symptoms, (3) patient functioning, (4) overall or general health perceptions, and (5) overall quality of life. The outcomes are linked causally and the model further proposes that characteristics of the individual and characteristics of the environment can influence the components of the model.

The biophysiological dimension of the PTRQoL that is fairly obvious how side effects or the biophysiologically determine negative consequences of drug can have an impact on a patient's HRQoL. Side effects of continuous medication use occurs as a consequence of alterations in the fundamental, underlying biological and physiological variables, and thus a patient's subsequent symptom status, influencing a patient's functional status and ultimately reducing his/her HRQoL. Conversely, the positive therapeutic effect of the medication use occurs concurrently along the

same conceptual pathway, resulting in changes in basic physiologic and biologic variables and eventually improvements in patient's overall quality of life. There are numerous examples of side effects of medications that may affect a patient's HRQoL. As an example, most drug used in the treatment of hypertension may induce adverse effects that affect HRQoL, antihypertensive therapy has been associated with varying negative impacts on physical state, emotional well-being, and social functioning (Erickson, Williams, & Gruppen, 2004).

The relationship between the psychosocial dimension of the PTRQoL and HRQoL is neither as obvious nor as well defined. Psychosocial domains of PTRQoL may influence patient HRQoL by influencing symptom status and thus functional status and so on, or they may also influence functional status directly. Finally, the psychosocial dimension of the PTRQoL may influence a patient's general health perception. In the process of taking a medication, patients may have many worries that may influence their functional, social, and psychological well being. As an example, patients may worry about the long term effects of taking medications and the possibility of harm (Kikkert et al., 2006).

CHAPTER III

METHODS AND RESULTS

This study was a methodological research that described the development and validation of a new QOL instrument specifically designed for use in patients taking continuous medications. The steps for developing a questionnaire in this study were mainly adapted based on an accepted methodology for measurement development which has successfully been used in previous studies (P. M. Fayers & Machin, 2007; Juniper, et al., 1996; Wongwiwatthananukit, Dhumma-Upakorn, & Naktuan, 2005b). The research involved 3 steps as follows: (1) instrument development, (2) expert review of the instrument and (3) testing of the instrument. The development of Continuous Medication Quality of Life (CM-QOL) of each process was dependent on the prior step. This section was displayed both the methodological descriptions and results of each step.

Three Main Steps in Developing the Continuous Medication Use Questionnaire

STEP 1: INSTRUMENT DEVELOPMENT

Objectives of the instrument development

The aims of this process were to: (1) define the quality of life for continuous medication use, (2) identify instrument domains, (3) generate items for the instrument, and (4) design the instrument format and response choice.

The development of new instrument was intended for use across multiple continuous medication condition or diseases from Thai patient's perspective. This new instrument was named as "the Continuous Medication Quality of Life (CM-QOL)". In addition, the developed instrument could be measured and generalized across different diseases with the same sensitivity as a condition quality of life instrument.

This instrument aimed to measure quality of life of patients using medications on an extended period. The difficulties occurred during continuous medication use could lead to non-adherence.

Methods

1. Identification definition of quality of life of continuous medication use

The quality of life of continuous medication use was defined by health-related quality of life concept and Pharmaceutical therapy-related quality of life (PTRQoL), the concept of Murawski and Bentley (2001). It was defined as the patient's sense of his/her own well-being in certain aspects that included domains related to physical, mental, emotional and social functioning aspects and satisfaction of life through the process of perception and self assessment regarding continuous medication use.

2. Identification purpose of QOL instrument

This QOL instrument was evaluative scales and a self-administered questionnaire. It would be used to measure either cross section condition or changes over time in the quality of life of patients who experience an ongoing incident of taking medication(s) during the period of at least one month.

3. Identification of Domains and Generation of Items.

3.1 Tentative domains were drafted based on the pharmaceutical literature related to patients' medication practices or medication-taking behaviors. The literature review was done by searching computerized literature: MEDLINE, Pubmed, ProQuest, ScienceDirectOnSite, SPRINGER. The literature search was conducted using terms: quality of life, well-being, health status, happiness, satisfaction, taking continuous medication, instrument development, tool, questionnaire, and psychometric testing. Additional publications were selected from the reference lists of articles identified in the original database search.

3.2 After literature review, interviews were used as a source of qualitative data. Because the CM-QOL was intended for use across multiple continuous medications use, these interviews were conducted across different chronic diseases. The researcher selected in-depth interview by using semi-structured interviews included open-ended questions. Each semi-structured interview took approximately an hour. Subjects for this study were recruited by convenience from Deja Hospital at outpatient clinic.

3.3 The subjects who participated in this phase were chronic disease patients and started continuous medication use at least one month ago. The researcher introduced herself and clearly explained the purpose of the study, and the risks and benefits of interviewing. After permission, the researcher interviewed each participant using a semi-structured questionnaire and took note. If preferred, some participants chose to the questionnaire by their own writing. The interviews were continued until saturation with no new information gained from new participants.

3.4 Data analysis

Data analysis was conducted by content analysis. The information was analyzed, extracted, pooled and generated tentative domains, and/or items.

4. Instrument Format and Design

The instrument was designed for use by patients with continuous medication use as a self-assessment tool or direct interview. (In the case of evaluative instrument, individual item must be responsive (sensitive to change). Scores on individual items must change when clinically or humanistically important improvement or deterioration occurs.) Items with five response choices were decided. The method of combining items was the method of summated ratings, as known as Likert summated scales. Items that represent negative HRQoL would be scored as reverse so that all items were scored in the same direction, with higher values indicating better health states. There were five Likert scale including “1 = Not at all, 2 = A little, 3 = A moderate, 4 = A lot, and 5 = Most”.

A missing value was assigned to a scale missing as coded 9. The evaluation of the missing data was used as excluded case listwise.

Results of Step 1: Instrument Development

The total participants in this step 1 were twenty-four. After reviewing with the expert, the pool items and domains contained 42 items and 10 domains.

The draft domains of continuous medications use-related quality of life (version 1) were as followed:

Domain 1: Physical domain (item CM1-CM5) = 5 items

Domain 2: Mental domain (item CM6-CM11) = 6 items

Domain 3: Psychosocial domain (item CM12-CM16) = 5 items

Domain 4: Travel domain (item CM17-CM19) = 3 items

Domain 5: Burden domain (item CM20-CM25) = 6 items

Domain 6: Role limitation domain (item CM26-CM28) = 3 items

Domain 7: Side effect on physical domain (item CM29-CM32) = 4 items

Domain 8: Side effect on role limitation domain (item CM33-CM36) = 4 items

Domain 9: Side effect on mental domain (item CM37-CM38) = 2 items

Domain 10: Positive consequence domain (item CM39-CM42) = 4 items

The version 1 which including 10 domains and 42 items of the instrument was developed and face validity was reviewed by one expert with consideration of the reading level of the respondents. This version 2 was tested by experts' opinions in the next step.

The CM-QOL version 2 consisted of 7 domains with 30 items (divided 2 groups: impacts from drug use process and impacts from the effect of drug) as follows:

Domain 1: Physical/Role limitation domain (item CM1-CM5) = 5 items

Domain 2: Mental domain (item CM6-CM9) = 4 items

Domain 3: Psychosocial domain (item CM10-CM13) = 4 items

Domain 4: Travel domain (item CM14-CM16) = 3 items

Domain 5: Burden domain (item CM17-CM21) = 5 items

Domain 6: Side effect domain (item CM22-CM26) = 5 items

Domain 7: Positive consequence domain (item CM27-CM30) = 4 items

The version 1 was changed to the version 2 what changes were detailed below:

Item 4 (version 1): “Planning the use of drugs can disrupt to me” and item 5 (version 1) “The instruction of medication use is difficult for me” were excluded in version 2 because they were similar. Then they were reconstructed in order to be appropriate in physical/role limitation aspect by an expert. Item 4 (version 2) was “The need to take medicines regularly disturbed about my daily life.”

Item 7 (version 1): “The need to take medicines regularly makes me feel like be a patient all the time.” This item was too similar with item 8 “The need to take medicines regularly makes me feel is unhealthy.” Because of redundancy item, we decided to remove item 7 but remained item 8 in version 2 of the questionnaire.

Item 10 (version 1): “I have been feeling worried about drugs use right on time.” This item was confused with item 11 (version 1): “I worry that I forget to take medication regularly.” In addition, item 10 seemed similar with item 11 and then the researcher decided to remove item10 but keep item11 in version 2.

Item 12 (version 1): “I feel uncomfortable to use drugs while on others or co-workers.” This seemed similar to item 13 (version 1): “I feel embarrassed to use while on others or co-workers.” The expert judged that item 13 was held in version 2 but removed item 12.

For burden domain, item 20 and item 21 (version 1) were very similar in meaning sentence regarding the costs of the regular drugs. At this point, there was new arrangement in sentence structure as I am concerned with the costs of the regular drugs.

For adverse drug reaction domain, item 29, 30, and item 31 in version 1 were redundant such as side effects of the drugs make me more discomfort, very sick, and health worsens. We decided to renew as side effects of the regular drugs make more discomfort.

STEP 2: EXPERT REVIEW OF THE INTRUMENT

Objectives of expert review of the instrument

The aim of this process was to examine content validity of the new QoL instrument items. The items should be relevant and representative of the domain of content for the construct.

Methods

1. In order to obtain validity, nine experts were asked to rate each proposed item's relevance in measuring a patient's quality of life with continuous medications use.
2. A content validity index (CVI) was used in this study. The CVI was a four-point ordinal scale: 1 = not relevant, 2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant, 3 = relevant, but needing minor alteration, and 4 = very relevant.

3. A CVI was calculated for each item. The CVI for each item is the proportion of experts who rated the item as content valid, e.g., a rating of three or four.

4. A CVI of 0.80 for the measure was desired in order to consider the measure to have adequate content validity (J. S. Grant & L. L. Davis, 1997). Because this study was judged by nine experts and meet desired at CVI of 0.80. Therefore seven experts out of nine have to rate the item either a three or a four before it was judged to have content validity.

5. The experts were also asked to suggest any additional components that should be included in the instrument. In addition, they were asked to suggest modifications for the individual items (e.g., reword, revise, grammatical corrections). Revision and correction of all items were conducted prior to testing for reliability. The version 3 of the instrument (30-item CM-QOL version 3) was developed to test in pilot testing with 30 convenient samples beyond.

Results of Step 2: Expert Review of The Instrument

All items were evaluated by nine experts as follows: three social science teachers, two clinical pharmacy teachers, three hospital pharmacists, and one community pharmacist.

The items that had CVI more than 0.75 remained and less than 0.75 were eliminated (Table 3). The remaining items were modified based on the experts' opinions and our team. Items were not related to the domain of quality of life of continuous medications use including item CM5 and item CM25, so there were remained 28 items in the instrument. The researcher decided to keep CM25 again because this item was developed from patients' perspective. Item 25 asked that "I am concerned that this will cause accumulation of the drug in the body when using a long term therapy". The researcher added 1 item that asked "I have to worry that it is time to take medication all the time" as was the suggested by experts. Therefore, there were 30 items in the instrument named CM-QOL 30 items version 2 which was intended to pilot test.

For the response choices, the researcher decided to use ordinal scale based on WHOQOL THAI version as the expert suggested. There were five Likert scale including "1 = Not at all, 2 = A little, 3 = A moderate amount, 4 = A lot, and 5 = An extreme amount". In Thai language were "1 = ไม่เลย, 2 = น้อย, 3 = ปานกลาง, 4 = มาก, and 5 = มากที่สุด". The Thai word between "เล็กน้อย" and "น้อย", the researcher tested few patients found that there were not much difference among two words. Therefore, our team used "น้อย" in order to be according with one word of "มาก". The results of response choices showed in table 4.

For experts' suggestions should clarify "continuous medication" that meant the drug as prescribed or the drug as self-medication use such as buying vitamin without the doctor's order. In this study, the researcher used term the drug as prescribed in order to treat chronic disease. Moreover, the word was used only "eating medication" they suggested as "taking medication" because it held the whole person who used tablet, capsule, local (e.g., eye drop, inject).

Table 3: Content validity index by experts' review (N = 9)

Domain	Items	Rate score by experts									Proportion Agreement (CVI)	Rejected or Accepted
		Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9		
D1 Daily activity												
	CM1	4	4	3	3	3	4	4	3	3	9/9 (1.00)	Accept
	CM2	4	4	3	4	3	4	3	4	3	9/9 (1.00)	Accept
	CM3	4	3	4	4	4	4	2	4	3	8/9 (0.88)	Accept
	CM4	3	4	3	3	4	3	3	4	4	9/9 (1.00)	Accept
	CM5	**1**	**3**	**1**	**1**	**1**	**4**	**3**	**1**	**3**	**4/9 (0.44)**	**Reject**
D2 Mental												
	CM6	4	4	4	4	3	4	3	3	4	9/9 (1.00)	Accept
	CM7	4	4	3	3	4	3	3	3	4	9/9 (1.00)	Accept
	CM8	3	4	4	4	4	4	4	3	4	9/9 (1.00)	Accept
	CM9	3	4	4	4	4	4	3	3	4	9/9 (1.00)	Accept
D3 Psychosocial												
	CM10	4	3	4	3	4	4	4	2	4	8/9 (0.88)	Accept
	CM11	4	4	3	4	4	4	4	4	4	9/9 (1.00)	Accept
	CM12	4	4	3	3	4	4	4	1	4	8/9 (0.88)	Accept
	CM13	4	3	3	4	4	4	4	3	4	9/9 (1.00)	Accept

Domain	Items	Rate score by experts									Proportion Agreement (CVI)	Rejected or Accepted
		Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9		
D4 Travel												
	CM14	4	4	3	4	4	4	4	3	4	9/9 (1.00)	Accept
	CM15	4	4	3	4	4	4	4	4	4	9/9 (1.00)	Accept
	CM16	4	4	4	4	4	4	4	4	4	9/9 (1.00)	Accept
D5 Burden												
	CM17	1	4	3	3	4	4	4	4	4	8/9 (0.88)	Accept
	CM18	4	4	3	3	3	2	3	1	4	7/9 (0.77)	Accept
	CM19	4	4	4	3	4	4	3	3	4	9/9 (1.00)	Accept
	CM20	4	4	4	4	2	4	4	3	4	8/9 (0.88)	Accept
	CM21	3	4	4	4	2	4	4	3	4	8/9 (0.88)	Accept
D6 Side effect												
	CM22	3	4	3	3	4	4	4	4	4	9/9 (1.00)	Accept
	CM23	3	4	3	3	4	4	3	4	1	8/9 (0.88)	Accept
	CM24	4	4	3	4	4	4	4	4	1	8/9 (0.88)	Accept
	CM25	**1**	**4**	**4**	**4**	**2**	**4**	**4**	**4**	**1**	**6/9 (0.66)**	**Reject**
	CM26	4	4	4	4	2	4	4	4	1	7/9 (0.77)	Accept

Domain	Items	Rate score by experts									Proportion Agreement (CVI)	Rejected or Accepted
		Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9		
D7 Positive consequence												
	CM27	4	4	4	4	4	4	3	4	4	9/9 (1.00)	Accept
	CM28	4	4	4	3	4	4	2	4	4	8/9 (0.88)	Accept
	CM29	4	4	3	3	4	4	3	4	4	9/9 (1.00)	Accept
	CM30	4	4	3	3	4	4	3	4	4	9/9 (1.00)	Accept

Note : 1 = not relevant

2 = unable to assess relevance, item need some revision

3 = relevant, but needing minor alteration

4 = very relevant

Table 4: The appropriateness of response choices

Experts	Appropriate	Inappropriate	Note
1		✓	Eliminated : ค่อนข้างมาก or Add response choice :มาก Preferred : modified to มาก
2		✓	Suggested : มาก instead of ค่อนข้างมาก as follows: ไม่มีเลย น้อย ปานกลาง มาก มากที่สุด
3		✓	Suggested : ไม่มีเลย/ น้อย /ปานกลาง /มาก /มากที่สุด
4		✓	Suggested: ไม่มีเลย/ เล็กน้อย /ปานกลาง /มาก /มากที่สุด
5	✓		Modified:ไม่มี / น้อย/ ปานกลาง/ ค่อนข้างมาก/ มากที่สุด
6	✓		
7	✓		
8	✓		I would like to see a variety question for the positive and negative aspect. Not to be boring or predictable respondents likely questions in advance.
9	✓		

Note : Original response choices were in Thai language such as ไม่มีเลย, เล็กน้อย, ปานกลาง, ค่อนข้างมาก, มากที่สุด

The version 3 of the instrument was developed to test in 30 convenient samples further.

STEP 3: TESTING OF THE INSTRUMENT (PSYCHOMETRIC PROPERTY TESTING)

STEP 3.1 Pilot Testing (Pretesting)

Purposes:

The goals were (1) to test domains and items of the questionnaire, redundant items with similar meaning and items causing any confusion were eliminated and (2) to test the feasibility of the questionnaire include time use for self-administration and appropriate sequence of all instruments.

Methods

1. The instrument that was developed in step 2 was used as a pilot test. In the field test, all of the convenient samples were interviewed and asked to answer a set of questionnaires that consisted of demographic data, the items of QoL in patients who take continuous medications (30-item CM-QOL), adherence items, EQ5D3L in Thai, and SF-36V2 in Thai instrument. The researcher included other instruments such as SF-36V2, EQ5D3L for testing the overall time for responding, testing the applicability, and testing the sequence of all instruments.

The SF-36V2 consisted of 8 domains:

(1) Physical functioning
(2) Role functioning
(3) Bodily pain
(4) Social functioning
(5) General health perception
(6) Vitality
(7) Mental health
(8) Role emotional

The scores were expressed in two summary scores: a physical component summary score (Physical functioning-PF, Role functioning-RF, Bodily pain-BP, General health perception-GH) and a mental component score (Social functioning-SF, Mental health-MH, Role emotional-RE, Vitality-VT).

The EQ5D3L was developed by a multidisciplinary group of researchers. It had five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each domain had 3 levels: no problems, some problems, and major problems which define 243 health states.

2. All purposive patients with continuous medication use were tested with the self-administered instrument to provide feedback about the content of the items and directions for the instrument. Patients were explained, in their own words, what they believed each item and the directions for the instrument meant. Items or directions associated with common misinterpretations were revised. Time spent for testing questionnaires was also recorded. Revision and correction of the whole instrument was adjusted properly, the final instrument was used in the large study testing further.

3. All respondents were approached and invited to participate in the study at the outpatient clinic of Deja Hospital. The researcher was the only person to collect the data. The overall purpose of the study, the risks and benefits, and the time required for participant were explained. Respondents were confirmed of anonymity and confidentiality. Moreover, they were informed that they could discontinue their participation at any time. Consent by action was obtained. There was no cost for participating and respondents would not receive an incentive fee for this participation.

4. After an uninterrupted administration of the questionnaire, the researcher asked patients to explain in their own words how they understand each item.

Results of Pilot Testing (Step 3.1)

The results of the study consisted of 2 parts as follows: (1) Respondent characteristics and (2) The results of pretest

1) Respondent characteristics

There were 30 respondents in this study by data collection as shown in table 5. The results showed that most respondents preferred to complete the questionnaire by themselves.

From table 6, it showed that the participants' age ranged from 25 – 66 years with a mean 46.90 (SD = 8.91 years). The majority of participants were female (66.7%), marriage (70.0%), and Bachelor degree (32.8%). All samples were distributed in various status of working: company employee (73.3%), employed daily (13.3%), business owner (3.3%), unemployed (3.3%), and retired (6.7%). The monthly incomes (baht per month) were varying in all: with ฿ 10,001 – 20,000 (33.3%), ฿ 5,000 – 10,000 (40.0%), and ฿ more than 20,000 (20.0%). Household incomes (baht per month) were also varying in all: with ฿ more than 20,000 (46.7%), ฿ 10,001 – 20,000 (30.0%), and ฿ 5,000 – 10,000 (20.0%). For health insurance, this survey displayed that Social Security Scheme (SSS) was most (96.7%), Civil Servant Medical Benefit Scheme (CSMBS) was 3.3%. Among 30 respondents, more than 60% had hypertension, diabetes (30.0%), and dyslipidemia (43.3%) which were the first three diseases founded in these group of samples. The participants had the proportion of being one chronic disease and two diseases about the same. The other chronic diseases were gout and AIDS. Participants have used varying continuous medication at the range from 1 – 8 items with a mean 3.2 (SD = 1.40) items: 3 prescription drugs (26.7%), 2 prescription drugs (26.7%), 4 prescription drugs (30.0%), one prescription drug (6.7%), and five or more drugs (10.0%). Most of the participants have used drug at the range from 10 – 120 months with a mean 50.67 (SD = 30.42 months).

Table 5: Numbers of respondents by data collection

Variable		**respondents**	
		N = 30	**%**
Data collection	Self-administered	24	80.0
	Interview	6	20.0

Table 6: Demographic data of respondents in pilot study testing of the instrument (N = 30)

Demographics		respondents	
		N = 30	%
Gender	Male	10	33.3
	Female	20	66.7
Age (years)	20-30	1	3.3
	31-40	6	20.0
	41-50	15	50.0
	51-60	5	16.7
	61-70	3	10.0
	> 70	0	0
Mean Age = 46.90, SD = 8.907, Min = 25, Max = 66			
Marital Status	Single	6	20.0
	Married	21	70.0
	Divorced/Separated	2	6.7
	Widowed	1	3.3
Education	Primary school or less	8	26.7
	Secondary school	5	16.7
	Diploma	7	23.3
	Bachelor degree	10	33.3
	Higher bachelor degree	0	0
Occupation	Business owner	1	3.3
	Employed daily	4	13.3
	Government employee/State Enterprises	0	0
	Company employee	22	73.3
	Unemployed	1	3.3
	Retired	2	6.7
	Others	0	0
Monthly income (Baht/month)	No income	1	3.3
	Less than 5,000	1	3.3
	5,000-10,000	12	40.0
	10,001-20,000	10	33.3
	More than 20,000	6	20.0

Demographics		respondents	
		N = 30	%
Household income (Baht/month)	Less than 5,000	0	0
	5,000-10,000	6	20.0
	10.001-20,000	9	30.0
	More than 20,000	14	46.7
	Missing cases	1	3.3
Health insurance	Civil Servant Medical Benefit Scheme	1	3.3
	Universal Coverage (gold card)	0	0
	Social Security Scheme	29	96.7
	Others	0	0
Chronic disease	Hypertension	19	63.3
	Diabetes	9	30.0
	Dyslipidemia	13	43.3
	Cerebrovascular	0	0
	Kidney	0	0
	Asthma	0	0
	Cardio	3	10.0
	Others	2	6.7
Number of chronic diseases	1	14	46.7
	2	16	53.3
Numbers of drugs used	1	2	6.7
	2	8	26.7
	3	8	26.7
	4	9	30.0
	5	2	6.7
	6	0	0
	$\geq$ 7	1	3.3

2) The results on reliability

The pilot set of items of the questionnaire including the CM-QOL instrument consisted of 30 items, EQ-5D3L, EQ-5D VAS, SF-36V2, Adherence score, Adherence VAS that was tested in 30 the convenient respondents. No items had been eliminated. All respondents understood how to fill in the questionnaire. Some subjects selected tick or cross instead of circle in the response choice. In addition, the results were found as follows:

1. Time spent for testing questionnaire ranged from 10 to 35 minutes, mean time 20.33±7.3 minutes. Most respondents complained there were too many items (95 items) in a set of questionnaire and it took a long time spent. They suggested that these items should be reduced.

2. From the adherence score found some respondents confused the response choices between "บ่อยครั้ง" and "ส่วนมาก" and when looking at the numbers the respondents were still ambiguous as follows: "1 = ทุกครั้ง, 2 = บ่อยครั้ง, 3 = บางครั้ง, 4 = ส่วนมาก, 5 = ไม่เลย". Then this set of the response choices was refined as "1 = ไม่เลย, 2 = นานๆครั้ง, 3 = บางครั้ง, 4 = บ่อยครั้ง, 5 = ทุกครั้ง"

3. Table 7 presented the internal consistency reliability by alpha Cronbarch's coefficient of the 30 item CM-QOL instruments that was used in this study. The alpha value of activity domain, mental domain, psychosocial domain, travel domain, burden domain, adverse drug reaction domain, positive domain, and sum CM-QOL were 0.836, 0.902, 0.898, 0.924, 0.783, 0.908, 0.826, and 0.943 respectively.

Table 7: The internal consistency reliability by Cronbarch's coefficient alpha of CM-QOL instrument (30-item) by each domain and total score for CM-QOL (N = 30)

Variable	Alpha Cronbarch's coefficient
Daily Activity domain (4 items)	0.836
Mental domain (6 items)	0.902
Psychosocial domain (6 items)	0.898
Travel domain (6 items)	0.924
Burden domain (6 items)	0.783
Adverse drug reaction domain (6 items)	0.908
Positive domain (6 items)	0.826
Sum CM-QOL (30 items)	0.943

After the version 3 of the instrument was tested in 30 purposive samples, the developed version 4 of this instrument contained 30-item CM-QOL instrument and was grouped with 7 tentative domains in table 8. This version 4 would be used in large study testing later.

Table 8: The tentative domains of version 4 of the 30-item CM-QOL instrument

Tentative Domain CM-QOL	Items
Daily Activity domain (4 items)	- be careful drug-drug interaction - be careful drug-food interaction - waste time for preparing - disturb daily life
Mental domain (6 items)	- concern about time use - be dispirited - bore daily use - make feel unhealthy - depress - worry about forget use
Psychosocial domain (6 items)	- embarrassment - limited doing social activity - self-confidence - keep secret
Travel domain (6 items)	- be a cumbersome when traveling - did not want to go anywhere - remind carry it
Burden domain (6 items)	- cost - need caregiver - caregiver's attentiveness - burden on the family
Adverse drug reaction domain (6 items)	- more discomfort - performing the work - interfere daily life - concerned drug accumulation - annoy from side effect
Positive domain (6 items)	- improve symptoms - no absence from work - controlled symptoms - have a normal life

From the survey of EQ5D-VAS found that our Thai samples preferred to cross on the VAS scale although the instruction was ordered by drawing a line from the box.

STEP 3.2 Large Study Testing of the Instrument

Purposes:

The objectives of this step were: to explore the subscale/factor structure of the 30-item developed instrument and to later reduce items for the developed instrument. Construct validity was tested by exploratory factor analysis (EFA). Criterion related validity was tested by Pearson correlation. After item reduction, final CM-QOL was created so that it was tested reliability using Alpha Cronbach.

Methods

Population and Sample

The population for this study included all individuals in Thailand who have to take continuously medication as prescribed for a long period of time.

The purposive samples were obtained of patients with chronic disease medication use as prescribed for at least six months prior to data collection. A six month time frame was selected because participants would still be in the period of ongoing medical treatment and also had to be clinically stable. The settings for data collection took place in the outpatient departments (OPD) from one government hospital and one private hospital in Thailand: Police General Hospital and Deja Hospital. Participants will be excluded if their Thai language was poor. All participants gave informed permission using consent by action before study entry.

Inclusion criteria

- Thai patients $\geq$ 20 years of age
- Before study entry, informed consent by action or agreement to participate in the study must be obtained from patient prior
- Patients receiving one or more prescriptions for drugs used in treating their chronic diseases at least six months

Exclusion criteria

- Pregnant women
- History of already received psychotherapy drug
- Unable to complete self-reported surveys (e.g. cognitive deficits)
- Not be able to understand Thai language

Sample size

The objective of this study was to develop a new instrument to measure health-related quality of life in Thai patients with continuous drug use. Because of the new tool, no data about the scale's variance is available and the researcher cannot conduct a power analysis. The sample size was based on criteria of factor analysis. Regarding the sample size question, Hair et al., (2006: 112) suggested the researcher generally would not factor analyze a sample of fewer than 50 observations, and preferably the sample size should be 100 or larger. As a general rule (rule of thumb), the minimum is to have at least five times as many observations as the number of variables to be analyzed, and the more acceptable sample size would have a 10:1 ratio. The sample size of this study was calculated from the 10 participants per item. There are 30 items, in which case the sample size should be 300 participants. This study used sample size equal 530 participants so that it would be sufficient and very good for the exploratory factor analysis (Tabachnick & Fidell, 2007).

Protection of Human Subjects

This study received approval from the Chulalongkorn University Institutional Review Board and Police General Hospital. Respondents were approached and invited to participate in the study at the outpatient department. The overall purpose of the study, the risks and benefits, and the time required for participant were explained before. Participants were assured of anonymity and confidentiality. They were informed that they could stop their participation at any time. Consent by action was obtained.

Confidentiality was maintained by omitting their names from the data. There was no any risk of participating in this study. It took approximately 30 minutes to complete the questionnaires. There was no cost for participating and participants would not receive an incentive fee for participation.

Data Collection

The researcher only collected the data by introducing myself and explained the purpose of the study, the risks and benefits, and the time required for participant. Participation did not affect any treatment as you received. After obtaining consent by action, the participants completed questionnaires in the waiting area of the OPD following the regularly scheduled appointment with their doctors. Participants received a thank you for their contribution of time and meaningful information following completion of the questionnaires.

Instruments

The questionnaire was designed on 12- page A4 sheet comprising four instruments were used in this study. They were: (1) modified adherence score, (2) CM-QOL 30 items, (3) EQ-5D3L in Thai and EQ5D-VAS, and (4) SF-36V2 in Thai.

For modified adherence scores were consisted of five items. The assumption of adherence was the patient's agreement with the doctor's recommendations. Measurement of medication adherence was used as subjective measurements. These items obtained by asking respondents about their continuous medication use as follows:

1. You take completely all kinds of your continuous medication as prescribed.

2. You take each continuous medication right dose according to their doctors ordered in each day.

3. You take continuous medication completely every meal as prescribed.

4. You take continuous medication on time according to their doctors ordered in each meal.

5. You get prescription refilled on a doctor's appointment.

Statistical Analysis

All statistical analyses were performed using the software SPSS for windows version 17.0 (SPSS Co., Ltd, Bangkok, Thailand). The level of significance for any statistical tests were at $\alpha = 0.05$. Reliability and validity data for the existing measures would also be computed.

Exclude case list wise was used in all statistical analyses that mean if the participant has any missing value for any variable then the participant is omitted from all our data analysis.

The CM-QOL instrument, 30-item version, was tested in 530 patients with chronic medication use at least six month. This questionnaire was tested construct validity using exploratory factor analysis (EFA). Two well-known instruments, SF36 version 2 in Thai and EQ5D3L in Thai, were used criterion-related validity. Internal consistency reliability was evaluated using Cronbach's alpha in the final item analysis.

Descriptive statistics

Demographic characteristics of the participants (e.g. age, sex, marital status, education, occupation, health system, income) and Drug use characteristics of the patients were summarized using descriptive statistics. Descriptive statistics included mean, standard deviation, range, frequency, and percent. Descriptive statistics would also be analyzed for all scales, including the CM-QOL, SF36V2, EQ5D3L, Adherence questionnaire. Item frequency of CM-QOL was displayed as the percentage of scores at the extremes of the scaling range, as well as, the maximum possible score (ceiling effect) and the minimum possible score (floor effect).

Psychometric property testing

Construct validity

Construct validity is directly concerned with the theoretical relationship of a variable. It is used to determine whether the instrument captures proposed theoretical relationship (S. S. Sen, et al., 1999). Factor analysis is designed on the basis of a conceptual framework, a measure to assess various dimensions or subscales of a phenomenon of interest and wishes to empirically justify these dimensions or factors (P. M. Fayers & Machin, 2007). A factor is a group of items that belong together. Items can be deleted that don't correlate well enough with a factor.

In this study, exploratory factor analysis (EFA) was used to test the construct validity (domain structure). EFA was a technique that the researcher had no a prior hypothesis about factors or constructs of measured variables(Tabachnick & Fidell, 2007). Because there were insufficient evidences to determine the component factors of measured variables, the component domains of CM-QOL, the researcher decided to use EFA. This method was explored to describe and summarize data by grouping together variables that are correlated. EFA was a useful

technique not only for grouping the dimensionality of a set of items but also for isolating items that did not measure the dimensions well. Because the goal this analysis was usually to explore the dimensionality of the scale itself, principal components would seem a reasonable factor analytic model to use, although other models were also available.

The 5- step Exploratory Factor Analysis

Step 1: Is the data suitable for factor analysis?

The first step of EFA was the testing assumptions that the data meet the statistical requirements for a proper estimation of the factor structure as follows:

(1) Sample size

The sample size should be large sufficient to yield reliable estimates of correlations among the variables. Data were collected from 530 patients with continuous medication use in this study so that it would be enough and very good for the exploratory factor analysis according to Tabachnick's rule of thumb.

(2) Factorability of the correlation matrix (Hair, Black, Babin, Anderson, & Tatham, 2006; Tabachnick & Fidell, 2007; Williams, Brown, & Onsman, 2012)

This is the assumption that there are at least some correlations among the variables. Factorability of the data can be checked by one or more of the following methods:

1) Inter-item correlations (correlation matrix) - using Pearson correlation that should be ≥ 0.30
2) Anti-image correlation matrix diagonals – Hair et al.(2006: 114) suggested that a partial correlation is the correlation that is unexplained when the effects of other variables are taken into account. If "true" factors exist in the data, the partial correlation should be small, because the variable can be explained by the variable loading on the factors. If the partial correlation high, indicating no underlying factors, then factor analysis is inappropriate. In this study, partial (anti-image) correlation matrix should be nearly zero or minus zero (Hair, et al., 2006; Panyawuthikrai, 2004).

3) Measures of sampling adequacy (MSAs) – Before the extraction of the factors some tests should be used to evaluate the appropriateness of data for factor analysis later. There were two tests as follows:

i) Kaiser-Meyer-Olkin Measure of Sampling Adequacy; KMOMSA for overall should be 0.60 – 1.00 (Tabachnick & Fidell, 2007).

ii) Bartlett's Test of Sphericity should be significant ($p < 0.05$) for factor analysis to be suitable. This test is recommended only if there are fewer than five cases per variable (Tabachnick & Fidell, 2007).

(3) Communality Estimation

The communality (common variance) is the squared multiple correlation for the variable using the factors as predictors. Squared Multiple Correlation (SMC) was used as initial estimates of the communality of a variable. Each variable (item) has a communality that means the proportion of its variance explained by the extracted factors; range 0 – 1 (Hair, et al., 2006). Although no statistical guidelines indicate exactly what is high or low, practical considerations establish a lower level of 0.50 for communalities in this study (Hair, et al., 2006). If the communality estimation was low (< 0.50) that showed this variance item unexplained by the extracted factors. Next step, the researcher would consider that item may need to extract more factors to explain the variance or remove this item from the EFA. If the communality was high (> 0.50) that showed that item had enough explanation to proceed in factor analysis later.

Step 2: Selecting the Factor Extraction Method

Extraction methods in SPSS were commonly used in factor analysis (EFA and CFA) as follows:

- Principal component analysis (PCA)
- Principal axis factoring (PAF)
- Maximum likelihood
- Unweighted least squares
- Generalised least squares
- Alpha factoring

- Image factoring

Using PCA and PAF in exploratory factor analysis were found most commonly in the social science literatures (Fabrigar, Wegner, MacCallum, & Strahan, 1999; Panyawuthikrai, 2004; Williams, et al., 2012). The PAF was common factor model that was commonly used in EFA because of using not limited of being normal distribution (Tabachnick & Fidell, 2007). Some researchers recommended that if your data were normally-distributed, maximum likelihood was the best choice (Costello & Osborne, 2005). PAF was recommended to use in exploratory factor analysis because it would provide the best results without consideration of the distribution of data ; in SPSS this was called "principal axis factors" (Fabrigar, et al., 1999). This step was selected using PAF as an extraction method because the researcher expected it would represent a high-quality decision (Conway & Huffcutt, 2003).

Step 3: Selecting the appropriate number of factors to extract

There were multiple criteria assigned to determine the appropriate number of factors to retain in EFA. These criteria were as follows:

(1) Cummulative Percentage of Variance

This criterion was based on achieving a specified cumulative percentage of total variance extracted by successive factors. In social sciences, the explained variance is commonly as low as 50 – 60%; as satisfactory (Hair, et al., 2006). In this study, the researcher considered a commulative percentage of variance accounts > 50% of the total variance.

(2) Eigenvalue > 1

Kaiser's (1960) eigenvalue-greater-than-one rule (K1 or Kaiser criterion) is well known as Kaiser's criteria or eigenvalue. Rule of thrumb; all factors with eigenvalus > 1 were considered significant. If all factors with eigenvalue less than 1 were considered insignificant and were disregarded (Hair, et al., 2006). This number was the number of factors to include in the model.

(3) Cattell's scree test

The scree test was used to identify the optimum numbers of factors that could be

extracted before the amount of unique variance begins to dominate the common variance structure (Hair, et al., 2006). The number of factors should be used or extracted on the steep slope. The components on the shallow slope contribute little to the solution. Because this test was subjective that was required researcher judgement. This study selected the number of plotted points before the last drop is the number of factors to include in exploratory factor analysis.

(4) Factor solution

The researcher used the difference of connecting factor > 0.2 as based on previous studies (Panyawuthikrai, 2004; Wongwiwatthananukit, et al., 2005b).

Step 4: Selection of Rotational Method

The main outcome of selecting rotational method was to achieve the simplest possible structure. In SPSS, there are two common rotation methods: orthogonal (varimax/quartimax) and oblique (direct oblimin/promax) rotation. CM-QOL has correlation among factors (domains), so the selecting oblique rotation was appropriate because it produced solutions with better simple structure by allowing factors to correlate. According to previous quality of life research found that dimensions/subscales scores were correlated and not independent each other, then direct oblimin and promax would be appropriate (Panyawuthikrai, 2004; Wongwiwatthananukit, et al., 2005b; Zebrack & Chesler, 2001).

The rotational method, principal axis factor with promax rotation, was used in this study.

In interpreting factors, a decision must be made regarding the factors loadings practical and statistical significance. The factor loadings represented relative importance of each item to each factor.

The next step was item selection for each factor that based on methodology prior studies (Panyawuthikrai, 2004; Wongwiwatthananukit, Dhumma-Upakorn, & Naktuan, 2005a). Three criteria were:

(1) Factor loadings

Using practical significance as the criteria, Some authors suggested assessing the loadings as follows (Hair, et al., 2006; Tabachnick & Fidell, 2007):

- Factor loadings in the range of ± 0.30 to ± 0.40 were considered to meet the minimal level for interpretation of structure.

- Loadings ± 0.50 or greater were considered practically significant.

- Loadings exceeding ± 0.70 were considered indicative of well-defined structure and were the goal of any factor analysis.

Some researchers decided using factor loading > 0.30 for the factor to account for 10 percent of the variance of a variable. Moreover, guidelines for identifying significant factor loadings based on sample size of 350 or greater would consider at factor loading 0.30. As mentioned, the sample size of this study were 530, then using factor loading > 0.30 was appropriate. The items were more loadings that refered greater reliability. If any items have factor loading > 0.3 on only one factor, that item would be hold on a given factor.

(2) Factor solution

Promax rotation maximized high item loadings and minimized low item loadings, then producing the output more understandable. The researcher used the simple structure as the criteria of factor grouping. There may be more than one good solution such as 2 factor model, 4 factor model, 7 factor model. The researcher may find that different rotation methods eliminate any cross-loadings and thus defined a simple structure.

(3) Number of items per factor

The study considered at least 3 – 4 items per factor were used to interpret the factor Solution based on previous study (Wongwiwatthananukit, Newton, & Popovich, 2002).

The next process, the suitability of the number of factor model was considered using residual analysis (Panyawuthikrai, 2004). The residual is difference between the actual and predicted correlation between variables. It shows how well the one factor model fits. Considering from residual correlation matrix (reproduced correlation matrix); if this value was lower or minus, it showed that the one factor model fit the data well.

Step 5: Interpretation and Labeling

This process involved examining a factor structure, selecting a final factor solution, and giving that factor a name or label. This label was not derived by the factor analysis computer program but the label was intuitively developed by the researcher based on its appropriateness for representing the underlying dimensions of a factor (Williams, et al., 2012).

Reliability

In this study, two methods were used to estimate reliability: item analysis and Cronbach's alpha. A value of 0.70 or greater would be considered to represent a questionnaire with acceptable reliability of QoL assessment (P. M. Fayers & Machin, 2007).

Item analysis and Cronbach's alpha

After the validity of the CM-QOL construct was tested with EFA, item analysis was considered using internal consistency reliability. Item analysis was yet the process used to remove items that had low inter-item correlations. Internal consistency reliability was defined as the homogeneity of the items comprising a domain. The reliability of each domain of the CM-QOL instrument was estimated by Cronbach's alpha. A value of 0.70 was considered an acceptable level of internal consistency (Nunnally, 1978).

Internal reliability was assessed on the items constituting each domain (dimension). Items was removed from each of the domains if they did not meet 3 criteria as follows (Nunnally, 1978):

- coefficient alpha or Cronbach's alpha coefficient ≥ 0.70
- corrected item-total correlation ≥ 0.30
- Alpha if item deleted < Cronbach's alpha coefficient

Criterion-Related Validity

Criterion-Related Validity was used to display the accuracy of a measure by comparing CM-QOL with other gold standard instruments which had been demonstrated to be reliable and valid. This research, the EQ5D3L in Thai, and the SF-36V2 in Thai as two generic measures were used to test criterion validity with new CM-QOL instrument. Criterion validity was assessed by Pearson's product moment correlation coefficient among the EQ5D3L in Thai, the SF-36V2 in

Thai, SF6D Utility Index derived from SF-36V2, Adherence self-reported scores, and the new CM-QOL instrument.

EQ5D3L in Thai

This study used the standard Thai EQ-5D3L that included a self-reported health state description and a visual analogue scale (VAS). The health state is five single-item domains as follows: (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort, and (5) anxiety/depression. Each domain is three response levels: no, some, and severe problems see Appendix E. The preference values for 243 health states were analyzed using time trade-off (TTO) method. The Thai version was authorized by using Thailand (Thai) ©2002 EuroQol Group. **EQ-5D™ is a trade mark of the EuroQol Group** (EuroQoL group). Our study selected to use the Thai population-specific preference weights to convert the EQ-5D health state into a single EQ-5D index score (S Tongsiri & Cairns, 2011). The Thai population-specific preference weights were collected in 1409 Thai subjects. The highest score for health state 11111 was 1.0 that represented the best health or full health. The lowest score for health state 33333 was 0.0 that represented the worst health. If calculating followed the equation for health state 11111, the best score index was 0.978 and for health state 33333, the lowest score index was -0.454.

The researcher used the equation of Tongsiri (2011) for calculating the Thai EQ-5D utility as follows:

Thai score = 1 - 0.202 – (0.121*mo) – (0.121*sc) – (0.059*ua) – (0.072*pd)
– (0.032*ad) – (0.190*m2) – (0.065*p2) – (0.046*a2) – (0.139*N3)

Note: mo is mobility, sc is self-care, ua is usual activities, pd is pain and discomfort, and ad is anxiety and depression. Each variable was calculated by using model of Dolan 1997 in Table 1 page 1144 (S Tongsiri & Cairns, 2011).

Method: criterion test

The thai algorithm EQ-5D index and EQ-5D VAS were analyzed in criterion validity (concurrent validity) in this study further.

SF-36V2 in Thai

The Medical Outcomes Study 36-item Short Form Version 2 (SF-36V2; QualityMetric, Lincoln, RI) was the standard generic health-related quality of life questionnaire. The researcher selected to use the standard Thai SF-36V2™ health survey. This version was authorized by QualityMetric Health Outcomes ™ (Quality Metric Company). The SF-36V2 recall was used to collect health status for the past four weeks. Respondents completed questionnaires based on their thoughts and feelings on their health states. The 36 items were included eight domains as follows: (1) physical functioning, (2) role limitations due to physical health problems, (3) bodily pain, (4) vitality, (5) general health, (6) social functioning, (7) role limitations due to emotional problems, and (8) mental health.

The SF-36 domain scores, the mental health component summaries, and the physical health component summaries were calculated by using licensed the QualityMetric SF-36 Scoring Software 4.5 (Saris-Baglama et al., 2011). This licensed program displayed a norm-based score (NBS) with a mean of 50 and standard deviation of 10 based on 2009 US general population norms. Low scores represented poor health related quality of life. Higher score indicated better quality of life (Nacul et al., 2011).

Method: criterion test

The standard Thai SF-36V2™ health survey was scored by using norm-based T scores for each domain scores, the Physical (PCS) and Mental (MCS) Component Summary scores were evaluated with pearson' correlation coefficients for criterion validity (concurrent validity) in this study later.

SF-6D derived SF-36V2 ™

This study was also analyzed SF-6D by using the data of respondents who completed the SF-36V2 in Thai version would be assigned to a health state classification e.g., SF-6D. This classification was described health on six multilevel dimensions: physical functioning, role limitations, social functioning, pain, mental health, and vitality. In principle, there were two versions of the SF-6D, one for use with the SF-36 and the other for the SF-12. The researcher preferred to select and calculate health state preference values (utilities) from general quality of

life data collected using the SF-36V2. This study was calculated using developed a preference-weighted version of the SF-6D (J. Brazier, Roberts, & Deverill, 2002).

Currently, the SF-6D has 18,000 health states. The valuation task for the SF-6D used the worst possible health state ('pits') on the SF-6D as is the worst outcome, valued with the standard gamble method. The SF-6D was computed using the algorithm provided by Brazier and colleagues (J. Brazier, et al., 2002). The scoring reflected a continuous outcome ranged on a 0.296 to 1.00 scale, with 1.00 indicating full health. On both instruments, 0.296 represented the maximum impaired level on all six dimensions and 1 represented full health. Both algorithms include an interaction term to account for an additional disutility in case one of the domains is scored at its most severe level (J. Brazier, Roberts, Tsuchiya, & Busschbach, 2004).

Calculating SF-6D health state

This study was calculated using the algorithm provided by Brazier and colleagues . This algorithm was collected a much larger representative sample of the UK population (249 states, 611 respondents). These health states were evaluated in a normal population using the Standard Gamble (SG) method.

The SF6D index was included 11 items from the SF-36. The SF-6D derived from seven of the eight health domains in the SF-36v2™ Survey: physical functioning, role participation (combined role-physical and role-emotional), social functioning, bodily pain, mental health, and vitality. Only the general health domain was not included. Then the number of domains was reduced from 8 to 6. The 11 items used to score the SF-6D were indicated in Table 9.

Table 9: SF-36v2™ Health Survey Items Scored for the SF-6D

SF-6D Domains	SF-36v2™ Health Survey Items
Physical Functioning	3a, 3b, 3j
Role Participation (RP & RE)	4c, 5b
Social Functioning	10
Bodily Pain	7, 8
Mental Health	9b, 9f
Vitality	9e

Note: An excerpt from www.qualitymetric.com/Portals/0/Uploads/Documents/.../SF-6D.pdf

The results were 6 domains, each with multiple levels as follows: (1) physical functioning, 6 levels; (2) role limitations, 4 levels; (3) social functioning, 5 levels; (4) pain, 6 levels; (5) mental health, 5 levels; and (6) vitality, 5 levels (see Appendix E).

The equation for calculating the SF-6D utility as follows:

Utility = C + PF + RL + SF + PAIN + MH + VIT + MOST

Methods in this study used MOST by Brazier (2004). For the SF-6D the interaction term is a simple dummy, MOST, which takes the value 1 if any dimension in health state is at the 'most severe' level, and 0 otherwise. 'Most severe' levels in SF-6D were defined as levels 4–6 for physical functioning; levels 3 and 4 for role limitations; levels 4 and 5 for social functioning, mental health, and vitality; and levels 5 and 6 for pain. Assuming SF-6D 111111 health state is to equal 1 and death is equal to zero.

Then the equation for calculating the SF-6D utility in this study as follows:

Utility = C + PF + RL + SF + PAIN + MH + VIT + MOST(-0.061)

Note: C = Constant = 1, MOST = term to use if any dimension is at its most several level as mentioned above. Example if most = 1 then MOST in the equation = 1(-0.061) = -0.061. If most = 0 then MOST in the equation = 0(-0.061) = 0 (see Table 10). This model in table 10 was conducted from table 4 in page 856 (J. E. Brazier & Roberts, 2004).

Method: criterion test

The SF-6D utility scores were evaluated with pearson' correlation coefficients for criterion validity (concurrent validity) in this study later.

Table 10: SF-6D Utility scoring model

General terms	Physical functioning (PF)		Role limitation (RL)		Social functioning (SF)		Pain		Mental health (MH)		Vitality (VIT)	
Term Score	Level	Score	Level	Score	Level	Score	Level	Score	Level	Score	Level	Score
C = 1.000 MOST = -0.061												
	PF 1	-0.000	RL 1	-0.000	SF 1	-0.000	Pain 1	-0.000	MH 1	-0.000	VIT 1	-0.000
	PF 2	-0.035	RL 2	-0.053	SF 2	-0.057	Pain 2	-0.042	MH 2	-0.042	VIT 2	-0.071
	PF 3	-0.035	RL 3	-0.053	SF 3	-0.059	Pain 3	-0.042	MH 3	-0.042	VIT 3	-0.071
	PF 4	-0.044	RL 4	-0.053	SF 4	-0.072	Pain 4	-0.065	MH 4	-0.100	VIT 4	-0.071
	PF 5	-0.056			SF 5	-0.087	Pain 5	-0.102	MH 5	-0.118	VIT 5	-0.092
	PF 6	-0.117					Pain 6	-0.171				

Utility 0-1: dead-healthy scale, C = constant term, PFx = level on the physical functioning dimension, same for other dimensions, MOST = term to use if any dimension is at its most several level. From Brazier et al. (2004); UK SG The estimation of a preference-based measure of health from the SF-12. Severe levels in SF-6D are defined as levels 4–6 for physical functioning; levels 3 and 4 for role limitations; levels 4 and 5 for social functioning, mental health, and vitality; and levels 5 and 6 for pain.

Utility = C + PF + RL + SF + PAIN + MH + VIT + MOST

Results of Large Study Testing (Step 3.2)

The data were organized in to 4 parts in the following:

Part 1 Demographic characteristics

Part 2 Descriptive result of study variables

Part 3 Psychometric property testing: construct validity by exploratory factor analysis (EFA)

Part 4 Psychometric property testing: reliability, criterion validity of CM-QOL

Part 1 Demographic characteristics

There were 530 respondents in this study by setting and data collection as shown in table 11. Both Police General Hospital and Deja Hospital found that there were excluded 24 respondents from the study as missing data which more than 50% of the items of the domain in questionnaire.

Table 11: Numbers of respondents large study by setting and data collection

Variable		respondents	
		N = 530	%
Setting	Police General Hospital	202	38.1
	Deja Hospital	328	61.9
Data collection	Self-administered	423	79.8
	Interview	107	20.2

From table12, it showed that the participants' age ranged from 21 – 81 years with a mean 50.13 (SD = 8.95 years). The majority of participants were female (55.7%), marriage (62.6%), and secondary school level (32.8%). All samples were distributed in various status of working: company employee (57.2%), employed daily (17%), business owner (9.4%), government employee/state enterprises (3.8%) and retired (6.4%). The monthly incomes (baht per month) were varying in all: with ฿ 10,001 – 20,000 (36.6%), ฿ 5,000 – 10,000 (35.5%), and ฿ more than 20,000 (15.7%). Household incomes (baht per month) were also varying in all: with ฿ more than 20,000 (43.8%), ฿ 10,001 – 20,000 (34.3%), and ฿ 5,000 – 10,000 (20.8%). For health insurance,

this survey displayed that Social Security Scheme (SSS) was most (79.8%), Civil Servant Medical Benefit Scheme (CSMBS) (13%), Universal Coverage (gold card) (6.4%), and others (0.8%) were out of pocket costs and private insurance.

Among 530 respondents, more than 60% had hypertension, diabetes (42.8%), and dyslipidemia (39.1%) which were the first three diseases founded in these group of samples. More than half of the participants had two or more chronic diseases such as hypertension + diabetes, diabetes + dyslipidemia, gout + hypertension, thyroid + hypertension + dyslipidemia. Other diseases (19.8%) were thyroid, cancer, AIDs, gout, hepatitis B, SLE, glaucoma etc. Participants have used varying continuous medication at the range from 1 – 15 items with a mean 3.3 (SD = 1.90 items): 3 prescription drugs (27.5%), 2 prescription drugs (24.5%), 4 prescription drugs (19.8%), 1 prescription drugs (11.5%), and five or more drugs (5.3%). Most of the participants have used drug at the range from 6 – 360 months with a mean 61.53 (SD = 47.86 months). A patient took chronic medication at maximum 15 items

Table 12: Demographic data of respondents in large study testing of the instrument

Demographics		respondents	
		N = 530	%
Gender	Male	235	44.3
	Female	295	55.7
Age (years)	20-30	7	1.3
	31-40	57	10.8
	41-50	220	41.5
	51-60	185	34.9
	61-70	52	9.8
	> 70	9	1.7
Mean Age = 50.13, SD = 8.953, Min = 21, Max = 81			
Marital Status	Single	88	16.6
	Married	332	62.6
	Divorced/Separated	65	12.3
	Widowed	45	8.5
Education	Primary school or less	131	24.7
	Secondary school	174	32.8
	Diploma	78	14.7
	Bachelor degree	134	25.3
	Higher bachelor degree	13	2.5
Occupation	Business owner	50	9.4
	Employed daily	90	17.0
	Government employee/State Enterprises	20	3.8
	Company employee	303	57.2
	Unemployed	30	5.7
	Retired	34	6.4
	Others	3	0.6
Monthly income	No income	38	7.2
(Baht/month)	Less than 5,000	27	5.1
	5,000-10,000	188	35.5
	10,001-20,000	194	36.6
	More than 20,000	83	15.7

Demographics		respondents	
		N = 530	%
Household income (Baht/month)	Less than 5,000	4	0.8
	5,000-10,000	110	20.8
	10.001-20,000	182	34.3
	More than 20,000	232	43.8
	Missing cases	2	0.4
Health insurance	Civil Servant Medical Benefit Scheme	69	13.0
	Universal Coverage (gold card)	34	6.4
	Social Security Scheme	423	79.8
	Others	4	0.8
Chronic disease	Hypertension	352	66.4
	Diabetes	227	42.8
	Dyslipidemia	207	39.1
	Cerebrovascular	10	1.9
	Kidney	15	2.8
	Asthma	14	2.6
	Cardio	22	4.2
	Others	105	19.8
Number of chronic diseases	1	203	38.3
	2	250	47.2
	3	63	11.9
	4	12	2.3
	5	1	0.2
	6	1	0.2
Numbers of drugs used	1	61	11.5
	2	130	24.5
	3	146	27.5
	4	105	19.8
	5	41	7.7
	6	19	3.6
	$\geq$ 7	28	5.3

Part 2 Descriptive result of study variables (items of CM-QOL)

The 30 items of CM-QOL questionnaire were presented with their mean, median, frequency, percentage, standard deviation, and ceiling/floor effects. Individual items were rated on a 5-point Likert scale. For ease of interpretability (Table 13), items were reversed scored and transformed to a 1 – 5 scale, so that higher score indicated better continuous medication use quality of life as follows:

Group 1 positively identified item: 4 items

Group 2 negatively identified item: 26 items

Table 13: Scoring rating scale

Response scale of all items (5-point Likert scale)	**Group 1 positively identified item (score)**	**Group 2 negatively identified item (score): reverse score**
Not at all (1)	1	5
A little (2)	2	4
A moderate amount (3)	3	3
A lot (4)	4	2
An extreme amount (5)	5	1

Scores on all of the scales were created by averaging items within scales based on summated rating scale construction (Spector, 1992). Domain scores were calculated by computing the mean of the facet score within the domain, as follows. The mean was computed as the sum of the items divided by the number of items answered in that domain, so that domain scores range between 1 and 5.

Interpretability scores were 5 intervals as follows:

Mean score			**Meaning**
4.50	-	5.00	highest
3.50	-	4.49	high
2.50	-	3.49	moderate
1.50	-	2.49	low
1.00	-	1.49	lowest

Table 14: Descriptive statistics and frequency of response of the instrument (30items), N = 530

Items	Mean ± S.D.	Median	numbers (Percentage of responses in each item)**					Missing data
			1	2	3	4	5	
Q01	2.89±1.17	3.00	65 (12.3)	134 (25.3)	190 (35.8)	77 (14.5)	64 (12.1)	-
Q02	2.59±1.15	3.00	105 (19.8)	143 (27.0)	192 (36.2)	45 (8.5)	45 (8.5)	-
Q03	3.79±1.02	4.00	13 (2.5)	43 (8.1)	136 (25.7)	186 (35.1)	152 (28.7)	-
Q04	3.90±1.01	4.00	14 (2.6)	28 (5.3)	131 (24.7)	181 (34.2)	176 (33.2)	-
Q05	3.33±1.21	3.00	36 (6.8)	100 (18.9)	167 (31.5)	108 (20.4)	119 (22.5)	-
Q06	3.81±1.09	4.00	19 (3.6)	46 (8.7)	119 (22.5)	178 (33.6)	168 (31.7)	-
Q07	3.77±1.10	4.00	21 (4.0)	52 (9.8)	115 (21.7)	182 (34.3)	160 (30.2)	-
Q08	3.73±1.15	4.00	26 (4.9)	53 (10.0)	125 (23.6)	161 (30.4)	165 (31.1)	-
Q09	3.90±1.08	4.00	19 (3.6)	40 (7.5)	100 (18.9)	185 (34.9)	186 (35.1)	-
Q10	3.35±1.17	3.00	33 (6.2)	94 (17.7)	166 (31.3)	129 (24.3)	108 (20.4)	-
Q11	4.29±0.95	5.00	8 (1.5)	20 (3.8)	74 (14.0)	134 (25.3)	294 (55.5)	-
Q12	4.11±0.97	4.00	9 (1.7)	25 (4.7)	94 (17.7)	173 (32.6)	229 (43.2)	-
Q13	4.20±0.91	4.00	9 (1.7)	15 (2.8)	80 (15.1)	183 (34.5)	243 (45.8)	-
Q14	4.33±0.97	5.00	13 (2.5)	22 (4.2)	48 (9.1)	140 (26.4)	307 (57.9)	-
Q15	3.89±1.00	4.00	9 (1.7)	39 (7.4)	126 (23.8)	181 (34.2)	175 (33.0)	-
Q16	4.06±0.97	4.00	9 (1.7)	23 (4.3)	110 (20.8)	171 (32.3)	217 (40.9)	-
Q17	3.05±1.15	3.00	54 (10.2)	112 (21.1)	183 (34.5)	115 (21.7)	66 (12.5)	-
Q18	4.23±0.96	5.00	11 (2.1)	18 (3.4)	78 (14.7)	156 (29.4)	267 (50.4)	-
Q19	4.27±0.92	5.00	9 (1.7)	19 (3.6)	62 (11.7)	171 (32.3)	269 (50.8)	-
Q20	3.90±1.06	4.00	12 (2.3)	52 (9.8)	96 (18.1)	186 (35.1)	184 (34.7)	-
Q21	4.30±0.82	4.50	1 (0.2)	11 (2.1)	83 (15.7)	170 (32.1)	265 (50.0)	-
Q22	4.25±0.86	4.00	4 (0.8)	13 (2.5)	85 (16.0)	175 (33.0)	253 (47.7)	-
Q23	4.20±0.94	4.00	4 (0.8)	31 (5.8)	76 (14.3)	163 (30.8)	256 (48.3)	-
Q24	4.20±0.90	4.00	3 (0.6)	27 (5.1)	75 (14.2)	181 (34.2)	244 (46.0)	-
Q25	2.95±1.12	3.00	58 (10.9)	125 (23.6)	178 (33.6)	122 (23.0)	47 (8.9)	-
Q26	4.08±0.97	4.00	5 (0.9)	35 (6.6)	94 (17.7)	172 (32.5)	224 (42.3)	-
Q27*	3.81±0.94	4.00	18 (3.4)	20 (3.8)	124 (23.4)	251 (47.4)	117 (22.1)	-
Q28*	3.63±1.14	4.00	40 (7.5)	39 (7.4)	124 (23.4)	203 (38.3)	124 (23.4)	-
Q29*	3.91±0.97	4.00	19 (3.6)	16 (3.0)	110 (20.8)	233 (44.0)	152 (28.7)	-
Q30*	3.98±0.94	4.00	16 (3.0)	13 (2.5)	105 (19.8)	229 (43.2)	167 (31.5)	-

* = Positively phrased items of quality of life

** = score = 1 indicated worst quality of life; score = 5 indicated best quality of life

Data Quality :Ceiling and floor effects

The proportion of missing data was zero. The ceiling and floor effects for CM-QOL domains were calculated as the proportion of respondents with the highest and lowest possible score, respectively (Table 14). There were no items with a frequency more than 70 percent of respondents selected the highest score at the end of choices in each item and the lowest score of each item (Leurmarkul, 2000). The researcher decided that all items were retained in this study because the percent of participants and missing data were acceptable.

Part 3 Psychometric property testing: construct validity by exploratory factor analysis

Data were collected from 530 respondents. Before starting to test exploratory factor analysis, it should be evaluated the assumptions of using factor analysis method. The data were evaluated about the correlation matrix of items, anti-image correlation matrix, Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett test of Sphericity for the 30 items of the CM-QOL was tested in 530 respondents.

After exclude case listwise, there were 530 participants that were enough for factor analysis. There were 2 steps in exploratory factor analysis as the following:

Step 1: the testing the assumptions as follows:

In this study, there were quite a number of correlations greater than 0.3 that tentatively indicated the data were suitable for factor analysis. Look at partial (anti-image) correlation matrix was nearly zero or minus zero that indicated the data were sufficient correlation with other variables for factor analysis. The next, checked Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO). KMO is a ratio of sum of squared correlations to the sum of squared correlation plus sum of squared partial correlation (Hair, et al., 2006). When KMO is 0.60 and above, it reveals that using factor analysis is suitable. The KMO of this study was equally 0.924 (Table 15) and suited to conduct factor analysis. Bartlett test of Sphericity is statistical testing to examine the overall correlation matrix and is appropriate for factor analysis by testing the hypothesis that the matrix is an identity matrix, and also providing determination of multivariate normal distribution (Hair, et al., 2006). In this survey, the Bartlett test of Sphericity was

significant (X^2 = 11,018.99, df = 435, p = .000), showing that items had multivariate normal distribution, and the correlation matrix was suitable for factor analysis.

Table 15: KMO and Bartlett's Test of 30-item CM-QOL

KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.924
Bartlett's Test of Sphericity	Approx. Chi-Square	11,018.9954
	df	435
	Sig.	.000

Step 2: Exploratory Factor Analysis

Exploratory Factor Analysis (EFA) was done to find the domain of the CM-QOL instrument. The first method and most common used (Fabrigar, et al., 1999) in the process of EFA, principal axis factoring for extraction, rotating with promax was chosen to set a group of correlated items to be a factor. The components method of extraction was used first, the next decision was to select the number of factors to be retained for further analysis. The decision of the retention of factors was eigenvalues greater than 1. In this study, the researcher considered a commulative percentage of variance accounts more than 50% of the total variance.

After the factors method of extraction was analyzed in the first round, the results of the 30-item CM-QOL version found that there were 12 iterations and 7 factor extractions with 72.429 % cumulative variance (Table 16). The 7 factors retained represent 72.4 percent of the variance of the 30 variables, considered sufficient in terms of total variance explained. Since 6 factors found that the eigenvalue difference of connecting factor was not different than 0.20.

The scree test (Figure 4) indicated that 6 – 8 factors may be appropriate that represented the percentage of total variance explained ranged between 69.057 and 75.177.

Table 16: Results for the Extraction of Component Factors: 30-item CM-QOL

Total Variance Explained

	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings[a]
Factor	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	11.356	37.852	37.852	11.008	36.695	36.695	9.303
2	3.807	12.690	50.542	3.488	11.628	48.323	8.934
3	1.841	6.136	56.678	1.516	5.053	53.376	3.357
4	1.365	4.550	61.228	.978	3.261	56.637	7.352
5	1.305	4.349	65.577	.944	3.146	59.783	5.831
6	1.044	3.480	69.057	.665	2.216	61.999	6.274
7	**1.012**	**3.372**	**72.429**	.570	1.900	63.899	.845
8	.825	2.749	75.177				
9	.682	2.275	77.452				
10	.617	2.058	79.510				
11	.546	1.821	81.331				
12	.522	1.741	83.072				
13	.483	1.611	84.683				
14	.420	1.399	86.082				
15	.413	1.376	87.458				
16	.385	1.284	88.743				
17	.351	1.169	89.911				
18	.346	1.153	91.064				
19	.317	1.057	92.121				
20	.300	.999	93.120				
21	.275	.918	94.038				
22	.260	.868	94.906				
23	.246	.821	95.727				
24	.235	.783	96.509				
25	.219	.729	97.238				
26	.200	.667	97.905				
27	.176	.586	98.491				
28	.173	.576	99.067				
29	.161	.537	99.604				
30	.119	.396	100.000				

Extraction Method: Principal Axis Factoring.

a. When factors are correlated, sums of squared loadings cannot be added to obtain a total variance.

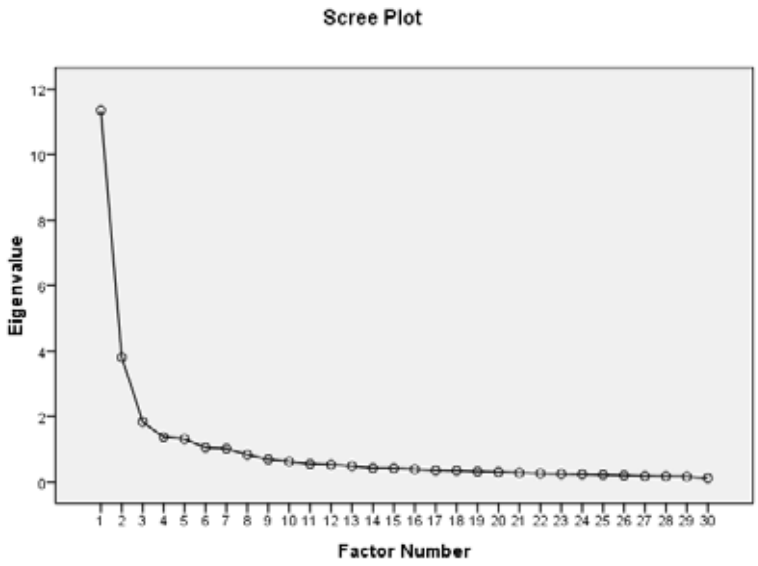


Figure 4: Scree plot of 30-item CM-QOL

Factor loadings and Item selection

Before rerun EFA, the 30-item version was evaluated factor loadings > 0.5 in order to give a simple structure. Two items were deleted because item17 had loadings less than 0.5 on all domains and item25 was found items cross-loading as items with loadings on more than one factor. A cross-loading was an item with coefficients greater than 0.4 on more than one domain/factor (Hair, et al., 2006). The research team decided to keep item4 though it had items cross-loading. Although factor analysis was a mathematical procedure, the item4 was subjective judgment as much as in the realm of statistical decision rules. Keeping item 4 was decided by subjective view because the researcher found that item4 had factor loadings > 0.5. In addition, item4 showed high reliability and the meaning of this item could represent in the daily activity domain. As the result, the 30-item version was revised to 28-item version.

Rerun EFA, principal axis factor by promax rotated, the result of the 28-item CM-QOL was displayed in table 17. There were 7 iterations and 6 factor extractions with 71.588 % cumulative variance. The scree test (Figure 5) indicated that 6 – 7 factors may be appropriate that represented the percentage of total variance explained ranged between 71.588 and 74.599. Factor loadings were shown in table 18.

Table 17: Results for the Extraction of Component Factors: 28-item CM-QOL

Total Variance Explained

Factor	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings[a]
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	10.951	39.112	39.112	10.602	37.864	37.864	9.106
2	3.748	13.386	52.499	3.429	12.248	50.112	8.245
3	1.675	5.983	58.482	1.381	4.933	55.045	3.283
4	1.353	4.832	63.314	.970	3.466	58.511	7.252
5	1.301	4.646	67.960	.926	3.308	61.819	5.169
6	**1.016**	**3.629**	**71.588**	.657	2.347	64.166	5.987
7	.843	3.011	74.599				
8	.708	2.528	77.127				
9	.598	2.136	79.264				
10	.567	2.023	81.287				
11	.499	1.783	83.070				
12	.460	1.644	84.714				
13	.423	1.510	86.224				
14	.416	1.485	87.709				
15	.355	1.269	88.978				
16	.354	1.263	90.240				
17	.326	1.165	91.405				
18	.309	1.105	92.510				
19	.284	1.013	93.523				
20	.269	.961	94.484				
21	.247	.882	95.366				
22	.239	.855	96.221				
23	.223	.797	97.018				
24	.201	.718	97.736				
25	.178	.637	98.373				
26	.174	.623	98.995				
27	.162	.578	99.573				
28	.119	.427	100.000				

Extraction Method: Principal Axis Factoring.

a. When factors are correlated, sums of squared loadings cannot be added to obtain a total variance.

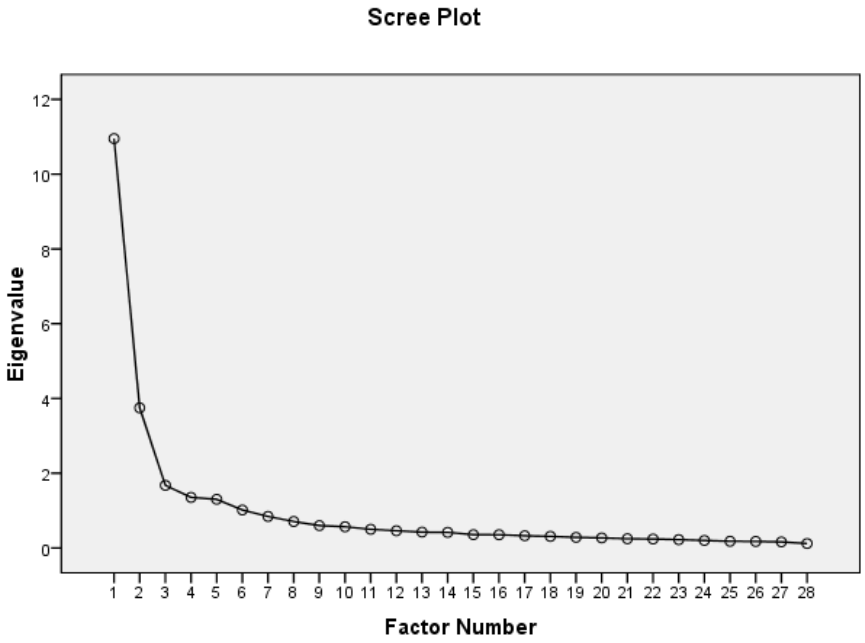


Figure 5: Scree plot of 28-item CM-QOL

Table 18: Structure Matrix of 28-item CM-QOL

Structure Matrix

	Factor					
	1	**2**	**3**	**4**	**5**	**6**
CM13R	**.870**	.478	-.077	.509	.403	.507
CM12R	**.831**	.485	-.055	.505	.431	.493
CM11R	**.805**	.570	.025	.550	.341	.516
CM14R	**.805**	.501	.036	.531	.297	.432
CM16R	**.790**	.535	-.183	.444	.491	.509
CM15R	**.765**	.632	-.154	.481	.495	.490
CM4R	**.635**	.622	-.100	.467	.614	.491
CM10R	**.614**	.548	-.303	.271	.565	.428
CM6R	.536	**.869**	.070	.582	.434	.393
CM9R	.581	**.865**	.070	.599	.364	.423
CM7R	.470	**.854**	.071	.519	.359	.385
CM8R	.522	**.771**	.115	.609	.357	.426
CM29R	-.025	.047	**.905**	.216	-.250	-.030
CM30R	-.023	.068	**.842**	.224	-.236	-.006
CM28R	-.123	.019	**.803**	.171	-.294	-.050
CM27R	-.079	.051	**.800**	.221	-.286	-.036
CM23R	.554	.588	.136	**.889**	.303	.496
CM24R	.653	.596	.098	**.798**	.323	.482
CM22R	.500	.549	.174	**.778**	.286	.425
CM26R	.612	.639	.061	**.759**	.355	.482
CM18R	**.525**	**.574**	.052	**.626**	.281	**.508**
CM2R	.271	.231	-.272	.055	**.696**	.251
CM1R	.271	.303	-.187	.224	**.656**	.242
CM5R	.546	.550	-.276	.246	**.635**	.403
CM3R	.562	.498	-.135	.382	**.617**	.491
CM19R	.531	.363	-.058	.393	.375	**.908**
CM21R	.658	.547	-.024	.594	.419	**.709**
CM20R	.350	.358	-.001	.395	.270	**.664**

Extraction Method: Principal Axis Factoring.
Rotation Method: Promax with Kaiser Normalization.

Item Analysis

Item analysis was yet the process used to remove items that had low inter-item correlations. The item analysis was considered by Cronbach's alpha, corrected item-total correlation and alpha if item deleted (Table 19, Table20).

Table 19: Reliability analysis of 28-item CM-QOL

No	Item	Cronbach's alpha	Corrected item-total correlation	Alpha if item deleted	Standardized item alpha
F1	Daily Activities	0.782			0.787
CM1R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการใช้ยาอื่น		0.498	0.763	
CM2R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการกินอาหารบางประเภท		0.507	0.759	
CM3R	ฉันต้องเสียเวลาในการจัดเตรียมยาที่ต้องใช้เป็นประจำ		0.618	0.724	
CM4R	การใช้ยาติดต่อกันเป็นประจำรบกวนชีวิตประจำวันของฉัน		0.617	0.725	
CM5R	ฉันต้องคอยกังวลว่าจะถึงเวลากินยา/ใช้ยาตลอดเวลา		0.567	0.739	
F2	Mental	0.911			0.912
CM6R	ฉันรู้สึกท้อแท้ที่ต้องใช้ยาติดต่อกันเป็นประจำ		0.827	0.874	
CM7R	ฉันรู้สึกเบื่อตัวเองที่ต้องใช้ยาทุกวัน		0.808	0.881	
CM8R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันรู้สึกเป็นคนสุขภาพไม่แข็งแรง		0.733	0.908	
CM9R	ฉันรู้สึกหดหู่เพราะต้องใช้ยาติดต่อกันเป็นประจำ		0.826	0.875	
F3	Psychosocial	0.912			0.913
CM11R	ฉันรู้สึกอายที่ต้องใช้ยาในขณะอยู่กับผู้อื่น หรือเพื่อนร่วมงาน		0.777	0.894	
CM12R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องหลีกเลี่ยงการออกงานสังคมบางประเภท (เช่น งานเลี้ยงสังสรรค์)		0.798	0.887	
CM13R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่มั่นใจเมื่อต้องเข้าสังคม		0.845	0.871	
CM14R	ฉันไม่ต้องการให้ผู้อื่นรู้ว่าฉันต้องใช้ยาติดต่อกันเป็นประจำ		0.783	0.893	
F4	Travel	0.829			0.837
CM10R	ในแต่ละวันฉันวิตกกังวลว่าจะลืมกินยา/ใช้ยา		0.601	0.866	
CM15R	การใช้ยาติดต่อกันเป็นประจำสร้างความยุ่งยากให้เมื่อฉันต้องออกจากบ้าน		0.772	0.683	
CM16R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่อยากเดินทาง		0.711	0.745	
F5	Burden	0.783			0.790
CM19R	ฉันต้องมีคนคอยดูแลการใช้ยาของฉัน		0.713	0.606	
CM20R	คนข้างเคียงต้องคอยเป็นห่วง ช่วยเตือนหรือดูแลไม่ให้ฉันลืมใช้ยา		0.588	0.761	
CM21R	การใช้ยาติดต่อกันเป็นประจำเป็นภาระต่อครอบครัวของฉัน		0.590	0.747	

No	Item	Cronbach's alpha	Corrected item-total correlation	Alpha if item deleted	Standardized item alpha
F6	Adverse drug reaction	0.886			0.886
CM22R	ผลข้างเคียงจากยาทำให้ฉันมีอาการไม่สบายมากขึ้น		0.711	0.864	
CM23R	ผลข้างเคียงที่เกิดจากการใช้ยาทำให้ประสิทธิภาพการทำงานของฉันลดลง		0.803	0.842	
CM24R	ผลข้างเคียงจากยาที่ใช้ประจำรบกวนการใช้ชีวิตประจำวันของฉัน		0.769	0.851	
CM26R	ผลข้างเคียงจากยาที่ใช้ประจำสร้างความรำคาญให้แก่ฉัน		0.746	0.856	
CM18R	การใช้ยาติดต่อกันเป็นประจำก่อให้เกิดภาระค่าใช้จ่ายแก่ฉัน		0.600	0.890	
F7	Positive consequence	0.901			0.904
CM27R	การใช้ยาติดต่อกันเป็นประจำทำให้อาการฉันดีขึ้น		0.754	0.881	
CM28R	การใช้ยาติดต่อกันเป็นประจำช่วยให้ฉันไม่ขาดงานหรือได้ทำกิจกรรมที่อยากทำ		0.753	0.888	
CM29R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันมั่นใจว่าอาการจะไม่กำเริบ		0.839	0.850	
CM30R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันใช้ชีวิตได้เป็นปกติ		0.789	0.869	

Note: CM18R was grouped in original domain (Adverse drug reaction) that analyzed using factor analysis.

Table 20: Reliability analysis of Item18 (CM18R) between Burden and Adverse Drug Reaction Domain

No	Item	Cronbach's alpha	Corrected item-total correlation	Alpha if item deleted	Standardized item alpha
F5	Burden	0.787			0.794
CM18R	**การใช้ยาติดต่อกันเป็นประจำก่อให้เกิดภาระค่าใช้จ่ายแก่ฉัน**		**0.497**	**0.783**	
CM19R	ฉันต้องมีคนคอยดูแลการใช้ยาของฉัน		0.673	0.695	
CM20R	คนข้างเคียงต้องคอยเป็นห่วง ช่วยเตือนหรือดูแลไม่ให้ฉันลืมใช้ยา		0.574	0.750	
CM21R	การใช้ยาติดต่อกันเป็นประจำเป็นภาระต่อครอบครัวของฉัน		0.661	0.709	
F6	Adverse drug reaction	0.886			0.886
CM22R	ผลข้างเคียงจากยาทำให้ฉันมีอาการไม่สบายมากขึ้น		0.711	0.864	
CM23R	ผลข้างเคียงที่เกิดจากการใช้ยาทำให้ประสิทธิภาพการทำงานของฉันลดลง		0.803	0.842	
CM24R	ผลข้างเคียงจากยาที่ใช้ประจำรบกวนการใช้ชีวิตประจำวันของฉัน		0.769	0.851	
CM26R	ผลข้างเคียงจากยาที่ใช้ประจำสร้างความรำคาญให้แก่ฉัน		0.746	0.856	
CM18R	**การใช้ยาติดต่อกันเป็นประจำก่อให้เกิดภาระค่าใช้จ่ายแก่ฉัน**		**0.600**	**0.890**	

Table 21: Item reduction by item analysis of 28-item version

	coefficient alpha or Cronbach's alpha coefficient ≥ 0.70	corrected item-total correlation ≥ 0.30	Alpha if item deleted < Cronbach's alpha coefficient	Note
F1				
CM1R	✓	✓	✓	
CM2R	✓	✓	✓	
CM3R	✓	✓	✓	
CM4R	✓	✓	✓	
CM5R	✓	✓	✓	
F2				
CM6R	✓	✓	✓	
CM7R	✓	✓	✓	
CM8R	✓	✓	✓	
CM9R	✓	✓	✓	
F3				
CM11R	✓	✓	✓	
CM12R	✓	✓	✓	
CM13R	✓	✓	✓	
CM14R	✓	✓	✓	
F4				
CM10R	✓	✓	✗	**maintained**
CM15R	✓	✓	✓	
CM16R	✓	✓	✓	
F5				
CM18R	✓	✓	✓	
CM19R	✓	✓	✓	
CM20R	✓	✓	✓	
CM21R	✓	✓	✓	
F6				
CM22R	✓	✓	✓	
CM23R	✓	✓	✓	
CM24R	✓	✓	✓	
CM26R	✓	✓	✓	
CM18R	✓	✓	✗	**removed**
F7				
CM27R	✓	✓	✓	
CM28R	✓	✓	✓	
CM29R	✓	✓	✓	
CM30R	✓	✓	✓	

Results of Item Analysis

Internal reliability was assessed on the items constituting each domain (dimension). Items was removed from each of the domains if they did not meet 3 criteria as follows (Nunnally, 1978):

(1) coefficient alpha or Cronbach's alpha coefficient ≥ 0.70

(2) corrected item-total correlation ≥ 0.30

(3) Alpha if item deleted < Cronbach's alpha coefficient

The reduction of the 28-item CM-QOL was evaluated using 3 criteria as mentioned. The results were exhibited in table 21.

Deleting item process:

The reliability coefficient of domain was Cronbach's alpha coefficient ≥ 0.70 that was considered an acceptable level of internal consistency.

Item CM10R and item CM18R did not meet one criteria as aboved.

Table 21 showed all items had corrected item-total correlation ≥ 0.30. One item was deleted at the time, preferably item CM18R because it produced a higher exam reliability coefficient if deleted, and the meaning of this item did not make sense if it was still in this domain (adverse drug reaction domain) and rerun reliability analysis to confirm we did not lower the overall alpha of the scale. The result showed that it highly contributed to the alpha value; old alpha = 0.886, new alpha = 0.890. Thus, item CM18R was removed in this adverse drug reaction domain of the questionnaire. The researcher examined that CM18R was regrouped into burden aspect as shown in table 20. This result found that item CM18R slightly increased to the alpha value; old alpha = 0.783, new alpha = 0.787. For item analysis, item CM18R was suitable to be in burden domain.

Item CM10R was still maintained in this questionnaire because on previous study recommended at least 3 – 4 items per factor sufficiently to interpreting the factor analysis.

For item analysis, the 28-item CM-QOL was reduced by one item (CM18R) then the final version was the 27-item CM-QOL questionnaire and the one open-ended rating item was added as visual analogue scale for overall quality of life with continuous medication use as called

as 28-item CM-QOL. CM18R was removed in this study prior because it produced cross-loading in many aspects by using factor analysis with promax (not be good simple structure) and item analysis found that item18 did not make sense if it still remained in adverse reaction domain though it slightly increased the reliability in new domain (burden) see in table 19, 20. By EFA, item CM18R had a cross-loading above 0.3 on mental, psychosocial, travel, adverse drug reaction and burden domain though it had a strong primary loading of 0.626 in factor 4 (adverse drug reaction aspect) see in table 18.

The final 27-item CM-QOL was analyzed again in the process of EFA. Principal axis factoring for extraction, rotating with promax was chosen to set a group of correlated items to be a factor. The components method of promax extraction was used in this study because it could make an explicit factor structure and a simple structure. The decision of the retention of factors was eigenvalues greater than 1. In this study, the researcher considered a commulative percentage of variance accounts more than 50% of the total variance. The result of EFA of 27-item CM-QOL was displayed in table 21. The mean of each item of final version at range between 2.589 and 4.332 as showed in table 22.

Descriptive Statistics

Table 22: The average scores of each item (items = 27)

	Mean	Std. Deviation
CM1R	2.8887	1.16699
CM2R	2.5887	1.14896
CM3R	3.7943	1.02390
CM4R	3.9000	1.01006
CM5R	3.3283	1.20716
CM6R	3.8113	1.08533
CM7R	3.7698	1.10328
CM8R	3.7283	1.14776
CM9R	3.9038	1.07567
CM10R	3.3491	1.16861
CM11R	4.2943	.94667
CM12R	4.1094	.96992
CM13R	4.2000	.91490
CM14R	4.3321	.97371
CM15R	3.8943	1.00291
CM16R	4.0642	.97008
CM19R	4.2679	.92227
CM20R	3.9019	1.05689
CM21R	4.2962	.81861
CM22R	4.2453	.86314
CM23R	4.2000	.94339
CM24R	4.2000	.90452
CM26R	4.0849	.97141
CM27R	3.8094	.93630
CM28R	3.6264	1.14211
CM29R	3.9113	.96521
CM30R	3.9774	.94031

Table 23: KMO and Bartlett's Test of 27-item version

KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.919
Bartlett's Test of Sphericity	Approx. Chi-Square	10,187.069
	df	351
	Sig.	.000

The KMO of this 27-item version was 0.919 (Table 23) and suited to conduct factor analysis. In addition, the Bartlett test of Sphericity was significant (X^2 = 10,187.069, df = 351, p = .000), revealing that variable had multivariate normal and the correlation matrix was suitable for factor analysis.

From table 24 presented in extracted communalities at range 0.444 – 0.875. Although there were the communalities < 0.5, these items were not deleted from the questionnaire. These items still shared their variance with six factors as well because the communalities were more than 0.30. Moreover, these items were high factor loadings that more than 0.5. Thus, all of the communalities were sufficiently high to proceed with the rotation of the factor matrix.

The factor correlation matrix of factor 1 and factor 2, factor 2 and 3, factor 3 and 4, factor 4 and 5, factor 5 and 6 were 0.665, 0.004, 0.227, 0.276, and 0.482 respectively (Table 25). Most residuals correlation matrix was close to zero and minus value.

Rerun EFA, principal axis factor by promax rotated, the result of the 27-item CM-QOL was displayed in table 26. There were 6 iterations (Table 27) and 6 factor extractions with 72.417% cumulative variance and eigen value was 1.014 (Table 26). The scree test (Figure 6) indicated that 5 – 7 factors may be appropriate that represented the percentage of total variance explained ranged between 68.663 and 75.493.

Table 24: Communalities of 27-item version

Communalities

	Initial	Extraction
CM1R	.398	.474
CM2R	.437	.534
CM3R	.542	.466
CM4R	.618	.542
CM5R	.572	.502
CM6R	.746	.769
CM7R	.703	.751
CM8R	.623	.612
CM9R	.720	.760
CM10R	.595	.511
CM11R	.692	.673
CM12R	.758	.705
CM13R	.793	.782
CM14R	.694	.689
CM15R	.707	.620
CM16R	.688	.635
CM19R	.580	.875
CM20R	.436	.444
CM21R	.605	.595
CM22R	.605	.635
CM23R	.695	.799
CM24R	.676	.684
CM26R	.615	.625
CM27R	.604	.644
CM28R	.610	.648
CM29R	.736	.828
CM30R	.680	.717

Extraction Method: Principal Axis Factoring.

Table 25: Factor Correlation Matrix of 27-item version

Factor Correlation Matrix

Factor	1	2	3	4	5	6
1	1.000	.665	-.117	.595	.548	.621
2	.665	1.000	.004	.633	.533	.504
3	-.117	.004	1.000	.227	-.358	-.078
4	.595	.633	.227	1.000	.276	.498
5	.548	.533	-.358	.276	1.000	.482
6	.621	.504	-.078	.498	.482	1.000

Extraction Method: Principal Axis Factoring.

Rotation Method: Promax with Kaiser Normalization.

Table 26: Results for the Extraction of Component Factors: 27-item CM-QOL

Total Variance Explained

Factor	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings[a]
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	10.534	39.016	39.016	10.192	37.747	37.747	8.838
2	3.730	13.815	52.831	3.415	12.646	50.393	7.908
3	1.674	6.199	59.030	1.381	5.113	55.507	3.287
4	1.348	4.992	64.022	.977	3.620	59.127	6.714
5	1.253	4.641	68.663	.892	3.302	62.429	5.086
6	**1.014**	**3.754**	**72.417**	.666	2.465	64.894	5.641
7	**.830**	**3.076**	**75.493**				
8	.689	2.551	78.044				
9	.580	2.149	80.193				
10	.566	2.098	82.291				
11	.466	1.725	84.016				
12	.427	1.581	85.597				
13	.423	1.565	87.162				
14	.359	1.330	88.492				
15	.354	1.313	89.805				
16	.331	1.227	91.031				
17	.309	1.146	92.177				
18	.289	1.072	93.249				
19	.270	.999	94.248				
20	.250	.925	95.173				
21	.240	.887	96.060				
22	.226	.837	96.897				
23	.202	.748	97.646				
24	.179	.664	98.309				
25	.174	.646	98.955				
26	.162	.600	99.555				
27	.120	.445	100.000				

Extraction Method: Principal Axis Factoring.

a. When factors are correlated, sums of squared loadings cannot be added to obtain a total variance.

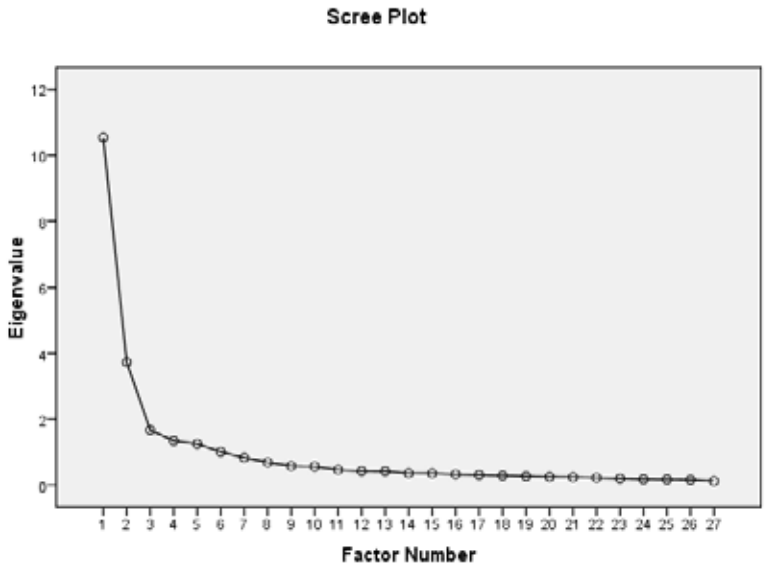


Figure 6: Scree Plot of 27-item version

Table 27: Pattern Matrix[a] of 27-item version

	Factor					
	1	**2**	**3**	**4**	**5**	**6**
CM13R	**1.022**	-.180	.015	.030	-.046	-.036
CM14R	**.942**	-.038	.071	.057	-.145	-.092
CM12R	**.919**	-.153	.050	.045	.035	-.040
CM11R	**.809**	.080	.066	.014	-.139	.032
CM16R	**.752**	.028	-.076	-.033	.039	.015
CM15R	**.612**	.239	-.077	-.022	.019	-.021
CM10R	.385	.305	-.165	-.176	.155	.040
CM7R	-.131	**1.007**	.027	-.040	-.092	.014
CM6R	-.063	**.895**	.043	.063	.018	-.063
CM9R	.065	**.880**	.014	.036	-.132	-.026
CM8R	-.009	**.680**	.069	.153	-.021	.013
CM5R	.213	.331	-.102	-.168	**.325**	.031
CM29R	.112	-.021	**.952**	-.055	.068	-.024
CM30R	.063	.021	**.872**	-.036	.040	.006
CM28R	-.078	.063	**.796**	-.015	-.009	.035
CM27R	-.039	.062	**.774**	.039	-.035	.010
CM23R	-.017	.004	-.052	**.883**	.035	.034
CM22R	-.005	.055	.028	**.737**	.066	.000
CM24R	.283	.032	-.021	**.628**	-.014	-.026
CM26R	.153	.182	-.046	.552	.006	.004
CM2R	-.045	-.129	.038	-.074	**.842**	-.017
CM1R	-.162	-.089	.028	.192	**.800**	-.091
CM3R	.197	.063	.031	.039	**.410**	.125
CM4R	.251	.234	.031	.049	.325	.039
CM19R	.052	-.106	.025	-.082	-.052	**1.014**
CM20R	-.166	.071	-.004	.106	-.032	**.683**
CM21R	.254	.037	-.005	.193	.005	**.422**

Extraction Method: Principal Axis Factoring.
Rotation Method: Promax with Kaiser Normalization.

a. Rotation converged in 6 iterations.

Table 28: Structure Matrix[a] of 27-item version

Structure Matrix

	Factor					
	1	**2**	**3**	**4**	**5**	**6**
CM13R	**.871**	.476	-.079	.497	.404	.500
CM12R	**.832**	.484	-.058	.495	.432	.488
CM14R	**.805**	.500	.033	.523	.296	.426
CM11R	**.805**	.568	.022	.537	.341	.508
CM16R	**.790**	.534	-.186	.433	.491	.504
CM15R	**.764**	.632	-.158	.471	.493	.484
CM4R	**.635**	.625	-.105	.463	.608	.491
CM10R	**.612**	.552	-.307	.271	.558	.433
CM6R	.536	**.872**	.067	.576	.432	.386
CM9R	.581	**.863**	.068	.585	.365	.411
CM7R	.470	**.853**	.069	.507	.359	.374
CM8R	.522	**.766**	.114	.594	.360	.411
CM29R	-.023	.047	**.903**	.221	-.249	-.034
CM30R	-.021	.068	**.842**	.226	-.234	-.011
CM28R	-.122	.018	**.803**	.174	-.291	-.055
CM27R	-.077	.051	**.800**	.227	-.284	-.040
CM23R	.557	.587	.135	**.890**	.306	.486
CM24R	.655	.596	.096	**.795**	.325	.473
CM22R	.502	.553	.172	**.793**	.286	.421
CM26R	.613	.638	.059	**.751**	.357	.472
CM2R	.272	.234	-.274	.049	**.706**	.256
CM1R	.272	.305	-.189	.221	**.663**	.242
CM5R	.543	.556	-.282	.251	**.624**	.412
CM3R	.561	.500	-.140	.379	**.612**	.494
CM19R	.531	.360	-.060	.378	.377	**.925**
CM21R	.658	.543	-.025	.577	.422	**.697**
CM20R	.350	.354	-.002	.382	.274	**.653**

Extraction Method: Principal Axis Factoring.

Rotation Method: Promax with Kaiser Normalization.

Table 29 : Item statement of 27-item CM-QOL, factor loadings, and communalities

Item	Statement	Factor loadings	Communalities
Factor 1	**Social activity**		
CM10R	ในแต่ละวันฉันวิตกกังวลว่าจะลืมกินยา/ใช้ยา	0.612	0.511
CM11R	ฉันรู้สึกอายที่ต้องใช้ยาในขณะอยู่กับผู้อื่น หรือเพื่อนร่วมงาน	0.805	0.673
CM12R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องหลีกเลี่ยงการออกงานสังคมบางประเภท (เช่น งานเลี้ยงสังสรรค์)	0.832	0.705
CM13R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่มั่นใจเมื่อต้องเข้าสังคม	0.871	0.782
CM14R	ฉันไม่ต้องการให้ผู้อื่นรู้ว่าฉันต้องใช้ยาติดต่อกันเป็นประจำ	0.805	0.689
CM15R	การใช้ยาติดต่อกันเป็นประจำสร้างความยุ่งยากให้เมื่อฉันต้องออกจากบ้าน	0.764	0.620
CM16R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่อยากเดินทาง	0.790	0.635
Factor 2	**Mental**		
CM6R	ฉันรู้สึกท้อแท้ที่ต้องใช้ยาติดต่อกันเป็นประจำ	0.872	0.769
CM7R	ฉันรู้สึกเบื่อตัวเองที่ต้องใช้ยาทุกวัน	0.853	0.751
CM8R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันรู้สึกเป็นคนสุขภาพไม่แข็งแรง	0.766	0.612
CM9R	ฉันรู้สึกหดหู่เพราะต้องใช้ยาติดต่อกันเป็นประจำ	0.863	0.760
Factor 3	**Positive consequence**		
CM27R	การใช้ยาติดต่อกันเป็นประจำทำให้อาการฉันดีขึ้น	0.800	0.644
CM28R	การใช้ยาติดต่อกันเป็นประจำช่วยให้ฉันไม่ขาดงาน หรือได้ทำกิจกรรมที่อยากทำ	0.803	0.648
CM29R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันมั่นใจว่าอาการจะไม่กำเริบ	0.903	0.828
CM30R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันใช้ชีวิตได้เป็นปกติ	0.842	0.717
Factor 4	**Adverse drug reaction**		
CM22R	ผลข้างเคียงจากยาทำให้ฉันมีอาการไม่สบายมากขึ้น	0.793	0.635
CM23R	ผลข้างเคียงที่เกิดจากการใช้ยาทำให้ประสิทธิภาพการทำงานของฉันลดลง	0.890	0.799
CM24R	ผลข้างเคียงจากยาที่ใช้ประจำรบกวนการใช้ชีวิตประจำวันของฉัน	0.795	0.684
CM26R	ผลข้างเคียงจากยาที่ใช้ประจำสร้างความรำคาญให้แก่ฉัน	0.751	0.625
Factor 5	**Daily activity disturbance**		
CM1R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการใช้ยาอื่น	0.663	0.474
CM2R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการกินอาหารบางประเภท	0.706	0.534
CM3R	ฉันต้องเสียเวลาในการจัดเตรียมยาที่ต้องใช้เป็นประจำ	0.612	0.466
CM4R	การใช้ยาติดต่อกันเป็นประจำรบกวนชีวิตประจำวันของฉัน	0.608	0.542
CM5R	ฉันต้องคอยกังวลว่าจะถึงเวลากินยา/ใช้ยาตลอดเวลา	0.624	0.502
Factor 6	**Family support**		
CM19R	ฉันต้องมีคนคอยดูแลการใช้ยาของฉัน	0.925	0.875
CM20R	คนข้างเคียงต้องคอยเป็นห่วง ช่วยเตือนหรือดูแลไม่ให้ฉันลืมใช้ยา	0.697	0.444
CM21R	การใช้ยาติดต่อกันเป็นประจำเป็นภาระต่อครอบครัวของฉัน	0.653	0.595

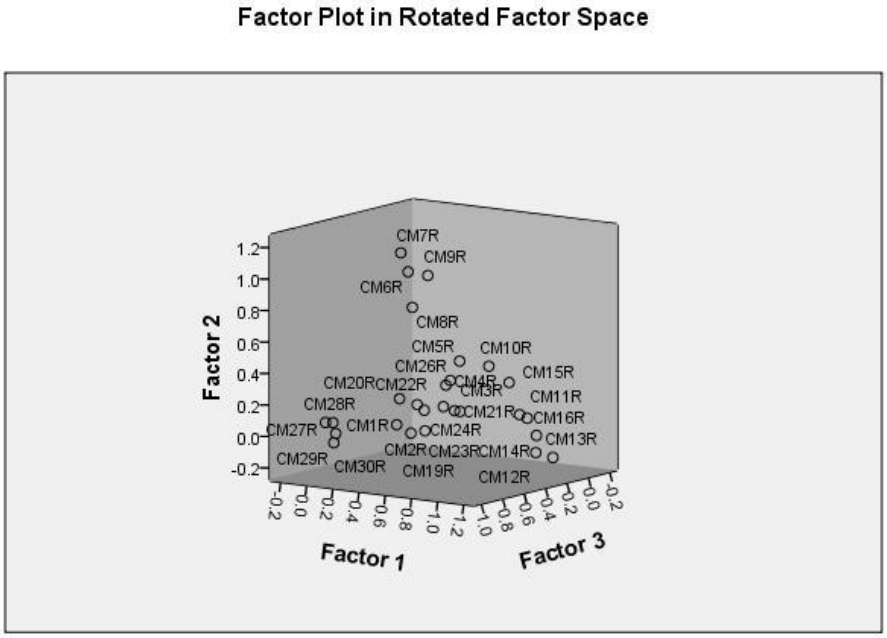


Figure 7: Factor plot in rotated factor space of 27-item version

During several steps, there was little difference between the promax and oblimin rotations. The researcher evaluated both rotations in the subsequent explorations before deciding on a promax rotation for the final rotation. Several rerun it revealed that promax solution contributed to a simple factor structure. From rerun exploratory factor analysis with promax rotation, there presented of 27 items in six factors of CM-QOL instrument that could be accounted for 72.417% of the total variance. The naming of final each domain in CM-QOL instrument (Table 26, Table 28, and Table 29) was as follows:

Construct Labeling (Named Domain)

Factor 1 which explained for 25.34% of the variance and was named Social Activity, had 7 items, factor loadings ranged between 0.612 and 0.871. This social activity included items that measured perceived impact of continuous drugs use on personal relations and social interactions. It also involved with social roles, avoidance or reduction of typical social activities.

Factor 2, accounting for 13.815% of the variance, was labeled Mental, had 4 items, factor loadings ranged between 0.766 and 0.872 and measured perceived dealt with perceived

psychological and emotional function. It included indicators of emotional state, bore, felt downhearted, and depression. It also involved perceived impact of drug use on general health: seem to be non-healthy person.

Factor 3, explanation with 6.199% of the variance and named Positive Consequence, had 4 items, factor loadings ranged between 0.800 and 0.903 (Table 25 and Table 26). These items in such domain measured perceived benefits of continuous drugs use on both positive psychological impacts (confidence because of taking continuous drug, effectiveness drug use) and physical impacts (improve symptoms, ability to perform regular work-related tasks, being a normal life).

Factor 4, that explained for 4.992% of the variance and was named Adverse Drug Reaction, had 4 items, factor loadings ranged between 0.751 and 0.890. This consisted of items related to perceived impact of continuous drugs use which related directly side effects of medication. In addition, it also concerned with perceived emotional function, role functioning: decrease performing work.

Factor 5, can be explained 4.641% of the variance and labeled Daily Activity Disturbance, had 5 items, factor loadings ranged between 0.608 and 0.706. This domain measured perceived be plagued from impact of continuous drug use on daily activities and difficulty to handle something over a period of time.

The last, factor 6, accounting for 3.754% of the variance and named Family Support. This domain had 3 items, factor loadings ranged between 0.653 and 0.925. These items measured perceived impact of drugs use on need for family and caregiver support.

As mentioned, all items had factor loadings above 0.50, the great majority above 0.60. The factor plot in rotated factor space of 27-item CM-QOL showed the loadings for 27 items on the six factors (Figure 7).

Part 4 Psychometric property testing: reliability, criterion validity of CM-QOL

Reliability analysis

Testing internal consistency reliability of the 27-item CM-QOL instrument was measured using Cronbach's alpha (α). From table 30, internal consistency of the whole CM-QOL instrument was 0.922 which was acceptable for a new instrument. The internal consistency reliability of each domain was found as follows: Daily activity (α = 0.782), Mental (α = 0.911), Social activity (α = 0.912), Family support (α = 0.783), Adverse Drug Reaction (α = 0.890), and Positive Consequence (α = 0.901).

In addition, all 27 items of CM-QOL instrument had the item-total correlation ranged from 0.498 to 0.839.

Table 30: Reliability and descriptive statistics of 27-item CM-QOL

Item	Statement	Mean	S.D.	Alpha	Corrected item-total correlation	Alpha if item deleted	Standardized item alpha
	Reliability of 27 items = 0.922			**0.922**			**0.925**
Domain1	**Daily activity (Factor 5)**	**3.3000**		**0.782**			**0.787**
CM1R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการใช้ยาอื่น	2.8887	1.16699		0.498	0.763	
CM2R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการกินอาหารบางประเภท	2.5887	1.14896		0.507	0.759	
CM3R	ฉันต้องเสียเวลาในการจัดเตรียมยาที่ต้องใช้เป็นประจำ	3.7943	1.02390		0.618	0.724	
CM4R	การใช้ยาติดต่อกันเป็นประจำรบกวนชีวิตประจำวันของฉัน	3.9000	1.01006		0.617	0.725	
CM5R	ฉันต้องคอยกังวลว่าจะถึงเวลากินยา/ใช้ยาตลอดเวลา	3.3283	1.20716		0.567	0.739	
Domain2	**Mental (Factor 2)**	**3.8033**		**0.911**			**0.912**
CM6R	ฉันรู้สึกท้อแท้ที่ต้องใช้ยาติดต่อกันเป็นประจำ	3.8113	1.08533		0.827	0.874	
CM7R	ฉันรู้สึกเบื่อตัวเองที่ต้องใช้ยาทุกวัน	3.7698	1.10328		0.808	0.881	
CM8R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันรู้สึกเป็นคนสุขภาพไม่แข็งแรง	3.7283	1.14776		0.733	0.908	
CM9R	ฉันรู้สึกหดหู่เพราะต้องใช้ยาติดต่อกันเป็นประจำ	3.9038	1.07567		0.826	0.875	
Domain3	**Social activity (Factor 1)**	**4.0348**		**0.912**			**0.916**
CM10R	ในแต่ละวันฉันวิตกกังวลว่าจะลืมกินยา/ใช้ยา	3.3491	1.16861		0.576	0.920	
CM11R	ฉันรู้สึกอายที่ต้องใช้ยาในขณะอยู่กับผู้อื่น หรือเพื่อนร่วมงาน	4.2943	0.94667		0.755	0.897	
CM12R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องหลีกเลี่ยงการออกงานสังคมบางประเภท (เช่น งานเลี้ยงสังสรรค์)	4.1094	0.96992		0.769	0.895	
CM13R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่มั่นใจเมื่อต้องเข้าสังคม	4.2000	0.91490		0.810	0.892	
CM14R	ฉันไม่ต้องการให้ผู้อื่นรู้ว่าฉันต้องใช้ยาติดต่อกันเป็นประจำ	4.3321	0.97371		0.755	0.897	
CM15R	การใช้ยาติดต่อกันเป็นประจำสร้างความยุ่งยากให้เมื่อฉันต้องออกจากบ้าน	3.8943	1.00291		0.751	0.897	
CM16R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่อยากเดินทาง	4.0642	0.97008		0.766	0.896	
Domain4	**Family support (Factor 6)**	**4.1553**		**0.783**			**0.790**
CM19R	ฉันต้องมีคนคอยดูแลการใช้ยาของฉัน	4.2679	0.92227		0.713	0.606	
CM20R	คนข้างเคียงต้องคอยเป็นห่วง ช่วยเตือนหรือดูแลไม่ให้ฉันลืมใช้ยา	3.9019	1.05689		0.588	0.761	
CM21R	การใช้ยาติดต่อกันเป็นประจำเป็นภาระต่อครอบครัวของฉัน	4.2962	0.81861		0.590	0.747	

Item	Statement	Mean	S.D.	Alpha	Corrected item-total correlation	Alpha if item deleted	Standardized item alpha
Domain5	**Adverse drug reaction (Factor 4)**	**4.1825**		**0.890**			**0.890**
CM22R	ผลข้างเคียงจากยาทำให้ฉันมีอาการไม่สบายมากขึ้น	4.2453	0.86314		0.735	0.867	
CM23R	ผลข้างเคียงที่เกิดจากการใช้ยาทำให้ประสิทธิภาพการทำงานของฉันลดลง	4.2000	0.94339		0.802	0.841	
CM24R	ผลข้างเคียงจากยาที่ใช้ประจำรบกวนการใช้ชีวิตประจำวันของฉัน	4.2000	0.90452		0.767	0.855	
CM26R	ผลข้างเคียงจากยาที่ใช้ประจำสร้างความรำคาญให้แก่ฉัน	4.0849	0.97141		0.732	0.869	
Domain6	**Positive consequence (Factor 3)**	**3.8311**		**0.901**			**0.904**
CM27R	การใช้ยาติดต่อกันเป็นประจำทำให้อาการฉันดีขึ้น	3.8094	0.93630		0.754	0.881	
CM28R	การใช้ยาติดต่อกันเป็นประจำช่วยให้ฉันไม่ขาดงาน หรือได้ทำกิจกรรมที่อยากทำ	3.6264	1.14211		0.753	0.888	
CM29R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันมั่นใจว่าอาการจะไม่กำเริบ	3.9113	0.96521		0.839	0.850	
CM30R	การใช้ยาติดต่อกันเป็นประจำทำให้ฉันใช้ชีวิตได้เป็นปกติ	3.9774	0.94031		0.789	0.869	

Criterion-related validity of CM-QOL

Criterion-related was the evidence that shows the extent to which scores of the instrument are related to a criterion measure (Lohr et al., 1996).

The main objective in this process was to examine the correlations between the domain scores of the new CM-QOL instrument and SF-36V2.

Criterion-related validity was assessed by calculating the correlation coefficient between the new CM-QOL instrument (27-item CM-QOL), EQ-5D3L in Thai, SF-36V2 in Thai, and SF-6D. Pearson's Correlation Coefficients were used to evaluate concurrent validity in this study.

There were four categories of strength of correlation (Nowels, McGloin, Westfall, & Holcomb, 2005) as follows: using r value

0.0 to 0.2	Very weak to negligible correlation
0.21 to 0.34	Weak, low correlation (not very significant)
0.35 to 0.5	Moderate correlation
> 0.5	Strong, high correlation

Scores of EQ-5D3L in 5 domains, named as EQ5D Thai Scores, were calculated by the formula to calculate the quality of life of Thai people was called Thai score. This formula was developed from previous study in Thai population as follows (S. Tongsiri, 2009).

Thai score = 1-0.202-(0.121*mo)-(0.121*sc)-(0.059*ua)-(0.072*pd)-(0.032*ad)-(0.190*m2)-(0.065*p2)-(0.046*a)-(0.139*N3)

The researcher hypothesized that the SF-36V2 subscales under the mental component summary would be associated more with the CM-QOL subscales under the mental domain than with the CM-QOL subscales under the physical domain. In addition, the SF-36V2 subscales under the physical component summary would correlate more with the CM-QOL subscales under the physical domain than with the CM-QOL subscales under the mental domain.

The results of the criterion-related validity were presented in Table 30. The CM-QOL overall score (CM-SUM) correlated positively with the physical component summary at 0.371 and mental component summary of the SF-36V2 at 0.559 and sub-domains scores of the SF-36V2. Correlations were found between each domain of the CM-QOL and the role emotional domain of the SF-36V2 (range 0.365-0.477), except for positive consequence domain score. In addition, correlations were also found significantly between each domain of the CM-QOL and the mental health domain of the SF-36V2 (range 0.156-0.485). In addition, the CM-QOL overall score (CM-SUM) and its domains were consistently correlated with the sub-scales of the SF-36V2 (see Table 31).

Mental domain of CM-QOL correlated highly with the mental component summary score of the SF-36 (r = 0.511), although social activity domain of CM-QOL was moderate correlation with a physical component summary score (r = 0.487). CM-SUM correlated strongly with the mental component summary scores at r = 0.559 and was moderate correlation with the physical component summary scores (r = 0.371).

The correlations between CM-QOL domains and EQ5D domains were found to be weak (r = -0.088 to -0.276). In additional, the direction of the correlations was a minus sign that showed an opposite direction of scores (Table 32).

Then the equation for calculating the SF-6D utility in this study as follows:

Utility = C + PF + RL + SF + PAIN + MH + VIT + MOST(-0.061)

The correlations between all CM-QOL domains and SF-6D utility were found to be similar with SF-36V2 (r = 0.086 to 0.442) see Table 31. All CM-QOL domains correlated moderately with SF-6D utility except positive consequence domain was weak correlation in SF-6D utility. In addition, CM-SUM score was moderate correlation with SF-6D utility at significant (r = 0.459).

Convergent validity of CM-QOL

Convergent validity defined as the extent to which two measures of constructs that theoretically are expected to correlate (P. M. Fayers & Machin, 2007).

The researcher expected that the scores on the CM-QOL would be positively associated with the scores on the medication adherence, a positive correlation between the scores were expected. This method tested by using the Pearson's correlation coefficients between CM-QOL domains and adherence scores.

The result presented in Table 31. The correlations between CM-QOL domains and adherence score were found that the positive consequence domain has statistically significant correlations with adherence score at 0.218. This also was moderate correlation with adherence VAS at 0.419. The CM-QOL overall score (CM-SUM) and all domain scores were positively correlated with the adherence score, weak positive correlations (range 0.10 to 0.22), except daily activity disturbance domain.

Table 31: Pearson' correlation coefficients between CM-QOL, SF36V2 Scores, EQ5D Thai Scores, EQ5D-VAS, Adherence Scores, and Adherence-VAS (N = 530)

Variable	SF36V2 Summary Score		SF36V2 Sub-domains								EQ5D Thai Score	EQ5D -VAS	SF6D	Adherence Score	Adher-VAS
	Physical Component Summary (PCS)	Mental Component Summary (MCS)	Physical Function (PF)	Role Physical (RP)	Bodily Pain (BP)	Social Functioning (SF)	General Health Perception (GH)	Vitality (VT)	Role Emotional (RE)	Mental Health (MH)					
CMQOL-6 domain Daily activity disturbance	0.152**	0.307**	0.193**	0.307**	0.200**	0.307**	NS	NS	0.381**	0.242**	NS	NS	0.256**	NS	NS
Mental	0.360**	0.511**	0.319**	0.422**	0.372**	0.461**	0.380**	0.397**	0.459**	0.485**	0.323**	0.232**	0.446**	0.170**	0.231**
Social activity	0.487**	0.227**	0.220**	0.399**	0.304**	0.473**	0.207**	0.247**	0.466**	0.418**	0.141**	0.111*	0.381**	0.104*	NS
Family support	0.237**	0.339**	0.230**	0.345**	0.259**	0.351**	0.162**	0.198**	0.365**	0.288**	0.180**	NS	0.278**	0.176**	0.138**
Adverse Drug Reaction	0.322**	0.524**	0.300**	0.412**	0.370**	0.485**	0.318**	0.383**	0.477**	0.472**	0.264**	0.161**	0.420**	0.174**	0.268**
Positive consequence	0.203**	0.113**	0.135**	NS	0.126**	0.093*	0.279**	0.288**	NS	0.156**	0.192**	0.195**	0.086*	0.218**	0.419**
CM-SUM	0.371**	0.559**	0.344**	0.476**	0.401**	0.530**	0.354**	0.396**	0.526**	0.507**	0.292**	0.205**	0.459**	0.207**	0.273**
CMQOL-VAS	0.230**	0.139**	0.172**	NS	0.169**	0.119**	0.331**	0.241**	0.088*	0.163**	0.210**	0.428**	0.190**	0.125**	0.451**

**. Correlation is significant at the 0.01 level (2-tailed). NS – Not significant
*. Correlation is significant at the 0.05 level (2-tailed).

Table 32: Pearson' correlation coefficients between CM-QOL and EQ5D domain (N = 530)

Variable	EQ5D Score : Domain				
	Mobility (MO)	**Self-care (SC)**	**Usual activities (UA)**	**Pain/discomfort (PD)**	**Anxiety/depression (AD)**
CMQOL-6 domain					
Daily activity disturbance	NS	- 0.098*	NS	NS	- 0.202**
Mental	- 0.147**	- 0.212**	- 0.182**	- 0.262**	- 0.276**
Social activity	NS	- 0.195**	- 0.094*	- 0.105*	- 0.208**
Family support	- 0.088*	- 0.186**	- 0.140**	- 0.106*	- 0.163**
Adverse Drug Reaction	- 0.123**	- 0.228**	- 0.154**	- 0.207**	- 0.164**
Positive consequence	- 0.219**	- 0.173**	- 0.152**	- 0.088*	NS
CM-SUM	- 0.123**	- 0.268**	- 0.197**	- 0.208**	- 0.237**
CMQOL-VAS	- 0.162**	- 0.090*	- 0.194**	- 0.176**	NS

**. Correlation is significant at the 0.01 level (2-tailed). NS – Not significant

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

A minus sign shows an opposite direction of scores.

CHAPTER IV

DISCUSSION AND CONCLUSION

There are four sections: discussion, conclusion, limitations of the study, and recommendations to the further study.

Discussion

STEP 1: INSTRUMENT DEVELOPMENT

In this study used patients' perspectives to identify pool items and domains and in order to develop domains that could be specific for patients with continuous medications use. Moreover, cooperating based on literature reviews generated many the initial questions. The generation of pool items is able to select appropriate questions and is a methodological development according to the standardized instrument development (Juniper, et al., 1996; Leurmarkul, 2000).

Semi-structured interviews involved open-ended questions, suggesting a topic and patients addressing it as they wish, then asking specific questions to elicit more focused information. The interviewees feel free to answer the questions. Open-ended questions can be useful in the survey study in order to explore the information (Bounthavong & Law, 2008). This provides the researcher to better access the respondents' true feelings on quality of life of medication use.

The designing of the scale including response choices, this study used as Likert scales. Items with five response choices were used appropriately in an evaluative instrument. These rank data can be converted to psychological scale values using mathematical method. Therefore, Likert scale are appropriate psychometric property in social science study. The respondents could rank easily and quickly. The directions of items are both positively and negatively directed items to minimize response bias effects (Spector, 1992).

The researcher used purposive samples in this study involving patients with chronic disease medication use that was defined as patients receiving one or more prescriptions for drugs used in treating their diseases. These samples are considered representative of the continuous medication use population.

The patients' perspectives on the sense of well-being of continuous medications use in the different diseases can identify relevant items and domains which are used to develop a new HRQOL instrument with scales can be measured and generalized across different diseases with the same sensitivity as a specific instrument.

STEP 2: EXPERT REVIEW OF THE INTRUMENT

The results from content validity can support the construct validity of the new instrument although they are not enough to display the construct validity (Yaghmaie, 2003). The content validity by heterogeneous experts' opinions help assessing whether the content is relevant to the concept of quality of life of continuous medication use defined for the study.

The qualitative method by using in-depth interview can be useful for exploring the domains of new instrument according to the researcher's requirement. For content validity, there is no a measuring statistical method then using content validity index which is a measuring quantitative method and also is the most widely used method. The 4-point rating scale is preferable because it does not include the ambivalent middle rating common in odd number rating scales. Moreover, designed as a likert scale helps in interpretation easier and prevents misunderstanding (Allahyari, Rangi, Khosravi, & Zayeri, 2011). This study uses the design as 4-point likert scale as follows: 1 = not relevant, 2 = unable to assess relevance, item need some revision, 3 = relevant, but needing minor alteration, and 4 = very relevant (Yaghmaie, 2003).

Using the experts' review of the instrument can help to identify any items that the researcher forgot from the development instrument. In case of expert's suggestion should add an item: "I feel discouraged to use continuing my drug regimen". This item is added on the mental domain of my instrument. Furthermore, using multidisciplinary experts can help to generate items

cover all domains of the construct (Wongwiwatthananukit, et al., 2005a). Having experts review your item pool can confirm or invalidate your definition of the event. The experts rate how relevant they think each item is to what you intend to measure. This is especially useful if you are developing a measure that will consist of separate scales to measure multiple constructs.

Lynn (1986) proposed the number of experts needed in the research at least five experts in that area of interest. The maximum number of experts has yet not been established but it should not exceed 10. The minimum of experts can use three persons that recommended in case of there are few the number of experts in that area (Lynn, 1986; Yaghmaie, 2003). In this study, there are nine experts for content validity testing. The use of nine experts could be statistically justifiable and reduce the erroneous conclusion.

The design with using rating scale and open-ended questionnaire can make more information than using agree or disagree scale (see Appendix D).

STEP 3: TESTING OF THE INSTRUMENT (PSYCHOMETRIC PROPERTY TESTING)

STEP 3.1 Pilot Testesting (Pretesting)

The researcher collected small samples (n = 30) in order to test the problem that may occur before the actual test (large study testing). The main objective of the pilot testing was to survey the understanding of the respondents such as ambiguous words, inability to answer the questionnaire, redundant items, and/or other problems associated with the questionnaire.

A purposive sampling of 30 respondents was used in this study including chronic disease medication use as prescribed for at least six months prior to data collection. A six month time frame was selected because participants would still be in the period of ongoing medical treatment and also had to be clinically stable. Although, the design of this study used the purposive samples there were heterogeneous in age, sex, education, number of diseases, number of drugs use, etc. Respondents who do not meet the researcher's purposes were excluded. Then, the patients from the purposive sampling are near to accurate representation of the population. Results of this study are expected to be more accurate.

Appropriately 80% of the respondents preferred to self-administer the questionnaire. The researcher observed that the respondents with self-report would have more incomplete questionnaire than face to face interview but spent time is quicker. The researcher collected from self-reported respondents by scanning all questionnaires after completed them. This procedure helps also decrease missing data. Interviewer-administered questionnaire is appropriate the method for complicated cases such as physical impairment, literacy of participants. The interview-administered instrument by the researcher can produce interview bias especially when asking about measurement of medication adherence. Bias effect of interview face to face is shown as the respondents rated themselves at the highest scores.

It took a long time to answer the set of items of the questionnaire completely (10 – 35 minutes) and the average time was about 20 minutes. Moreover, most respondents complained there were too many items (95 items) in a set of questionnaire and it took a long time spent in their senses. They suggested that these items should be reduced. Therefore, the researcher decides to remove some items and modify some items and response choices in order to easier answer, increase the participation, and decrease the problem from unintended answer.

Some respondents in pilot test confused the adherence questionnaire about the number that represented response choices, they could not identify these differences as follows:

Original response choices:

1 = every time (ทุกครั้ง), 2 = often (บ่อยครั้ง), 3 = sometimes (บางครั้ง), 4 = mostly (ส่วนมาก), 5 = never (ไม่เลย)

In order to achieve the best respond rate and decrease misunderstanding, the researcher decides to modify the response choices based on target population characteristics as follows:

New response choices:

1 = Never (ไม่เลย), 2 = rarely (นานๆ ครั้ง), 3 = sometimes (บางครั้ง), 4 = often (บ่อยครั้ง), and 5 = every time (ทุกครั้ง)

From the survey of EQ5D-VAS found that our Thai samples preferred to cross on the VAS scale although the instruction ordered to do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today. The result showed that most respondents crossed on the scale. Besides, the samples preferred using VAS in horizon line because this designs format understood easily in Thai samples. As the results, the format of VAS easy to understanding may be line in horizon instead of vertical design. It may be an idea for developing instrument of EQ5D-VAS beyond. According to previous study, a horizontal VAS format is preferred over a vertical format (Wee et al., 2008).

In this stage, the version 3 of CM-QOL developed by experts would be used in pilot test further. The internal consistency reliability by alpha Cronbarch's coefficient of the 30 item CM-QOL instruments was applied in this study. The alpha value of activity domain, mental domain, psychosocial domain, travel domain, burden domain, adverse drug reaction domain, positive domain, and sum CM-QOL were 0.836, 0.902, 0.898, 0.924, 0.783, 0.908, 0.826, and 0.943 respectively. As a result, a Cronbarch's alpha more than 0.70 considers the CM-QOL version 3 and its domains have good internal consistency reliability.

STEP 3.2 Large Study Testing of the Instrument

The researcher collects large samples in order to test psychometric property of the new instrument. The objectives of the large testing were to test reliability, construct validity, and criterion validity.

For the purposive sampling survey was conducted at only two hospitals, trying to increase the issue of generalizability of the findings. To minimize this concern, broad eligibility criteria (over 20 years of age, with chronic medication use, duration of drug use at least 6 months) were employed. However, the researcher noted that there were heterogeneous patients in this study. The researcher would like to get the diversity from all opinions or information then we collected the data by using heterogeneous purposive survey. This heterogeneous sampling method is appropriate with a generic instrument of quality of life of patients with continuous medication.

A purposive large sampling of 530 respondents was used in this study including chronic disease medication use as prescribed for at least six months prior to data collection. A six month time frame was selected because the participants would still be in the period of ongoing medical treatment and also had to be clinically stable. Although, the design of this study used the purposive samples there were heterogeneous target population in age, sex, education, incomes, health insurance, number of diseases, number of drugs use, etc. This study is a heterogeneous population so that these scales can be measured and generalized across different diseases.

Among 530 respondents, more than 60% had hypertension, diabetes (42.8%), and dyslipidemia (39.1%) which were the first three diseases founded in these group of samples. This finding agrees with previous studies in that hypertension, diabetes, and dyslipidemia are still the most common non-communicable diseases in Thailand (Kaufman, et al., 2011; Promthet et al., 2011).

Quality of the data found that there are acceptable. There were no items with a frequency more than 70 percent of respondents selected the highest score at the end of choices in each item and the lowest score of each item. This instrument had not ceiling and flooring effect. As a result, this summarizes the new CM-QOL instrument can discriminate the level of quality of life of continuous medication use. All items have not ceiling and flooring effect, therefore no items are deleted in this stage.

In order to test the psychometric property in large study testing, there were construct validity (exploratory factor analysis; EFA), reliability, and criterion validity. The researcher will discuss each test as follows:

Construct validity (EFA)

Factor analysis was used to test the construct validity by either confirming or exploring the underlying factors in a multi-dimensional instrument. Choosing exploratory factor analysis (EFA) is appropriate especially in case of the researcher had no a prior hypothesis about factors or constructs of measured variables (Tabachnick & Fidell, 2007). The EFA is still suitable though the researcher had some the tentative domains of the CM-QOL instrument based on Murawski's concept. This method is explored to describe and summarize data by grouping together variables

that are correlated. Results of EFA can provide grouping the dimensionality of a set of items and isolating items that are not measured the dimensions.

It is very important that an appropriate sample size is used for factor analysis, so the researcher uses a large sample size in the present study. Comrey and Lee (1992) recommend that 100 = poor, 200 = fair, 300 = good, 500 = very good, 1,000 or more = excellent. Sample size in this study is 530 participants so that it will be sufficient and very good for the exploratory factor analysis (Tabachnick & Fidell, 2007).

The promax rotation was performed in this analysis. Promax rotation was an oblique rotation that allows factors to be correlated (Hair, et al., 2006; Tabachnick & Fidell, 2007). Because of the social science studies, most variables correlate each other the same as the quality of life studies. According to previous studies (Panyawuthikrai, 2004; Samsa et al., 2004; Wongwiwatthananukit, et al., 2005a), the selection of the oblique rotation such as oblimin, or promax is suitable for correlating of each other factors in the instrument. Both oblimin and promax are independent component analysis. The researcher tried both direct oblimin and promax. This result showed that promax rotation would provide a simple structure better than direct oblimin, then this study was performed by running promax rotation. According to previous studies, promax rotation will give a simple structure and a good quality result (Conway & Huffcutt, 2003; Wongwiwatthananukit, et al., 2005a).

The version 4 of 30-item CM-QOL instrument is the first step in EFA. After exploratory factor analysis of this version, the 28-item CM-QOL instrument was created, the next stage is re-run EFA with item analysis which the researcher could decide to delete one item and see the grouping factors as a simple structure again. The re-run EFA was ended when received a potential simple structure with factor loadings > 0.5. This study produced the 27-item CM-QOL instrument in the final. While earlier studies (Nunnally, 1978; Surit, Laohasiriwong, Sanchaisuriya, & Schelp, 2008) use factor loadings $\geq$ 0.4, this study selected factor loadings > 0.5.

From exploratory factor analysis, there were six factors of the 27-item CM-QOL instrument and factor loadings of six domains ranged between 0.608 and 0.925. These results confirm that each domain is correlated and support that the domains of CM-QOL are congruent with the domain developed from data based on patients' perspective and quality of life theory (Hair, et al., 2006; Tabachnick & Fidell, 2007). The researcher selected factor loadings more than

0.5 because the selection of factor loadings less than 0.5 affected on the unclear interpretation. This considering criterion of factor loading > 0.5 is similar to a previous study (Wongwiwatthananukit, et al., 2005a).

The factor correlation matrix of factor 1 and factor 2, factor 2 and 3, factor 3 and 4, factor 4 and 5, factor 5 and 6 were 0.665, 0.004, 0.227, 0.276, and 0.482 respectively. Most residuals correlation matrix was close to zero and minus value. The factor correlation matrix is the table showing the intercorrelation among all variables. Considered value should > 0.30 shows that each pair of variables have common variance $\geq$ 10% (Tabachnick & Fidell, 2007). This confirms that each domain is correlated.

From the 27-item CM-QOL instrument presented the final communalities at range 0.444 – 0.875. Although there were the communalities < 0.5, these items were not deleted from the questionnaire. These items still share their variance with six factors as well if considering the communalities are more than 0.30 (Wongwiwatthananukit, et al., 2005a). Moreover, these items are high factor loadings that more than 0.5. Thus, all of the communalities are sufficiently high to proceed with the rotation of the factor matrix. Considering with most residuals correlation matrix is close to zero and minus value. This supports that six domains are appropriate to explain the constructs of quality of life of patients with continuous medications use.

Reliability

Testing internal consistency reliability of the 27-item CM-QOL instrument was measured using Cronbach's alpha (α). Internal consistency reliability assesses the homogeneity of the items that are formed into the same domain of the questionnaire. The Cronbach's alpha is an inter-item correlation statistic with a range of 0-1 (Nunnally, 1978). If the alpha value > 0.7 and the corrected item-total correlation (as known as item-scale correlation) > 0.30 that are represented the homogeneity of these items in the same domain. From the results, internal consistency of the whole 27-item CM-QOL instrument is high (α =0.922) which is acceptable for a new instrument (Nunnally, 1978). The internal consistency reliability of each domain was found as follows: Daily activity disturbance (α = 0.782), Mental (α = 0.911), Social activity (α = 0.912), Family support

(α = 0.783), Adverse Drug Reaction (α = 0.890), and Positive Consequence (α = 0.901). As the results, Cronbach's alpha in this study is a high value indicates that items on a scale are correlated. In addition, all 27 items of CM-QOL instrument have the item-total correlation ranged from 0.498 to 0.839 which they are high. This confirms that all of the items in each domain are homogeneity. In case of social activity domain has high an alpha value (α > 0.90). A high alpha can be due to a great number of items like social activity domain consisted of 7 items (Kim et al., 2000; Tavakol & Dennick, 2011).

Criterion validity

Criterion validity was a validity test which measures the correlation between the scores of the new CM-QOL instrument and a gold standard instrument (criterion variables). This study used concurrent validity was defined as the extent to which scores on a new measure are related to scores from a criterion measure administered at the same time (Lohr, et al., 1996). A gold standard was the other measures already held to be valid. The example, both SF36V2 in Thai and EQ5D3L in Thai were commonly validated between measures of health-related quality of life. The validity could be evaluated based on by determining the degree of Pearson correlation between new instrument (CM-QOL) and criterion scores (SF36V2, EQ5D3L).

Currently, there is no gold standard measure for comparing with the quality of life for patients with medication use (Samsa, et al., 2004). Both SF36V2 in Thai and EQ5D3L in Thai were used as a gold standard measure in this study.

The results of the criterion-related validity were presented that the CM-QOL overall score (CM-SUM) were positively correlated with the physical and mental component summary of the SF-36V2 and sub-domains scores of the SF-36V2 did similarly. In addition, the CM-QOL overall score (CM-SUM) and its domains were significant consistently correlated with the sub-scales of the SF-36V2. The moderate levels of correlation with SF-36V2 scores are evidence that the new proposed instrument can measure the effects of continuous medication use across the different domains of health and quality of life. Then the new CM-QOL instrument could measure the quality of life same as using the SF-36V2. In support of previous research (Lai, Asher, & Burton, 2006) these findings confirm that the new instrument needs to correlate with accepted criterion measure which is evidence that these scales measure concepts that are related so

confirming the concurrent validity. It can be implied that the CM-QOL instrument will have relevant and accuracy of measurement of the quality of life. While earlier work about the validity of the anticoagulant-related QOL (Samsa, et al., 2004) notes that the satisfaction positive psychosocial impact domain is not significant correlated with SF-36V2, this study found that positive consequence domain consistently correlated with sub-scales of SF-36V2 (except role physical and role emotional). As mentioned, the possible reason may be due to items in positive consequence domain for CM-QOL instrument relate to the patient's perception toward the positive effects their continuous medication use, whereas items of SF-32V2 (role physical, role emotional) relate the patient' perception toward their limitation activity.

For the correlations between CM-QOL domains and SF-6D utility found that there were moderate correlation in all six domains of CM-QOL except positive consequence which was weak correlation ($r = 0.086$). This finding can be implied that CM-QOL could evaluate the health-related quality of life like as the generic instrument (SF-36V2).

Convergent validity

In this result of correlations between CM-QOL domains and adherence score found that positive consequence domain had strongest correlations with medication adherence followed by adverse drug reaction and mental domain. This result is inconsistent with a previous study (Bharmal et al., 2009) that the convenience domain had the strongest association with medication adherence followed by effectiveness. This finding may be the context of Thai patients with chronic medication use. Most Thai patients with continuous drugs for chronic diseases concern about positive consequence or drug effectiveness domain and they hope that taking prescribed medication ongoing will make them a full recovery or relieve from diseases. For convenience domain, most Thai patients in this study took oral tablet dosage form as pills pack so they can easy to use these drugs and some patients will manage by using pill box, insulin as Pen injection.

In addition, a total score of quality of life with continuous medication use (CM-SUM) was positive significantly correlated with adherence score and adherence VAS. As in a previous

study (Holt, Muntner, Joyce, Webber, & Krousel-Wood, 2010), there were associated between physical and mental measures of health-related quality of life and medication adherence. This may indicate that low CM-QOL score are more likely to have lower adherence to medication use. Although adherence instrument in this study showed that there were weak correlated with CM-QOL instrument, the possible reason may be due to Thai patients may exhibit *white-coat adherence* by the researcher as interviewer so they answer in a positive way (rate yourself as good adherence). Another possible reason is the adherence instrument in this study lack of validity. These may make systematic error. The researcher should use the adequate reliability and validity adherence instrument in several ways e.g., MARS (Medication Adherence Report Scale), Modified Morisky Scale, Pill counts, etc.

Conclusion

This study provides good reliability and validity for evaluating quality of life in patients with continuous medications use.

The scaling and psychometric properties of CM-QOL instrument indicate that this instrument can be used as evaluation of pharmacy intervention in determining the value of medication therapy both community pharmacists and hospital pharmacists. This instrument represents a humanistic outcome by patients' perspectives measurement which specific for continuous medication use. Furthermore, CM-QOL will also be a valuable instrument for evaluating the impact of continuous medication use and it will provide information which is useful for patients, pharmacists, clinicians, nurses, and medical personnels.

The CM-QOL has demonstrated evidence of internal consistency reliability and preliminary evidence of validity.

Development of quality of life for patients with continuous medications use are retained at 27 items and included six domains as follows: (1) daily activity disturbance (5 items), (2) mental (4 items), (3) social activity (7 items), (4) family support (3 items), (5) adverse drug reaction (4 items), and (6) positive consequence (4 items).

Based on the findings of this study, the CM-QOL is a potentially useful tool for estimating adherence rate, for monitoring quality of life with medication use as a part of pharmaceutical care process, and for the evaluation of humanistic outcomes.

Limitations of the study

Designing purposive sampling may be with bias. In case of this research, the researcher designed the purposive respondents who had chronic disease medications use at least six months. These criteria are a measure of bias to the sample, therefore the limitation is the conclusions of this study will be limited under only studied the samples (patients with chronic disease mediation use at least six months) since the development use one month but large scale use 6 months the item is applicable less than 6 months but need further study.

Since the CM-QOL instrument was developed by using the words of interview from Thai patients with chronic medications use in Thai country, it was diverse from the western QOL instruments in culture, religion, and life style of the patients with continuous drug use. In Thai culture, sex was a very personal issue and was not discussed with others. Although the experts suggested the idea including sex domain should be included in the questionnaire, the researcher did not include this domain because most participants were old ages and this domain was not a strong influence domain from interviewing. The other limitation of this study is lack of data about sex domain. Domains from existing measurements included sex domain (Aversa, Kimberlin, & Segal, 1998), but it was excluded in this study.

For the survey is collected at only two hospitals in Bangkok using purposive sampling that means nonprobability sampling technique. Therefore, the results of this study can't be used in generalization to the whole population especially rural society. Since participants were collected in outpatient clinic and lived in a city, the results couldn't be easily transferred to all chronic disease patients.

This instrument was assessed in patients $\geq$ 20 years old. For this reason, the CM-QOL instrument could not use in the age group under 20 years.

The cross-sectional study design was used in this study at the same time that meant everything would be measured at one specific time point. Moreover, the findings in this study

cannot make conclusions about cause and effect or sequence of events. Although, there was an association between quality of life with medication use and adherence rate, by using cross-sectional design the result could not conclude that if higher scores in quality of life could have caused adherence or if non-adherence could have caused lower scores in quality of life.

Recommendations to the further study

Future validation of the CM-QOL instrument should seek to establish its suitability for use in patients with complexity of chronic medication use e.g. dosage form (inject drug, eye preparations), complex regimen use, etc.

Known-group validity analysis should be studied further in order to determine the ability of the CM-QOL instrument to discriminate among patients known to differ in their quality of life for continuous medications use.

The further researcher should be used the Confirm Factor Analysis (CFA) to confirm the factor structure that the researcher extracted in the EFA (exploring the factor structure; how the items relate and group based on inter variable correlations) and to confirm the number of latent variables underlining the items consistent with the expected number.

It should also be noted that further responsiveness (an instrument's ability to detect change) assessment is necessary, although a questionnaire had good reliability and validity. Evaluating responsiveness is useful for monitoring quality of life change over time.

The future study should explore the correlations between CM-QOL instrument and adherence rate by using both subjective (using validated instrument such as Morisky Medication Adherence Scale) and objective adherence measurement (e.g. pill counts, serum drug level, blood pressure, etc.).

The longitudinal study design needs to explore further because the quality of life scores are continuums and they may change over time. This design could predict the non-adherence could have caused lower scores in quality of life from continuous medication use by controlling for confounders.

REFERENCES

Allahyari, T., and others. Development and evaluation of a new questionnaire for rating of cognitive failures at work. International Journal of Occupational Hygiene 3 (January 2011) : 6-11.

Aversa, S., and others. The Medication Attribution Scale: perceived effcets of antiretrovirals and quality of life. Quality of Life Research 7 (April 1998) : 205-214.

Bharmal, M., and others. Validation of an abbreviated Treatment Satisfaction Questionnaire for Medication (TSQM-9) among patients on antihypertensive medications. Health and Quality of Life Outcomes [Online]. 2009. Available from : http://www.hqlo.com/content/7/1/36 [2010, May 27]

Bounthavong, M., and others. Identifying health-related quality of life (HRQL) domains for multiple chronic conditions (diabetes, hypertension and dyslipidemia): patient and provider perspectives. Journal of Evaluation in Clinical Practice 14 (December 2008) : 1002-1011.

Brazier, J., and others. The estimation of a preference-based measure of health from the SF-36. Journal of Health Economics 21(March 2002) : 271-292.

Brazier, J., and others. A comparison of the EQ-5D and SF-6D across seven patient groups. Journal of Health Economics 13(September 2004) : 873-884.

Brazier, J. E., and others. The estimation of a preference-based measure of health from the SF-12. Medical Care 42(September 2004) : 851-859.

Bryant, D., and others. Patient reported outcomes: general principles of development and interpretability. Polish Archives of Internal Medicine 117(April 2007) : 5-11.

Conway, J. M., and others. A review and evaluation of exploratory factor analysis practices in organizational research. Organizational Research Methods 6(April 2003) : 147-168.

Costello, A. B., and others. Best practices in exploratory factor analysis: four recommendations forgetting the most from your analysis. Practical Assessment, Research and Evaluation[Online]. 2005. Available from : http://pareonline.net/getvn.asp?v=10&n=7 [2011, June 27]

Debavalya, U., and others. The impacts of home care pharmacy services in diabetic patients. Thai Journal of Hospital Pharmacy 18 (January-April 2008) : 39-51.

Erickson, S. T., and others. Relationship between symptoms and health-related quality of life in patients treated for hypertension. Pharmacotherapy 24 (March 2004) : 344-350.

Fabrigar, L. R., and others. Evaluating the use of exploratory factor analysis in psychological research. Psychological Methods 4 (September 1999 : 272-299.

Fayers, P. M., and Machin, D. Quality of Life: assessment, analysis and interpretation (1 st ed.). Great Britain : John Wiley and Sons, 2000.

Fayers, P. M., and Machin, D. Quality of Life: the assessment, analysis and interpretation of patient-reported outcomes (2 ed ed.): Great Britain : John Wiley and Sons, 2007.

Gao, X., and others. Health-related quality of life burden of women with endometriosis: a literature review. Current Medical Research and Opinion 22 (September 2006) : 1787-1797.

Goldfarb, N., and others. Impact of appropriate pharmaceutical therapy for chronic conditions on direct medical costs and workplace productivity: a review of the literature. Disease Management 7 (Spring 2006) : 61-75.

Gordon, K., and others. Effective chronic disease management: patients' perspectives on medication-related problems. Patient Education and Counseling Journal 65 (March 2007) : 407-415.

Grant, J. S., and others. Focus on quantitative methods selection and use of content experts for instrument development. Research in Nursing and Health 20 (June 1997) : 269-274.

Gutteling, J. J., and others. Overview of research on health-related quality of life in patients with chronic liver disease. The Netherlands Journal of Medicine 65 (July-August 2007) : 227-234.

Guyatt, G. H., and others. Measuring health-related quality of life. Annals of Internal Medicine 118 (April 1993) : 622-629.

Hair, J. F., Jr., and others. Multivariate Data Analysis. Prentice-Hall, Inc., NJ : Upper Saddle River, 2006

Helper, C. D., and others. Opportunities and responsibilities in pharmaceutical care. American journal of hospital pharmacy 47 (Mar 1990) : 533-543.

Hickey, A., and others Measuring health-related quality of life in older patient populations. Pharmacoeconomics, 23 (July 2005). : 971-993.

Holt, E. W., and others.Health-related quality of life and antihypertensive medication adherence among older adults. Age and Ageing 39 (July 2010) : 481-487.

Isetts, B. J., and others. Effects of collaborative drug therapy management on patients' perceptions of care and health-related quality of life. Research in Social and Administrative Pharmacy 2 (March 2006) : 129-142.

Jin, J., and others. Factors affecting therapeutic compliance: a review from the patient's perspective. Therapeutics and Clinical Risk Management 4 (2008) : 269-286.

Jones, G. L., and others. Health-related quality of life measurement in women with polycystic ovary syndrome: a systematic review. Human Reproduction Update 14 (January-February 2008) : 15-25.

Juniper, E. F., and others. How to develop and validate a new health-related quality of life instrument. In B. Spilker (ed.), Quality of Life and Pharmacoeconomics in Clinical Trial, pp. 49-56. Philadelphia : Lippincott-Raven, 1996.

Kaufman, N. D., and others. Public health in Thailand: emerging focus on non-communicable diseases. The International Journal of Health Planning and Management 26 (July-September 2011) : e197-212.

Kheir, N. M., and others. Health-related quality of life measurement in pharmaceutical care targeting an outcome that matters. Pharmacy World and Science 26 (June 2004) : 125-128.

Kikkert, M. J., and others. Medication adherence in schizophrenia: exploring patients' carers' and professionals' views. Schizophrenia Bulletin 32 (October 2006) : 786-794.

Kim, W. R., and others. Reliability and validity of the NIDDK-QA instrument in the assessment of quality of life in ambulatory patients with cholestatic liver disease. HEPATOLOGY 32 (July 2000) : 924-929.

Kimberlin, C. L., and others. Validity and reliability of measurement instruements used in research. American Journal of Health-System Pharmacy 65 (December 2008) : 2276-2284.

Lai, S. M., and others. Estimating SRS-22 quality of life measures with SF-36: application in idiopathic scoliosis. Spine, 31 (February 2006) : 473-478.

Lam, C. L., and others. The impact of chronic diseases on the health-related quality of life (HRQOL) of chinese patients in primary care. Journal of Family Practice 17(April 2000) : 159-166.

Leurmarkul, W. Health-related quality of Life questionnaire development. Thai Journal of Pharmaceutical Sciences 24 (July 2000): 71-85.

Lohr, K. N., and others. Evaluating quality-of-life and health status instruments: development of scientific review criteria. Clinical Therapeutic, 18 (September-October 1996) : 979-992.

Lynn, M. R. Determination and quantification of content validity. Nursing Research 35 (November-December 1986) : 382-385.

MacKeigan, L. D., and others. Overview of health-related quality of life measures. American Journal of Hospital Pharmacy 49 (September 1992) : 2236-2245.

Mahler, D. A. How should health-related quality of life be assessed in patients with COPD? CHEST, 117(February 2000) : 54s-57s.

Murawski, M. M., and others. Pharmaceutical therapy-related quality of life: conceptual development. Journal of Social and Administrative Pharmacy 18(January 2001) : 2-14.

Nacul, L. C., and others. The functional status and well being of people with myalgic encephalomyelitis/chronic fatigue syndrome and their carers. BMC Public Health [Online]. 2011. Available from : http://www.biomedcentral.com/1471-2458/11/402 [2012,May 17]

Nichol, M. B., and others. Measuring the effects of medication use on health-related quality of life in patients with rheumatoid arthritis. a review. Pharmacoeconomics, 16 (November 1999) : 433-448.

Nowels, D., and others. Validation of the EQ-5D quality of life instrument in patients after myocardial infarction. Quality of Life Research 14 (February 2005) : 95-105.

Nunnally, J. Psychometric Theory (2 nd ed.). NY: McGraw-Hill, 1978.

Odegard, P. S., and others. Medication Taking and Diabetes: A systematic review of the literature. The Diabetes Educator 33 (November-December 2007) : 1014-1029.

Patcharaporn Panyawuthikrai. Development of the Perceived Community Pharmacy Service

Quality Scale (PCPSQ): Client Perspective. Doctoral dissertation, Department of Social and Administrative Pharmacy, Faculty of Pharmaceutical Sciences, Chulalongkorn University. (2004).

Pickard, A. S., and others. An update on evidence of clinical pharmacy services' impact on health-related quality of life. Annals of Pharmacotherapy 40 (September 2006) : 1623-1634.

Pippalla, R. S., and others. Interrelationships of quality of life, compliance, clinical outcomes and life satisfaction: a cross-sectional study on hypertensive geriatrics. Journal of Clinical Pharmacy and Therpeutics 22(October-December 1997) : 357-369.

Promthet, S., and others. Situation Analysis of Risk Factors Related to Non-communicable Diseases in Khon Kaen Province, Thailand. Asian Pacific Journal of Cancer Prevention12 (2011) : 1337-1340.

Samsa, G., and others. A new instrument for measuring anticoagulation-related quality of life: development and preliminary validation. Health Qual Life Outcomes [Online]. 2004. Available from : http://www.ncbi.nlm.nih.gov/pmc/articles/PMC420491/ [2011, May 22]

Saris-Baglama, and others. QualityMetric Outcomes Scoring Software 4.5. User's Guide. Lincoln, RI: Quality Metric Incorporated, 2011.

Sen, S. S., and others. Selecting among health-related quality-of-life instruments. American Society of Health-System Pharmacist 56 (October 1999) : 1965-1973.

Spector, P. E. Summated Rating Scale Construction: An Introduction (1 st ed.), Newbury Park: SAGE,1992

Summary of the Executive Sessions on Medication Therapy Management Programs: Bethesda, Maryland, June 14 and August 18,2004. (2005). American Society of Health-System 62: 585-592.

Surit, P., and others. Development of Quality of life instrument for urban poor in the Northeast of Thailand. Journal of the Medical Association Thailand 91 (September 2008) : 1447-1454.

Swaddiwudhipong, W., and others. Screening assessment of the elderly in rural Thailand by a mobile unit. Transactions of the Royal Society of Tropical Medicine and Hygeine 90 (May-June 1996) : 223-227.

Tabachnick, B. G., and Fidell, L. S. Using Multivariate Statistics. Boston, MA: Allyn & Bacon, 2007

Tanvatanakul, V., and others. Awareness of chronic diseases in the rapidly developing community of Chon Buri, Thailand. Southeast Asian J Trop Med Public Health 38 (May 2007) : 576-581.

Tavakol, M., and others. Making sense of Cronbach's alpha. International Journal of Medical Education, 2 (2011) : 53-55.

Testa, M. A., and others. Assesment of quality-of-life outcomes. New England Journal of Medicine 334 (March 1996) : 835-840.

Tongsiri, S. The Thai population-based preference scores for EQ-5D health states. University of London, UK, 2009.

Tongsiri, S., and others. Estimating population-based values for EQ-5D health states in Thailand. Value in Health 14(2011) : 1142-1145.

Tunpichart, S., and others. Chronic care model for diabetics by pharmacist home health in Bangkok Metropolitan: A community based study. International Journal of Medicine and Medical Sciences 4 (2012) : 90-96.

Varmeire, E., and others. Patient adherence to treatment: three decades of research: a comprehensive review. Journal of Clinical Pharmacy and Therapeutics 26(October 2001) : 331-342.

Wanitkun, N., and others. Building equity in chronic disease management in Thailand: a whole-system provincial trial of systematic, pro-active chronic illness care. Chronic Illness 7 (March 2011) : 31-44.

Wee, H. L., and others. Optimizing the design of visual analogue scales for assessing quality of life: a semi-qualitative study among Chinese-speaking Singaporeans. Journal of evaluation in clinical practice 14 (February 2008) : 121-125.

Weingart, S. N., and others. Patient-Reported Medication Symptoms in Primary Care. Archives of Internal Medicine 165 (January 2005) : 234-240.

World Health Organization (WHO). Chronic diseases and health promotion. [Online]. 2011. Available from: http://www.who.int/chp/en/index.html [2011,June 16]

Williams, B., and others. Exploratory factor analysis: a five-step guide for novices. Journal of Emergency Primary Health Care 8 (2012) : 1-14.

Wilson, I. B., and others. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. Journal of the American Medical Association 273 (January 1995) : 59-65.

Winkeljohn, D. Adherence to oral cancer therapies: nursing interventions. Clinical Journal of Oncology Nursing 14 (August 2010) : 461-466.

Wongwiwatthananukit, S., and others. Development and testing of Thai smoking cessation health-related quality of life assessment instrument. Thai Journal of Pharmaceutical Sciences 19 (March 2005) : 49-74.

Wongwiwatthananukit, S., and others. Development and testing of Thai smoking cessation pharmaceutical therapy-rleated quality of life assessment instrument. Thai Journal of Pharmaceutical Sciences 29 (2005) : 43-57.

Wongwiwatthananukit, S., and others. Development and validation of an instrument to assess the self-confidence of students enrolled in the Advanced Pharmacy Practice Experiences. American Journal of Pharmaceutical Education 66 (Spring 2002) : 5-19.

Yaghmaie, F. Content validity and its estimation. Journal of Medical Education 3 (Spring 2003) : 25-27.

Zebrack, B. J., and Chesler, M. A. (2001). A psychometric analysis of the Quality of Life-Cancer Survivors (QOL-CS) in survivors of childhood cancer. Quality of Life Research 10 (2001) : 319-329.

APPENDICES

Appendix A : 30 ITEM CM-QOL

ตอนที่ 1 ข้อมูลส่วนบุคคล

คำชี้แจง ให้ทำเครื่องหมาย ✕ **ลงในช่องหน้าคำตอบที่ตรงกับตัวท่านมากที่สุดและเติมคำในช่องว่างที่กำหนดให้และโปรดทำทุกข้อ**

ยาต่อเนื่องหรือยาประจำ หมายถึง ยาที่ แพทย์สั่งและเป็นยาที่ผู้ป่วยจำเป็นต้องใช้เพื่อการบำบัดบรรเทา รักษาโรคประจำตั วของผู้ป่วยซึ่งเป็นยาที่ต้องใช้อยู่เป็นประจำหากไม่ได้รับยาอย่างต่อเนื่องจะมีผลกระทบต่อผลการรักษา ป้องกันโรคหรือภาวะแทรกซ้อนจากโรคประจำตัวที่เป็นอยู่ได้

1. เพศของท่าน ❑ **ชาย** ❑ **หญิง**

2. ท่านมีอายุ.....ปี (ให้นับอายุเต็มปี เกิน 6 เดือนปัดขึ้น)

3. สถานภาพสมรส

❑ **โสด** ❑ **สมรส**

❑ **หย่า/แยกกันอยู่** ❑ **หม้าย**

4. ระดับการศึกษาของท่าน

❑ **ประถมศึกษาหรือต่ำกว่า** ❑ **มัธยมศึกษา** ❑ **อนุปริญญา**

❑ **ปริญญาตรี** ❑ **สูงกว่าปริญญาตรี**

5. อาชีพของท่าน

❑ **ประกอบธุรกิจส่วนตัว/ค้าขาย** ❑ **รับจ้างรายวัน** ❑ **ราชการ/รัฐวิสาหกิจ**

❑ **พนักงานบริษัท** ❑ **ไม่ได้ประกอบอาชีพ** ❑ **เกษียณอายุ**

❑ **อื่นๆ (ระบุ).....**

6. ท่านต้องจ่ายค่ายาที่ใช้ประจำ

❑ **ไม่ได้จ่ายเพราะได้รับสวัสดิการ** ❑ **จ่ายเองบางส่วนเฉลี่ยเดือนละ..... บาท**

❑ **จ่ายเองทั้งหมดเฉลี่ยเดือนละ..... บาท**

7. รายได้เฉลี่ยต่อเดือนของท่าน

❑ **ไม่มีรายได้** ❑ **ต่ำกว่า 5,000 บาท** ❑ **5,000 – 10,000 บาท**

❑ **10,001 – 20,000 บาท** ❑ **มากกว่า 20,000 บาท**

8. รายได้ครัวเรือนเฉลี่ยต่อเดือน

❑ ต่ำกว่า 5,000 บาท ❑ 5,000 – 10,000 บาท

❑ 10,001 – 20,000 บาท ❑ มากกว่า 20,000 บาท

9. สิทธิในการรักษา

❑ สิทธิข้าราชการ/รัฐวิสาหกิจ ❑ บัตรประกันสุขภาพ(บัตรทอง30บาท)

❑ บัตรประกันสังคม ❑ อื่นๆ (ระบุ)…… ……

10. โรคประจำตัว (ตอบได้มากกว่า 1 ข้อ)

❑ ความดันโลหิตสูง ❑ เบาหวาน ❑ ไขมัน

❑ โรคหลอดเลือดสมอง ❑ โรคไต ❑ โรคหืด

❑ อื่นๆ (ระบุชื่อโรค)……

11. ปัจจุบันท่านมียาที่ต้องใช้ติดต่อกันเป็นประจำตามแพทย์สั่งทั้งหมดจำนวน……อย่าง (รายการ)

12. ระยะเวลาที่เริ่มใช้ยาประจำ (ยาต่อเนื่อง) จนถึงปัจจุบัน ใช้มาประมาณ……ปี……..เดือน

13. ข้อใดต่อไปนี้ตรงกับลักษณะการใช้ยาประจำของท่าน

❑ ไม่ค่อยใช้ หรือนานๆ ใช้ที เพราะ……..…….

❑ ใช้บ้างไม่ใช้บ้าง เพราะ……..…….

❑ ใช้ตามแพทย์สั่งอย่างเคร่งครัด เพราะ…….

14. **ใน 1 เดือน**ที่ผ่านมาการใช้ยาประจำของท่านเป็นอย่างไร

กา x ลงในช่องสี่เหลี่ยมของคำถามแต่ละข้อ	ไม่เลย	นานๆ ครั้ง	บางครั้ง	บ่อยครั้ง	ทุกครั้ง
1. ท่านกินยา/ใช้ยาครบทุกชนิดตามแพทย์สั่ง	1	2	3	4	5
2. ท่านกินยา/ใช้ยาแต่ละชนิดตามจำนวนที่แพทย์สั่งในแต่ละวัน	1	2	3	4	5
3. ท่านกินยา/ใช้ยาครบทุกมื้อตามแพทย์สั่ง	1	2	3	4	5
4. ท่านกินยา/ใช้ยาตรงตามเวลาที่แพทย์สั่งในแต่ละมื้อ	1	2	3	4	5
5. ท่านไปรับยาที่ใช้ประจำตรงตามแพทย์นัด	1	2	3	4	5

ตอนที่ 2 แบบสอบถามวัดคุณภาพชีวิตจากการใช้ยาต่อเนื่อง

คำแนะนำ : แบบสอบถามฉบับนี้ถามถึงประสบการณ์ ความรู้สึกของท่านเกี่ยวกับยาที่ท่านต้องใช้ติดต่อกันเป็นระยะเวลานาน และการใช้ยาเหล่านั้นเป็นประจำกระทบชีวิตของท่านอย่างไร

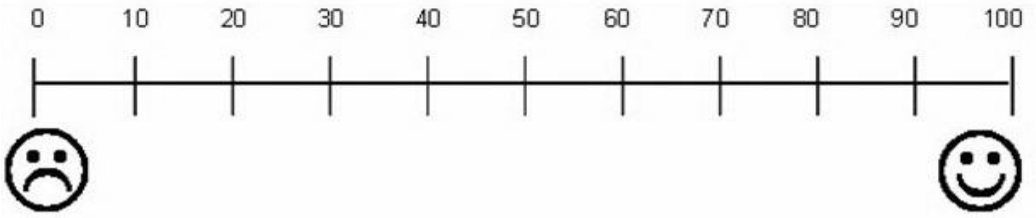
โปรดตอบคำถามทุกคำถามโดยให้กา ✕ **ตัวเลขแต่ละข้อ** คำถามทุกข้อไม่มีคำตอบที่ถูกหรือผิด เมื่อตอบคำถามเหล่านี้ให้คิดถึงเฉพาะยาที่แพทย์สั่งให้ท่านใช้เป็นประจำ ถ้าหากไม่แน่ใจให้เลือกคำตอบที่คุณคิดว่าใกล้เคียงที่สุด

การใช้ยาติดต่อกันเป็นประจำมีผลต่อท่านอย่างไรในข้อต่อไปนี้	**ไม่เลย 1**	**น้อย 2**	**ปานกลาง 3**	**มาก 4**	**มากที่สุด 5**
1. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการใช้ยาอื่น	1	2	3	4	5
2. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการกินอาหารบางประเภท	1	2	3	4	5
3. ฉันต้องเสียเวลาในการจัดเตรียมยาที่ต้องใช้เป็นประจำ	1	2	3	4	5
4. การใช้ยาติดต่อกันเป็นประจำรบกวนชีวิตประจำวันของฉัน	1	2	3	4	5
5. ฉันต้องคอยกังวลว่าจะถึงเวลากินยา/ใช้ยาตลอดเวลา	1	2	3	4	5
6. ฉันรู้สึกท้อแท้ที่ต้องใช้ยาติดต่อกันเป็นประจำ	1	2	3	4	5
7. ฉันรู้สึกเบื่อตัวเองที่ต้องใช้ยาทุกวัน	1	2	3	4	5
8. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันรู้สึกเป็นคนสุขภาพไม่แข็งแรง	1	2	3	4	5
9. ฉันรู้สึกหดหู่เพราะต้องใช้ยาติดต่อกันเป็นประจำ	1	2	3	4	5
10. ในแต่ละวันฉันวิตกกังวลว่าจะลืมกินยา/ใช้ยา	1	2	3	4	5
11. ฉันรู้สึกอายที่ต้องใช้ยาในขณะอยู่กับผู้อื่น หรือเพื่อนร่วมงาน	1	2	3	4	5
12. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องหลีกเลี่ยงการออกงานสังคมบางประเภท (เช่น งานเลี้ยงสังสรรค์)	1	2	3	4	5
13. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่มั่นใจเมื่อต้องเข้าสังคม	1	2	3	4	5

การใช้ยาติดต่อกันเป็นประจำมีผลต่อท่านอย่างไรในข้อต่อไปนี้	ไม่เลย 1	น้อย 2	ปานกลาง 3	มาก 4	มากที่สุด 5
14. ฉันไม่ต้องการให้ผู้อื่นรู้ว่าฉันต้องใช้ยาติดต่อกันเป็นประจำ	1	2	3	4	5
15. การใช้ยาติดต่อกันเป็นประจำสร้างความยุ่งยากให้เมื่อฉันต้องออกจากบ้าน	1	2	3	4	5
16. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่อยากเดินทาง	1	2	3	4	5
17. ฉันต้องคอยเตือนตัวเองไม่ให้ลืมพกยาติดตัวเมื่อต้องเดินทาง	1	2	3	4	5
18. การใช้ยาติดต่อกันเป็นประจำก่อให้เกิดภาระค่าใช้จ่ายแก่ฉัน	1	2	3	4	5
19. ฉันต้องมีคนคอยดูแลการใช้ยาของฉัน	1	2	3	4	5
20. คนข้างเคียงต้องคอยเป็นห่วง ช่วยเตือนหรือดูแลไม่ให้ฉันลืมใช้ยา	1	2	3	4	5
21. การใช้ยาติดต่อกันเป็นประจำเป็นภาระต่อครอบครัวของฉัน	1	2	3	4	5
22. ผลข้างเคียงจากยาทำให้ฉันมีอาการไม่สบายมากขึ้น	1	2	3	4	5
23. ผลข้างเคียงที่เกิดจากการใช้ยาทำให้ประสิทธิภาพการทำงานของฉันลดลง	1	2	3	4	5
24. ผลข้างเคียงจากยาที่ใช้ประจำรบกวนการใช้ชีวิตประจำวันของฉัน	1	2	3	4	5
25. ฉันกังวลว่าจะเกิดการสะสมของยาในร่างกายเมื่อใช้ยาติดต่อกันเป็นระยะเวลานาน	1	2	3	4	5
26. ผลข้างเคียงจากยาที่ใช้ประจำสร้างความรำคาญให้แก่ฉัน	1	2	3	4	5
27. การใช้ยาติดต่อกันเป็นประจำทำให้อาการฉันดีขึ้น	1	2	3	4	5
28. การใช้ยาติดต่อกันเป็นประจำช่วยให้ฉันไม่ขาดงานหรือได้ทำกิจกรรมที่อยากทำ	1	2	3	4	5
29. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันมั่นใจว่าอาการจะไม่กำเริบ	1	2	3	4	5
30. การใช้ยาติดต่อกันเป็นประจำทำให้ฉันใช้ชีวิตได้เป็นปกติ	1	2	3	4	5

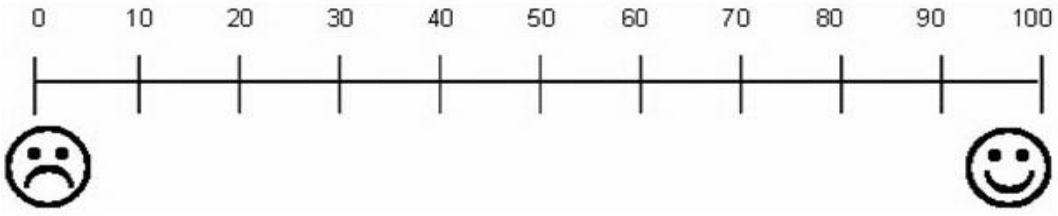
คำถามวัดคุณภาพชีวิตจากการใช้ยาต่อเนื่องโดยรวม (ให้กา × ลงในเส้น)

1. ท่านคิดว่าการใช้ยาติดต่อกันเป็นประจำส่งผลต่อคุณภาพชีวิต (ชีวิตความเป็นอยู่) ของท่านในระดับใด



แย่ที่สุด ดีที่สุด

2. โดยรวมแล้วท่านให้ความร่วมมือในการใช้ยาต่อเนื่องของท่านระดับใด



น้อยที่สุด ดีมาก

Appendix B : EQ5D-3L THAI

ตอนที่ 3 แบบสอบถามวัดคุณภาพชีวิตด้านสุขภาพทั่วไป

ให้กา x ลงในช่องสี่เหลี่ยมของคำถามแต่ละข้อที่ตรงกับภาวะสุขภาพของท่าน**ในวันนี้**มากที่สุด

1. ความสามารถในการเคลื่อนไหว

- ❑ ข้าพเจ้าไม่มีปัญหาในการเดิน
- ❑ ข้าพเจ้ามีปัญหาในการเดินบ้าง
- ❑ ข้าพเจ้าไม่สามารถไปไหนได้ และจำเป็นต้องอยู่บนเตียง

2. การดูแลตนเอง

- ❑ ข้าพเจ้าไม่มีปัญหาในการดูแลตนเอง
- ❑ ข้าพเจ้ามีปัญหาในการอาบน้ำหรือการแต่งตัวบ้าง
- ❑ ข้าพเจ้าไม่สามารถอาบน้ำหรือแต่งตัวด้วยตนเองได้

3. กิจกรรมที่ทำเป็นประจำ *(เช่น การทำงาน, การเรียนหนังสือ, การทำงานบ้าน, การทำกิจกรรมในครอบครัว หรือการทำกิจกรรมยามว่าง)*

- ❑ ข้าพเจ้าไม่มีปัญหาในการทำกิจกรรมที่ทำเป็นประจำ
- ❑ ข้าพเจ้ามีปัญหาในการทำกิจกรรมที่ทำเป็นประจำอยู่บ้าง
- ❑ ข้าพเจ้าไม่สามารถทำกิจกรรมที่ทำเป็นประจำได้

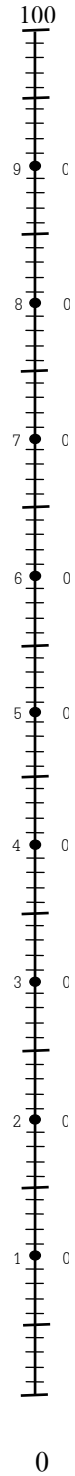
4. ความเจ็บปวด/ความไม่สุขสบาย

- ❑ ข้าพเจ้าไม่มีอาการเจ็บปวดหรืออาการไม่สุขสบาย
- ❑ ข้าพเจ้ามีอาการเจ็บปวดหรืออาการไม่สุขสบายปานกลาง
- ❑ ข้าพเจ้ามีอาการเจ็บปวดหรืออาการไม่สุขสบายมากที่สุด

5. ความวิตกกังวล/ ความซึมเศร้า

- ❑ ข้าพเจ้าไม่รู้สึกวิตกกังวลหรือซึมเศร้า
- ❑ ข้าพเจ้ารู้สึกวิตกกังวลหรือซึมเศร้าปานกลาง
- ❑ ข้าพเจ้ารู้สึกวิตกกังวลหรือซึมเศร้ามากที่สุด

ภาวะสุขภาพที่ท่าน
รู้สึกว่าดีที่สุด



เพื่อช่วยในการประเมินภาวะสุขภาพของท่าน, ทางเราได้จัดทำสเกลวัดระดับสุขภาพขึ้น
เริ่มตั้งแต่ระดับ 0 ถึง 100 โดยที่ 100 หมายถึงภาวะสุขภาพที่ดีที่สุด
และ 0 หมายถึง ภาวะสุขภาพที่แย่ที่สุด ตามความคิดของท่าน

กรุณาประเมินภาวะสุขภาพของท่านในวันนี้ว่าดีหรือไม่ดี
เพียงไร
โดยกา X ลงบนสเกลวัดระดับสุขภาพที่ตรงกับภาวะสุขภาพ
ของท่านในวันนี้

ภาวะสุขภาพของท่าน
ในวันนี้

ภาวะสุขภาพที่ท่าน
รู้สึกว่าแย่ที่สุด

Appendix C: SF36V2 THAI

สุขภาพและความผาสุกของคุณ

แบบสอบถามนี้ถามความคิดเห็นของคุณเกี่ยวกับสุขภาพของคุณ ข้อมูลนี้จะช่วยในการบันทึกว่าคุณรู้สึกอย่างไร และคุณสามารถทำกิจกรรมต่างๆ ตามปกติของคุณได้ดีแค่ไหน *ขอบคุณที่ให้ความร่วมมือในการตอบแบบสอบถามนี้*

ในแต่ละคำถามต่อไปนี้ โปรดทำเครื่องหมาย ☒ ลงในช่องเพียงช่องเดียวที่ตรงกับคำตอบของคุณมากที่สุด

1. โดยทั่วไป คุณจะบอกว่าสุขภาพของคุณ:

ดีที่สุด	ดีมาก	ดี	พอใช้	แย่
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. คุณจะประเมินสุขภาพโดยทั่วไปของคุณ <u>ในตอนนี้ เปรียบเทียบกับเมื่อ 1 ปีที่ผ่านมา</u> ว่าอย่างไร

ตอนนี้ดีกว่าเมื่อ 1 ปีที่ผ่านมามาก	ตอนนี้ค่อนข้างดีกว่าเมื่อ 1 ปีที่ผ่านมา	คล้ายๆ กับเมื่อ 1 ปีที่ผ่านมา	ตอนนี้ค่อนข้างแย่กว่าเมื่อ 1 ปีที่ผ่านมา	ตอนนี้แย่กว่าเมื่อ 1 ปีที่ผ่านมามาก
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. คำถามต่อไปนี้เป็นคำถามเกี่ยวกับ กิจกรรมที่คุณอาจจะทำในช่วงวันปกติทั่วๆ ไป สุขภาพของคุณในตอนนี้ทำให้คุณถูกจำกัดในการทำกิจกรรมเหล่านี้หรือไม่ ถ้าใช่ ถูกจำกัดมากน้อยแค่ไหน

	ใช่ ถูกจำกัดมาก	ใช่ ถูกจำกัดเล็กน้อย	ไม่ใช่ ไม่ถูกจำกัดเลย
a. กิจกรรมที่ใช้แรงมาก เช่น การวิ่ง การยกของหนัก การเล่นกีฬาที่ต้องออกแรงมาก	☐ 1	☐ 2	☐ 3
b. กิจกรรมที่ใช้แรงปานกลาง เช่น การย้ายโต๊ะ การกวาดพื้น การทำสวน การปั่นจักรยาน หรือการว่ายน้ำ	☐ 1	☐ 2	☐ 3
c. การยกหรือถือถุงใส่ของชำ	☐ 1	☐ 2	☐ 3
d. การเดินขึ้นบันไดขึ้นตึก 2-3 ชั้น	☐ 1	☐ 2	☐ 3
e. การเดินขึ้นบันไดขึ้นตึก 1 ชั้น	☐ 1	☐ 2	☐ 3
f. การก้ม การคุกเข่า หรือการงอตัว	☐ 1	☐ 2	☐ 3
g. การเดินเป็นระยะทางมากกว่า 1 กิโลเมตร	☐ 1	☐ 2	☐ 3
h. การเดินเป็นระยะทางหลายร้อยเมตร	☐ 1	☐ 2	☐ 3
i. การเดินเป็นระยะทาง 100 เมตร	☐ 1	☐ 2	☐ 3
j. การอาบน้ำหรือแต่งตัวเอง	☐ 1	☐ 2	☐ 3

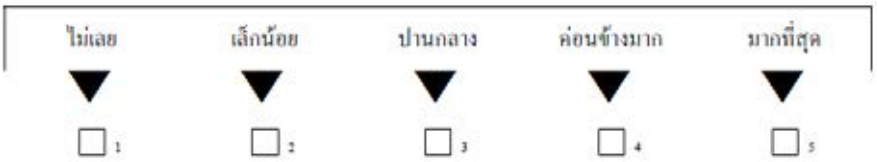
4. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่คุณมีปัญหาต่างๆ ต่อไปนี้ ในการทำงาน หรือทำกิจวัตรประจำวันอื่นๆ อันเนื่องมาจากสุขภาพทางกายของคุณ

	คลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นานๆครั้ง	ไม่เคยเลย
a. จำเป็นต้องลดระยะเวลาที่คุณใช้ในการทำงาน หรือกิจกรรมอื่นๆ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. ทำงานหรือกิจวัตรประจำวันอื่นๆ สำเร็จได้น้อยกว่าที่คุณต้องการ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. ถูกจำกัดชนิดของงานหรือกิจกรรมที่คุณสามารถทำได้	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. มีความลำบากในการทำงาน หรือกิจกรรมอื่นๆ (เช่น ต้องใช้ความพยายามมากขึ้น)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

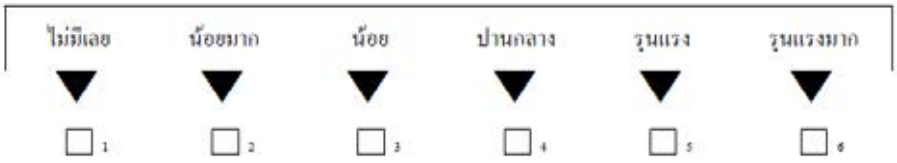
5. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่คุณมีปัญหาต่างๆ ต่อไปนี้ ในการทำงาน หรือทำกิจวัตรประจำวันอื่นๆ ของคุณ อันเนื่องมาจากปัญหาด้านอารมณ์ (เช่น รู้สึกซึมเศร้า หรือ วิตกกังวล)

	คลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นานๆครั้ง	ไม่เคยเลย
a. จำเป็นต้องลดระยะเวลาที่คุณใช้ในการทำงาน หรือกิจกรรมอื่นๆ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. ทำงานหรือกิจวัตรประจำวันอื่นๆ สำเร็จได้น้อยกว่าที่คุณต้องการ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. ทำงานหรือกิจกรรมอื่นๆ ด้วยความระมัดระวังน้อยกว่าปกติ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. ในช่วง 4 สัปดาห์ที่ผ่านมา สุขภาพทางกายหรือปัญหาด้านอารมณ์ของคุณ มีผลรบกวนกิจกรรมทางสังคม ตามปกติของคุณ ที่มีกับครอบครัว เพื่อนฝูง เพื่อนบ้าน หรือกลุ่มคนอื่นๆ มากน้อยแค่ไหน



7. คุณมีความเจ็บปวดทางร่างกายมากน้อยแค่ไหน ในช่วง 4 สัปดาห์ที่ผ่านมา



8. ในช่วง 4 สัปดาห์ที่ผ่านมา ความเจ็บปวดมีผลรบกวนการทำงานตามปกติของคุณ (ทั้งงานนอกบ้านและงานบ้าน) มากน้อยแค่ไหน

9. คำถามต่อไปนี้จะถามเกี่ยวกับว่าคุณรู้สึกอย่างไร และคุณเป็นอย่างไร ในช่วง 4 สัปดาห์ที่ผ่านมา แต่ละคำถามต่อไปนี้ โปรดเลือกเพียงคำตอบเดียว ที่ใกล้เคียงกับความรู้สึกของคุณมากที่สุด ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่...

	ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นาน ๆ ครั้ง	ไม่เคยเลย
	▼	▼	▼	▼	▼
a. คุณรู้สึกมีชีวิตชีวา กระปรี้กระเปร่า	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. คุณวิตกกังวลเกินกว่าเหตุ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. คุณรู้สึกหดหู่จนไม่มีอะไรที่จะทำให้คุณรู้สึกดีขึ้นได้	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. คุณรู้สึกใจเย็นและสงบ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. คุณรู้สึกเต็มไปด้วยพลัง	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f. คุณรู้สึกท้อแท้และซึมเศร้า	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g. คุณรู้สึกหมดเรี่ยวแรง	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h. คุณมีความสุข	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i. คุณรู้สึกเหนื่อย	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่สุขภาพทางกายหรือปัญหาด้านอารมณ์ของคุณ มีผลรบกวนกิจกรรมทางสังคมของคุณ (เช่น การไปเยี่ยมเพื่อน หรือ ญาติมิตร เป็นต้น)

ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นาน ๆ ครั้ง	ไม่เคยเลย
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. แต่ละข้อความต่อไปนี้เป็นจริง หรือ ไม่จริง สำหรับคุณแค่ไหน

	จริงแน่นอน	จริงเป็นส่วนใหญ่	ไม่ทราบ	ไม่จริงเป็นส่วนใหญ่	ไม่จริงเลย
ก ฉันดูเหมือนจะเจ็บป่วยได้ง่ายกว่าคนอื่น	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ข ฉันมีสุขภาพดีพอๆ กับคนอื่นที่ฉันรู้จัก	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ค ฉันคาดว่าสุขภาพของฉันจะแย่ลง	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ง สุขภาพของฉันดีเยี่ยม	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

ขอบคุณที่ให้ความร่วมมือในการตอบคำถาม

Appendix D: CVI

แบบสอบถามฉบับผู้เชี่ยวชาญตรวจสอบความตรงทางเนื้อหา

เรื่อง การพัฒนาเครื่องมือประเมินคุณภาพชีวิตสำหรับผู้ป่วยที่ใช้ยาต่อเนื่อง

ผู้วิจัย นางสาววรรณา ตั้งภักดีรัตน์

อาจารย์ที่ปรึกษา ผศ.ภญ.ดร. รุ่งเพ็ชร สกุลบำรุงศิลป์

วัตถุประสงค์ 1. เพื่อจำแนกองค์ประกอบของคุณภาพชีวิตที่เป็นผลจากการใช้ยาต่อเนื่อง

2. เพื่อสร้างข้อคำถามของคุณภาพชีวิตจากการใช้ยาต่อเนื่อง

3. เพื่อทดสอบความตรง และความเที่ยงของเครื่องมือวัดคุณภาพชีวิตจากการใช้ยาต่อเนื่อง

คำจำกัดความ

การใช้ยาต่อเนื่อง คือ การใช้ยาที่ใช้ควบคุมอาการหรือความรุนแรงของโรคเรื้อรัง มีจุดมุ่งหมายเพื่อให้ยาออกฤทธิ์อย่างต่อเนื่องสม่ำเสมอ และสามารถควบคุมอาการและความรุนแรงของโรคดังกล่าวได้อยู่ตลอดเวลา เพื่อไม่ให้ระดับความรุนแรงของโรคลุกลามมากขึ้น อาจก่อให้เกิดอันตรายได้ จึงเป็นการใช้ยาเพื่อป้องกันอันตรายจากโรคเรื้อรัง จะต้องใช้ยาอย่างต่อเนื่องและสม่ำเสมอตามแพทย์สั่ง ห้ามหยุดยาด้วยตัวเองหรือหยุดยาเมื่ออาการทุเลาลงแล้ว หรือไม่มีอาการแล้วก็ตาม (ยกเว้นกรณีที่มีอาการอันไม่พึงประสงค์อย่างรุนแรง จะต้องปรึกษาแพทย์ทันที)

คำชี้แจงในการประเมิน

เครื่องมือประเมินคุณภาพชีวิตสำหรับผู้ป่วยที่ใช้ยาต่อเนื่องแบ่งออกเป็น 2 มิติหลัก คือ

1. คุณภาพชีวิตด้านผลกระทบจากการใช้ยา	จำนวน	21	ข้อ
2. คุณภาพชีวิตด้านผลกระทบจากผลของตัวยา	จำนวน	9	ข้อ

❁ ในแต่ละมิติหลักประกอบด้วยด้านต่างๆ ซึ่งในแต่ละด้านจะประกอบด้วยข้อคำถามที่เกี่ยวข้องกับด้านนั้น เมื่อท่านอ่าน กรุณาทบทวนข้อคำถามด้านความตรงทางเนื้อหา **โดยพิจารณาว่าเนื้อหาของแต่ละข้อคำถามตรงกับมิติ/ด้านที่จำแนกไว้หรือไม่**

❁ ให้ท่านวงกลม ○ เลือกระดับความสอดคล้องของข้อคำถามกับด้าน/มิติที่ได้จำแนกไว้เพียงระดับเดียว หากท่านพบว่า**ข้อคำถามใดมีความสอดคล้องกับมิติ/ด้านอื่นๆ มากกว่า** กรุณาเขียนข้อเสนอแนะลงบริเวณที่ว่างภายใต้ข้อนั้น

❁ ให้ท่านตรวจสอบความถูกต้องและความชัดเจนของเนื้อหา การใช้ภาษาในแต่ละข้อคำถาม ถ้าท่านคิดว่าข้อใดควรเรียบเรียงใหม่หรือภาษาไม่ชัดเจน กรุณาเขียนข้อเสนอแนะลงบริเวณที่ว่างภายใต้ข้อนั้น

ขอขอบพระคุณอย่างสูงในการให้ความอนุเคราะห์ข้อมูลมา ณ. โอกาสนี้

ด้านหลัก และด้านย่อยในเครื่องมือประเมินคุณภาพชีวิตสำหรับผู้ป่วยที่ใช้ยาต่อเนื่อง

Domain	มิติ (Subscale)	หมายเลขข้อ
1. ผลกระทบจากการใช้ยา	1.1 ผลกระทบจากการใช้ยาต่อกิจกรรมประจำวัน (Physical /Role limitation)	ข้อ 1-5
	1.2 จิตใจ (Mental)	ข้อ 6-9
	1.3 จิตวิทยาสังคม (Psychosocial)	ข้อ 10-13
	1.4 การเดินทาง (Travel)	ข้อ 14-16
	1.5 ภาระ (Burden)	ข้อ 17-21
2. ผลกระทบจากผลของตัวยาเอง	2.1 ผลข้างเคียงจากยา	ข้อ 22-26
	2.2 ผลด้านดีของยา	ข้อ 27-30

หลักเกณฑ์การเลือกระดับคะแนนของความสอดคล้องของข้อคำถามกับด้านที่ได้จำแนกไว้

ระดับ 1 หมายถึง ไม่มีความสอดคล้องกันเลยระหว่างข้อคำถามกับด้านที่ได้จำแนกไว้

ระดับ 2 หมายถึง ไม่สามารถประเมินความสอดคล้องได้ ควรต้องมีการแก้ไขข้อคำถามใหม่

ระดับ 3 หมายถึง มีความสอดคล้องกัน แต่ควรมีการแก้ไขเล็กน้อย เช่น แก้ภาษาที่ใช้

ระดับ 4 หมายถึง มีความสอดคล้องกันดีมากระหว่างข้อคำถามกับด้านที่ได้จำแนกไว้

ให้ท่านวงกลม ○ เลือกระดับความสอดคล้องของข้อคำถามกับด้านที่ได้จำแนกไว้เพียงระดับเดียว

ความตรงทางเนื้อหาของเครื่องมือวัดคุณภาพชีวิตสำหรับผู้ป่วยที่ใช้ยาต่อเนื่อง

ด้านและข้อคำถาม	ให้ท่านวงกลม ○ ระดับความสอดคล้องของข้อคำถามกับมิติที่ได้จำแนกไว้เพียงระดับเดียว
1.1 ด้านผลกระทบจากการใช้ยาต่อกิจกรรมประจำวัน(Physical /Role limitation)	
1. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังการใช้ยาอื่น เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
2. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องระมัดระวังอาหารการกิน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
3. ฉันต้องเสียเวลาในการจัดเตรียมยาที่ต้องใช้เป็นประจำ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
4. การที่ต้องใช้ยาติดต่อกันเป็นประจำรบกวนชีวิตประจำวันของฉัน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
5. ฉันต้องคอยกังวลเรื่องการใช้ยาในขณะทำงาน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
☒ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านผลกระทบจากการใช้ยาต่อกิจกรรมประจำวัน(Physical /Role limitation)	

ด้านและข้อคำถาม	ให้ท่านวงกลม O ระดับความสอดคล้องของข้อคำถามกับมิติที่ได้จำแนกไว้เพียงระดับเดียว
1.2 ด้านจิตใจ (Mental)	
6. ฉันรู้สึกเบื่อการกินยา เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
7. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันรู้สึกเป็นคนสุขภาพไม่แข็งแรง เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
8. ฉันรู้สึกหดหู่เนื่องจากต้องใช้ยาติดต่อกันเป็นประจำ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
9. ฉันวิตกกังวลว่าจะลืมกินยา เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
⌦ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านจิตใจ (Mental)	
1.3 ด้านจิตวิทยาสังคม (Psychosocial)	
10. ฉันรู้สึกลำบากใจที่ต้องใช้ยาในขณะอยู่กับผู้อื่น หรือเพื่อนร่วมงาน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
11. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันต้องหลีกเลี่ยงการทำกิจกรรมทางด้านสังคมบางประเภท (เช่น งานเลี้ยงสังสรรค์) เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
12. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้สูญเสียความมั่นใจเมื่อต้องเข้าสังคม เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก

ด้านและข้อคำถาม	ให้ท่านวงกลม ○ ระดับความสอดคล้องของข้อคำถามกับมิติที่ได้จำแนกไว้เพียงระดับเดียว
13. ฉันไม่ต้องการให้ผู้อื่นรู้ว่าฉันต้องใช้ยาติดต่อกันเป็นประจำ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
⌦ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านจิตวิทยาสังคม (Psychosocial)	
1.4 ด้านการเดินทาง (Travel)	
14. การที่ต้องใช้ยาติดต่อกันเป็นประจำสร้างความยุ่งยากให้ฉันเมื่อต้องเดินทาง เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
15. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันไม่อยากเดินทาง เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
16. ฉันต้องคอยเตือนตัวเองไม่ให้ลืมพกยาติดตัวเมื่อต้องเดินทาง เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
⌦ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านการเดินทาง (Travel)	
1.5 ด้านภาระ (Burden)	
17. ฉันวิตกกังวลกับภาระค่าใช้จ่ายจากยาที่ใช้ประจำ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
18. การที่ต้องใช้ยาติดต่อกันเป็นประจำก่อให้เกิดภาระค่าใช้จ่ายอื่นๆ นอกเหนือจากค่ายาที่ฉันใช้ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก

ด้านและข้อคำถาม	ให้ท่านวงกลม ○ ระดับความสอดคล้องของข้อคำถามกับมิติที่ได้จำแนกไว้เพียงระดับเดียว
19. ฉันต้องมีคนคอยดูแลการใช้ยาของฉัน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
20. คนข้างเคียงต้องคอยเป็นห่วงเรื่องการใช้ยาของฉัน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
21. ฉันรู้สึกว่าการที่ต้องใช้ยาติดต่อกันเป็นประจำเป็นภาระต่อครอบครัวของฉัน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
⌦ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านด้านภาระ (Burden)	
2.1 ด้านผลข้างเคียงจากยา	
22. ผลข้างเคียงจากยาทำให้ฉันมีอาการไม่สบายมากขึ้น เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
23. ผลข้างเคียงที่เกิดจากการใช้ยาของฉันทำให้ประสิทธิภาพการทำงานของฉันลดลง เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
24. ผลข้างเคียงจากยาที่ใช้ประจำรบกวนการใช้ชีวิตประจำวันของฉัน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
25. ฉันกังวลว่าจะเกิดการสะสมของยาในร่างกายเมื่อใช้ยาติดต่อกันเป็นระยะเวลานาน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก

ด้านและข้อคำถาม	ให้ทำนวงกลม ○ ระดับความสอดคล้องของข้อคำถามกับมิติที่ได้จำแนกไว้เพียงระดับเดียว
26. ผลข้างเคียงจากยาที่ใช้ประจำสร้างความรำคาญให้แก่ฉัน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
☒ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านผลข้างเคียงจากยา	
2.2 ผลด้านดีของยา	
27. การใช้ยาติดต่อกันเป็นประจำทำให้อาการฉันดีขึ้น เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
28. การใช้ยาติดต่อกันเป็นประจำช่วยให้ฉันไม่ขาดงาน เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
29. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันมั่นใจว่าอาการจะไม่กำเริบ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
30. การที่ต้องใช้ยาติดต่อกันเป็นประจำทำให้ฉันใช้ชีวิตได้เป็นปกติ เสนอแก้ไข.....	1 = ไม่สอดคล้อง 2 = ไม่สามารถประเมินได้ ต้องแก้ไขข้อคำถามใหม่ 3 = มีความสอดคล้อง ควรมีการแก้ไข เช่น แก้ภาษาที่ใช้ 4 = มีความสอดคล้องดีมาก
☒ ข้อคำถามที่เสนอเพิ่มเติมสำหรับด้านผลด้านดีของการใช้ยา	

ตัวเลือกในเครื่องมือประเมินคุณภาพชีวิตสำหรับผู้ป่วยที่ใช้ยาต่อเนื่องทุกข้อคำถาม แบ่งได้เป็น 5 ระดับ

ท่านคิดว่าตัวเลือกแต่ละข้อคำถามที่ตั้งไว้เป็น 5 ระดับคือ ไม่มีเลย เล็กน้อย ปานกลาง ค่อนข้างมาก มากที่สุด

❑ เหมาะสม ❑ ไม่เหมาะสม ระบุคำแนะนำ.....

❁ **ข้อเสนอแนะอื่นใดนอกจากที่ได้กล่าวมาแล้ว หรือมีมิติ/ด้านอื่นที่ยังขาดไปเพิ่มเติม**

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ขอขอบพระคุณอย่างสูงสำหรับคำแนะนำในการพัฒนาเครื่องมือ

นางสาววรรณา ตั้งภักดีรัตน์

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Appendix E: THE SF-6D AND EQ-5D3L DOMAINS

The SF-6D and EQ-5D; Reference from page 875 Brazier, et. al (2004).

Level	SF-6D		EQ-5D
	Physical Functioning		*Mobility*
1	Your health does not limit you in *vigorous activities*	1	No problems walking about
2	Your health limits you a little in *vigorous activities*	2	Some problems walking about
3	Your health limits you a little in *moderate activities*	3	Confined to bed
4	Your health limits you a lot in *moderate activities*		
5	Your health limits you a *little in bathing and dressing*		*Self care*
6	Your health limits you a *lot in bathing and dressing*	1	No problems with self-care
		2	Some problems washing or dressing myself
	Role limitations	3	Unable to wash or dress self
1	You have no problems with your work or other regular daily activities as a result of your physical health or any emotional problems		
2	You are limited in the kind of work or other activities as a result of your physical health		*Usual activities*
3	You accomplish less than you would like as a result of emotional problems	1	No problems with performing usual activities (e.g. work, study, housework, family or leisure activities)
4	You are limited in the kind of work or other activities as a result of your physical health and accomplish less than you would like as a result of emotional problems	2	Some problems with performing usual activities
		3	Unable to perform usual activities
	Social functioning		
1	Your health limits your social activities *none of the time*		
2	Your health limits your social activities *a little of the time*		
3	Your health limits your social activities *some of the time*		
4	Your health limits your social activities *most of the time*		
5	Your health limits your social activities *all of the time*		
	Pain		*Pain/discomfort*
1	You have *no* pain	1	No pain or discomfort
2	You have pain but it does not interfere with your normal work (both outside the home and housework)	2	Moderate pain or discomfort
3	You have pain that interferes with your normal work (both outside the home and housework) *a little bit*	3	Extreme pain or discomfort
4	You have pain that interferes with your normal work (both outside the home and housework) *moderately*		
5	You have pain that interferes with your normal work (both outside the home and housework) *quite a bit*		
6	You have pain that interferes with your normal work (both outside the home and housework) *extremely*		
	Mental health		*Emotions*
1	You feel tense or downhearted and low *none of the time*	1	Not anxious or depressed
2	You feel tense or downhearted and low *a little of the time*	2	Moderately anxious or depressed
3	You feel tense or downhearted and low *some of the time*	3	Extremely anxious or depressed
4	You feel tense or downhearted and low *most of the time*		
5	You feel tense or downhearted and low *all of the time*		
1	*Vitality*		None
2	You have a lot of energy *all of* the time		
3	You have a lot of energy *most of* the time		
4	You have a lot of energy *some of* the time		
5	You have a lot of energy *a little of* the time		
	You have a lot of energy *none of* the time		

BIOGRAPHY

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