DEVELOPMENT OF A MEDICATION-PROBLEM COPING SCALE USING ITEM RESPONSE THEORY

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Dedication

This dissertation is dedicated to my parents and family.

Abstract

Adverse drug problems (ADPs) have become a serious and urgent health issue, causing significant morbidity, mortality, and economic burden to patients. A brief questionnaire asking patients how they coped with such problems can be a useful tool for providing timely interventions given information about their level of coping. The objective of this study was to develop a medication-problem coping scale to measure patients' coping responses to their ADP using item response theory (IRT).

Candidate items were developed based on a comprehensive literature review that identified relevant items for measuring how patients coped with their ADPs. To fill in the content gaps, new items were added to the initial item pool. The items were administered to patients at community pharmacies that are incorporated into the Minnesota practice-based research network (PBRN). Psychometric analyses based on IRT were performed. Items that satisfied the model assumptions and achieved an adequate model fit remained in the final item bank. Reliability was assessed by analyzing the item information and test information. Convergent validity was evaluated by testing *a priori* formulated hypotheses about expected correlations between the coping scores on this scale and other related scales.

A total of 140 patients participated in this study by answering all items. Confirmatory factor analysis suggested unidimensionality of 11 items. These items demonstrated adequate psychometric properties when calibrated using the two-parameter logistic (2PL) model. Reliability was evaluated by the information of the 11-item bank and a 6-

item short-form. Respondents reporting their ADP as relatively large showed higher coping scores than those who perceived their ADP as small. Health literacy levels were higher in patients who sought out information as a coping strategy than in those who did not. However, there was unexpectedly little or no relationship between patients' coping levels and their coping self-efficacy.

This study presents a medication-problem coping scale developed with IRT. The final item bank and its short-form may be applied to clinical samples to evaluate their usefulness.

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Chapter 1 : INTRODUCTION

1.1 Concern with Medication-Related Problems (MRPs)

Medication-related problems (MRPs) have become a serious and urgent health problem, causing significant morbidity, mortality, and economic burden to patients. More than 100,000 deaths were attributed to MRPs each year, and the annual MRP-related costs were estimated in excess of $177 billion (Ernst & Grizzle, 2001; J. A. Johnson & Bootman, 1995). One study indicated that MRPs accounted for approximately 28% of all emergency department visits, 24% of which resulted in hospitalization (Zed, 2005). Among MRPs, patients' experience of adverse effects, in particular, have been consistently reported as one of the reasons for non-adherence to medication , resulting in negative health outcomes to such patients, including low quality of life, high risk of hospitalization, and increased healthcare costs (Ammassari et al., 2001; Bender & Bender, 2005; Brown, Rehmus, & Kimball, 2006; McCann, Clark, & Lu, 2009; McHorney, Schousboe, Cline, & Weiss, 2007; Wu et al., 2008). This suggests that a substantial opportunity exists for improving patients' outcomes by addressing adverse drug problems (ADPs) and improving ADP management. This not only can help develop remedial interventions by identifying the potential causes, but can also reduce rates of hospitalization by improving adherence to medication or stopping medications that cause major problems.

1.2 Patients' coping with their perceived Adverse Drug Problems (ADPs)

As an approach for handling ADPs, asking patients directly about their ADPs is questionable. Physicians may avoid discussing patients' aversions to prescribed medication (Britten, Stevenson, Gafaranga, Barry, & Bradley, 2004). Alternatively, a significant discrepancy may exist between patients' perceived ADPs and physicians' evaluations of ADPs (Larsen & Gerlach, 1996). In addition, patients sometimes consider their perceived ADPs are under their control and modify their treatment regimen independent of their physicians (e.g. they arbitrarily reduce the dosage or discontinue their medication to eliminate the burden from ADPs). Therefore, asking patients, not about the problem, but whether and how they coped with such problems could be more useful for gathering information about new or worsening problems that patients perceive after they start taking a medication and how they decide to handle them. Clinicians should somehow routinely ask their patients about problems related to their medications.

1.3 Scales to measure patients' coping with health problems

Over the past few decades, numerous scales have been developed or applied to measure patients' coping with their health-related problems. These scales include the Coping with Health Injuries and Problems scale (CHIP) (Endler, Parker, & Summerfeldt, 1998), the Coping Inventory for Stressful Situations (CISS) (Endler & Parker, 1990), the COPE scale (Carver, Scheier, & Weintraub, 1989) and its brief version (Carver, 1997), the COping STrategies Scales (COSTS) (Beckham & Adams,

1984), the Coping Response Inventory (CRI) (R. Moos, 1997), the Coping Self Efficacy (CSE) scale (Chesney, Neilands, Chambers, Taylor, & Folkman, 2006), the Coping Strategy Indicator (CSI) (Amirkhan, 1990), the Ways of Coping Scale (WCS) (Lazarus & Folkman, 1984) and its revised version, the Revised Ways of Coping Scale (RWCS) (Vitaliano, Russo, Carr, Maiuro, & Becker, 1985). However, many of these scales have methodological weaknesses that limit their practical use (Folkman & Moskowitz, 2004; Parker & Endler, 1992). Information on validity and reliability of many of the scales is frequently limited or has not been reported; inadequate sampling of coping items and populations has been inherent; and the length of the scale has been potentially burdensome.

In addition, these scales assess a variety of coping dimensions, although a specific type of coping, i.e., problem-focused coping, is more likely to be represented by patients who perceive ADPs from their medication. Among the various coping dimensions measured by the existing scales, two main coping reactions have been consistently reported to date: emotion-focused coping, which serves to regulate the negative emotions associated with the problem, and problem-focused coping, which aims at solving or managing the problem (Folkman & Lazarus, 1980). Examples of emotion-focused coping include looking on the bright side, seeking emotional support, having a drink or using drugs, and engaging in distracting activities. Problem-focused coping includes gathering information, planning, making decisions, and resolving conflicts. It involves instrumental, situation-specific, and task-oriented actions. In addition to these two coping dimensions, other coping responses, such as meaning-focused coping, social coping, and avoidance, have been reported (Amirkhan, 1990;

Billings & Moos, 1981; Pearlin & Schooler, 1978). However, most attention should be focused on the problem-focused coping when the patient believes that he or she has the power to eliminate ADPs. In cases in which patients perceive ADPs while taking their medication, they interpret this medication as a causal factor for the ADPs, and thus they consider ADPs as controllable by modifying their medication use (e.g., reducing the dosage or discontinuing medication) (De Smedt, Haaijer-Ruskamp, Groenier, van der Meer, & Jaarsma, 2011). When the problem involves a controllable aspect, it generally calls for a greater proportion of active and instrumental problem-focused coping than other types of coping (Folkman & Moskowitz, 2004). For this reason, this study highlighted problem-focused coping rather than other types of copings.

Notably, the existing scales are intended to measure patients' coping with health problems other than ADPs. Recently, Johnson and Neilands developed a Side Effect Coping questionnaire (SECope) to measure patients' coping with their HIV treatment side effects, and showed its reliability (internal consistency and test-retest) and construct and criterion validity (M. O. Johnson & Neilands, 2007). By adding two items to the SECope scale, De Smedt et al. also used this slightly revised version to assess coping with adverse drug events in patients with heart failure (De Smedt, Haaijer-Ruskamp, Groenier, van der Meer, & Jaarsma, 2011). The samples in these studies, however, were limited to patients with HIV and HF, although coping items in the SECope are applicable to patients with other medical conditions. Moreover, there was a lack of information on how precisely each item measures across the full spectrum of patient's coping with ADPs. In other words, the relationship between a patient's coping

level and the probability of endorsing the individual item was not examined in the studies.

1.4 Use of Item Response Theory (IRT) in health outcomes research

A novel technique, item response theory (IRT), has been increasingly applied in developing and assessing health-related outcome measures over the past few years. This theory compensates for several limitations that classical test theory (CTT) possesses, including sample-dependent item- and scale- statistics, and unreasonable assumptions such as item equivalence and identical measurement errors over all of the scores (De Champlain, 2010). In addition, the IRT model can allow us to measure the latent trait more precisely by yielding the most information from each patient; it relates item characteristics and patient characteristics to the probability of a positive response.

Moreover, it can improve efficiency by minimizing the number of items required to obtain a desired degree of precision without compromising reliability. It also enables optional use of interchangeable items. For these reasons, the National Institutes of Health have undertaken a major initiative to develop standardized and well-calibrated measures of patient-reported outcomes using IRT since 2004. In particular, the use of IRT models has grown considerably in such areas as physical function (Fries, Bruce, Bjorner, & Rose, 2006; Rose, Bjorner, Becker, Fries, & Ware, 2008), asthma (Yeatts et al., 2010), COPD (Choi, Victorson, Yount, Anton, & Cella, 2011), fatigue in cancer (Garcia et al., 2007), sleep disturbance (Buysse et al., 2010), depression (Gibbons et al., 2011), and anxiety (Becker et al., 2008). This study is the first to use IRT to assess patients' responses to their perceived ADP.

1.5 Objectives and aims

The objective of this study was to develop a reliable and valid patient-reported ADP coping scale. Asking patients about their level of coping with perceived ADPs, clinicians can provide interventions tailored to the individual, which represents an efficient and economical way to discuss and resolve ADPs. By improving ADP management, patients can achieve safer and more effective medication use.

To achieve the objective, this study had the following specific aims:

Aim 1: To construct an item pool to evaluate patients' coping with their perceived ADP.

Candidate items were identified from the existing coping scales by conducting a comprehensive literature review. The content relevance of each item was assessed to decide whether it should be considered for a new scale. Items were considered to be included in the new scale if they measure patients' behaviors that respond to their perceived ADP aiming to solve or manage the problem. (A latent variable defined in this study is detailed in chapter 2.) In addition, new items were created to fill in the content gaps. The constructed item pool was expected to cover the whole range of patients' ways of coping. The developed items were then administered to patients who perceive an ADP.

Aim 2: To conduct psychometric analyses based on item response theory (IRT).

To create the final item bank, psychometric analyses were conducted. The analyses included evaluating the assumptions of the IRT model, estimating item

parameters, and assessing the model fit to the data. Items that satisfied the model assumptions and achieved an adequate model fit remained in the final item bank.

Aim 3: To assess reliability and construct validity of the constructed scale.

To assess precision at the item level, the item information function (IIF) was examined for each individual item. At the scale level, the test information (the sum of each item's information), was analyzed to examine the reliability of the scale as a set of items. To assess convergent validity, *a priori* formulated hypotheses about expected correlations between the coping scores on the new scale and other related scales were tested. These other related scales included a problem scale, a health literacy scale, and the problem-focused subscale of coping self-efficacy (CSE). Positive relationships between scores on the coping level and scores from these scales were hypothesized.

1.6 Significance of the study

In this study, data were directly from patients who experience an ADP, and not from their providers. Typically, clinical measures by healthcare providers are narrowly focused and assess physiological, biomedical, and/or limited functional dimensions of an ADP. Sometimes providers are not even aware of their patients' perceived ADP. In contrast, patient-reported measures capture problems as perceived by patients that affect their medication-taking behavior (Barr, 1995). Notably, outcomes important to patients are influenced not just by clinical indicators but also by a complex interaction of physical, social, and psychological factors (Chang et al., 2011). Patients' self-reports are particularly important when they do not correspond to those drawn from clinical

measures. Clinicians may concentrate more on the severe side effects that impact directly on morbidity or mortality, whereas patients may also attend to mild, but bothersome side effects (Larsen & Gerlach, 1996).

Use of patient-reported outcomes (PROs) reflect patients' changing role with regard to the care they receive and their increased participation in the health-related decision-making process. In other words, self-reported measures can facilitate a patient-centered care. Over the past few decades, patients have become active players in the healthcare process, shifting away from passive recipients of treatment, and they have become more actively engaged in the decision-making process (Linacre, 1994; Meadows, 2011). In accordance with this trend, PROs have gained increasing prominence, which is reflected in recent national policy and initiatives in the U.K. (Darzi, 2008). For example, since April 1st, 2009, NHS-funded hospitals have been required to ask patients to complete a PRO-measures questionnaire before and after four surgical procedures defined by the NHS (Palfreyman, 2011). Likewise, the National Institutes of Health in the U.S. have undertaken a major initiative to develop standardized and well-calibrated measures of PROs since 2004. The U.S. Food and Drug Administration (FDA) has also recognized the growing value of PROs and responded by publishing guidelines on the use of PRO measures in medical product development in 2006 (the draft version) and 2009 (the revised version). These guidelines confirm the expanded role of PROs in the drug approval process. All of these suggest that the influence of patients' perspectives in health-related decisions will grow in importance throughout the process of providing care.

The importance of using a patient-reported measure becomes greater when addressing a patient's perception of an ADP and assessing his or her coping behaviors. Previous evidence suggests that between one-third and one-half of patients do not spontaneously report ADPs or ADP-related modifications they made to their treatment regimen to their healthcare providers (Jarernsiripornkul, Krska, Capps, Richards, & Lee, 2002; Pound et al., 2005). This may lead to suboptimal medication use and more severe morbidity and mortality later; therefore, a patient's perceived ADP and his or her responses should be ascertained. Using a self-report measure, providers can identify how patients have coped with an ADP and provide timely interventions to such patients. Also, by applying this measure as a screening device for clinical assessments of ADPs to busy clinical settings, practitioners can save their time. After receiving practitioners' timely assistance with an ADP, patients can optimize their medication use.

1.7 Contribution to the field

The developed item set can be used by clinicians to receive their patients' feedback on coping with a perceived ADP. Since this item set is brief and easy to administer, clinicians can find their patients' ADP immediately and provide timely interventions tailored to the individual without imposing heavy burdens to them. This could be an efficient and economical way to discuss and resolve ADPs. By improving ADP management, patients can achieve safer and perhaps more effective medication use. This can contribute to reducing healthcare expenditures, which have been increasing dramatically in recent decades, by preventing potential morbidity and mortality from the ignored ADPs.

Chapter 2 : LITERATURE REVIEW

This chapter reviews the literature on the measures of patients' coping with their perceived health-related problems, and provides the theoretical framework of this study. The electronic databases Pubmed® (1950 through January 2012) and PsycINFO® (1806 through January 2012) were searched using a keyword "coping" in combination with "adverse drug problem" and its synonyms (e.g., side effect*, adverse drug event*, adverse drug reaction*, adverse effect*, medication (related) problem*, and drug therapy (related) problem*) and "scale" and its synonyms (e.g., questionnaire* and instrument*). This resulted in about 34,400 articles, and articles were reviewed if they involved a development or evaluation of the coping behaviors to health-related problems.

2.1 Measures of coping in response to health-related problems

Ways of Coping Scale (WCS) and its revised version (RWCS): 66 items (Lazarus & Folkman, 1984) and 42 items (Vitaliano, Russo, Carr, Maiuro, & Becker, 1985)

The original form of the WCS was designed to measure an individual's constantly changing cognitive and behavioral efforts to manage the internal and/or external demands of particular stressful situations. The authors conceptualized coping as a dynamic process in which a person employs different forms of coping depending on the status of the person-environment relationship. Therefore, it intends to measure coping as a dynamic process, not as coping style or trait. After conducting a factor analysis with 42 items from the pool of 66 items, the authors identified eight subscales (one problem-focused and seven emotion-focused), which were labeled as problem-focused coping, wishful

thinking, detachment, seeking social support, focusing on the positive, self-blame, tension-reduction, and keep to self (Folkman & Lazarus, 1985). However, a study using a different 50-item subset identified slightly different eight subscales which were conceptualized as confrontive coping, planful problem-solving, distancing, self-controlling, seeking social support, accepting responsibility, escape avoidance, and positive appraisal. The first two subscales measure problem-focused coping, while the other six measure emotion-focused coping strategies (Folkman, Lazarus, Dunkel-Schetter, DeLongis, & Gruen, 1986). The WCS was then revised by eliminating the redundant items, rewording the unclear items, and adding several items. The response options were also changed from a dichotomized format (Yes/No) in the original version to a 4-point scale (0 = does not apply and/or not used; 3 = used a great deal) in the revised version. The revised version had five subscales: problem-focused coping (15 items), blaming self (3 items), wishful thinking (8 items), seeking social support (6 items), and avoidance (10 items). There was evidence to support the internal consistency of the WCS and RWCS (Cronbach alphas ranging from 0.61 to 0.79 and from 0.77 to 0.83, respectively). Construct validity was assessed by examining correlations between the various subscales of RWCS and persons' responses to the stressors such as anxiety and depression (Vitaliano, Russo, Carr, Maiuro, & Becker, 1985). Depression was negatively related to the problem-focused coping and positively related to wishful thinking. Also, medical students in group therapy were shown to receive significantly higher scores than students not having such therapies.

Respondents are asked to indicate to what extent they employed each coping strategy presented in the RWCS using a 4-point scale, ranging from 0 = *not used* to 3 =

used a great deal. Sample items include, “talked to someone to find out more about the situation,” “made a plan of action and followed it,” and “just concentrated on what I had to do next.”

Medical Coping Modes Questionnaire (MCMQ) and its revised version: 19 items (Feifel, Strack, & Nagy, 1987a) and 20 items (Feifel, Strack, & Nagy, 1987b)

The MCMQ was designed to assess coping with illnesses. This was particularly developed for use in medical settings and items focused on coping responses to a current illness. It provides scores on three subscales: confrontation with eight items, avoidance with seven items, and acceptance-resignation with four items. The MCMQ had evidence of internal consistency (Cronbach alphas ranging from 0.66 to 0.70). In those subscales, acceptance-resignation was a particularly manifest coping strategy employed by patients with little expectation of recovery and a lack of hope. Coping strategies such as avoidance and acceptance-resignation were negatively associated with effectiveness of coping assessed by their physicians and significant others (e.g., wives). To investigate the coping strategies employed by patients confronting different conditions, patients with life-threatening illnesses (e.g., cancer, heart disease) were compared to those with nonlife-threatening illnesses (e.g., arthritis, orthopedic low back pain, dermatitis). Results showed that patients with life-threatening illnesses employed more confrontation coping than nonlife-threatened patients. However, there was no significant difference for the avoidance and acceptance-resignation coping scales between them. The scale developer revised the original MCMQ version based on factor analyses of an item pool that they

generated. The revised version, MCMQ-R, consists of 20 items, grouped into four subscales: information seeking, social support seeking, avoidance, and resignation.

Respondents are asked to indicate how often they use each coping strategy presented in the MCMQ-R using a 5-point scale, ranging from *never* to *always*. Sample items include, “I have asked my doctor questions about my illness” (information seeking) and “I try to talk about my illness with my friends or relatives” (social support seeking).

Coping Responses Inventory (CRI): 48 items (R. Moos, 1993; R. H. Moos, 1988)

The CRI was developed to identify the cognitive and behavioral responses employed to cope with a recent problem or stressful situation. It consisted of 48 items grouped into two subscales (approach coping and avoidance coping). Each subscale was then divided further into two cognitive coping subdomains and two behavioral coping subdomains. That is, approach coping consisted of four subdomains such as logical analysis, positive appraisal, guidance/support, and problem solving; avoidance coping was composed of cognitive avoidance, resigned acceptance, alternative rewards, and emotional discharge. The first two subdomains in each subscale reflected cognitive coping, while the last two subdomains reflected behavioral coping. All eight subdomains showed internal consistencies with Cronbach alphas ranging from 0.58 to 0.74. The authors assessed convergent validity by means of correlations with previous versions of the test. Results showed that the correlation coefficients varied from 0.56 (emotional discharge) to 0.95 (seeking guidance and support) between these conceptually comparable scales.

Separate versions of the CRI have been developed for adults (older than 18 years of age) and for youth (ages between 12 and 18). Respondents indicate how often they used various coping strategies to deal with the most important problem they faced during the past year on a 4-point scale from *not at all* to *fairly often*. Sample items include, "talk with a professional person," "try to find out more about the situation," and "try to learn to do more things on your own."

COPE and its brief version: 60 items (Carver, Scheier, & Weintraub, 1989) and 28 items (Carver, 1997)

The original COPE inventory was developed to measure different ways in which people respond to stress. In developing the COPE, the authors used Lazarus' transactional stress model which was used for the development of the WCS, but they also used a self-regulatory model as a theoretical framework. There were 13 subscales defined in the original COPE, each with a specific conceptual focus: five subscales (active coping, planning, suppression of competitive activities, restraint coping, and seeking of instrumental social support) incorporate problem-focused coping, while another five subscales (seeking of emotional social support, positive reinterpretation, acceptance, denial, and turning to religion) measure emotion-focused coping. The other three subscales (focus on and venting of emotions, behavioral disengagement, and mental disengagement) measure coping responses that arguably were less useful. Its brief version, the Brief COPE (BCOPE), had three subscales (i.e., dysfunctional coping, problem-focused coping, and emotion-focused coping) with 28 items. The dysfunctional coping strategy includes coping reactions such as behavioral disengagement, self-

distraction, self-blame, substance use, and venting; the problem-focused coping incorporates active coping, instrumental support, and planning, while emotional-focused coping includes acceptance, emotional support, humor, positive reframing, religion, and denial. Although internal consistency varied with Cronbach alphas ranging from 0.50 to 0.90 across all subscales (Carver, Scheier, & Weintraub, 1989), it was adequate for some subscales such as emotion-focused, problem-focused, and dysfunctional coping with alpha values of 0.72, 0.84, and 0.75, respectively (Cooper, Katona, & Livingston, 2008). There was evidence of convergent and concurrent validity by showing that the subscales were predicted by secure attachment, burden, avoidant attachment, and social support (Cooper, Katona, & Livingston, 2008).

Respondents are asked to rate their degree of agreement with each statement on a 4-point scale, ranging from 0 ("I haven't been doing this at all") to 3 ("I've been doing this a lot"). Sample items include, "I take additional action to try to get rid of the problem," "I take direct action to get around the problem," and "I ask people who have had similar experiences what they did."

Coping Inventory for Stressful Situation (CISS): 48 items (Endler & Parker, 1990)

The CISS was derived from its earlier version, the Multidimensional Coping Inventory (MCI). After a series of factor analyses, the MCI has been revised and renamed as the CISS. The CISS was developed to be used for determining an individual's preferred coping style and contributing to understanding of the differential relationship between coping style and other personality variables. It measures three subscales which assess task- , emotion-, and avoidance-oriented coping. The avoidance subscale is divided

further into two separate domains assessing avoidance through social interaction and avoidance based on distraction. The authors argued that the alpha coefficients were highly satisfactory across the normative groups. Test-retest reliabilities were moderate to high: coefficients for the task- and emotion-oriented coping subscales were equal to or greater than 0.68. The avoidance-oriented coping and its two subdomains had limited reliabilities ranging from 0.51 to 0.60. Construct validity was supported by negative relationships between task-oriented coping and depression (Mitchell & Hodson, 1983). Also, numerous studies showed that emotion-oriented coping was employed more frequently in individuals with depression compared to non-depressed individuals (Billings, Cronkite, & Moos, 1983; Billings & Moos, 1984; Mitchell, Cronkite, & Moos, 1983). A more recent study showed that depressive symptoms and anxiety levels were positively associated with emotion-oriented coping and negatively with task-oriented coping (McWilliams, Cox, & Enns, 2003).

Respondents are asked to rate how much they engage in each activity when they encounter a difficult, stressful, or upsetting situation using a 5 point Likert scale ranging from 1 (not at all) to 5 (very much). Sample items include, “think about how I have solved similar problems,” “consider different solutions to the problem,” and “decide course of action.”

Coping Strategy Indicator (CSI): 33 items (Amirkhan, 1990)

The CSI is distinct in that it combined both inductive and deductive methodologies when it was developed. That is, the developer first derived 161 coping responses from existing scales and from his previous research, and then reduced items by

conducting a series of factor analyses with independent large samples. The final version of CSI consisted of three subscales (problem solving, seeking support, and avoidance), each with 11 items. The scale measures coping strategies employed in response to a worrisome problem that was experienced within the last six months. Three subscales showed adequate internal consistency with Cronbach alphas ranging from 0.84 to 0.93. Tests of convergent validity showed that the CSI and WCS were moderately but significantly correlated. The CSI was shown to be resistant to social desirability biases.

Respondents are asked to indicate the extent to which they engaged in each of 33 coping strategies using a 3-point scale (*not at all*, *a little*, or *a lot*). Sample items include, "tried to solve the problem," "brainstormed all possible solutions before deciding what to do," and "set some goals for yourself to deal with the situation."

Coping with Health Injuries and Problems (CHIP): 32 items (Endler, Parker, & Summerfeldt, 1998)

The CHIP scale was designed to measure coping reactions to health problems. Coping was defined as cognitive and behavioral attempts to change, modify, or regulate internal or external factors which may be adaptive or maladaptive, and health problems were defined as a specific type of stressors that may vary according to duration, degree of chronicity, or amount of personal control. Factor analyses supported its 4-factor structure (distraction, palliative, instrumental, and emotional preoccupation), each with 8 items: distraction coping represents the extent to which the person uses action and cognitions that are aimed at avoiding preoccupation with the health problem; palliative coping involves a variety of self-help responses aimed at alleviating the unpleasantness of the

situation; instrumental coping involves task-oriented responses such as actively seeking out health information or seeking medical advice; and emotional preoccupation coping involves fixation with the emotional consequences of the health problem. The CHIP subscales had evidence of adequate internal consistency in adults, general medical patients, and patients with lower back pain (Cronbach alphas ranging from 0.70 to 0.88). Preliminary validity was suggested by comparing CHIP scores with basic coping styles and by comparing the coping behaviors of patients with acute and chronic illnesses.

Respondents indicate the frequency in which they were involved in 32 specific coping responses on a five-point scale, ranging from *1 = not at all* to *5 = very much*. In addition to these 32 items, they are asked about the name of the illness, a rating of severity of the illness, and the actual duration of the illness. The scale is copyrighted by Multi-Health Systems.

Coping Self-efficacy (CSE): 26 items (Chesney, Neilands, Chambers, Taylor, & Folkman, 2006)

The CSE scale was designed to measure individuals' evaluations of their self-efficacy for coping with challenges or threats. It particularly focuses on changes in an individual's confidence in his or her ability to cope, which results in the individual's changing coping behavior according to self-efficacy theory (Bandura, 1977). The scale items were developed based on stress and coping theory and the ways of coping scale. The CSE consisted of 13 items grouped into three subscales: problem-focused coping (6 items), emotional-focused coping (4 items), and support from friends and family (3 items). There was evidence of the internal consistency of the CSE subscales (Cronbach

alphas ranging from 0.80 to 0.91). Predictive validity was assessed by showing that problem- and emotional-focused coping were predictive of reduced psychological distress and increased psychological well-being over time.

Respondents are asked, “when things aren’t going well for you, or when you’re having problems, how confident or certain are you that you can do the following,” and then asked to rate on an 11-point scale the extent to which they believe they could perform behaviors important to adaptive coping (e.g., “sort out what can be changed, and what cannot be changed”, “break an upsetting problem down into smaller parts”, “look for something good in a negative situation”, and “get emotional support from friends and family”). Anchor points on the scale were 0 (“cannot do at all”), 5 (“moderately certain can do”) and 10 (“certain can do”).

Side Effect Coping Questionnaire (SECope): 20 items (M. O. Johnson & Neilands, 2007)

Recently, the SECope was developed to measure patients’ coping with HIV treatment side effects. Although items were developed through qualitative interviews with persons who reported side effects from their HIV treatment, they were applicable to patients with other medical conditions. De Smedt et al., applied the SECope to patients with heart failure after adding two items based on their pilot cognitive interviews with seven patients (De Smedt et al., 2012). After conducting factor analysis, authors identified five subscales such as positive emotion focused coping, social support seeking, nonadherence, information seeking, and taking another medication to ameliorate the side effect. Internal consistency for the global SECope was assessed with a coefficient value of 0.87. Construct and criterion validity were supported by correlations between the

subscales and other construct measures. For example, there was association between the nonadherence subscale and poor provider relations, low treatment knowledge, and high beliefs of treatment effectiveness.

Respondents are asked to indicate how often they used each coping strategy on a 5-point scale from 0 = *never* to 4 = *very often*. Sample items include, "think about good times in the past" (positive emotion focused coping), "reduce the dose of the medication that is causing the side effect" (nonadherence), and "take a medication that will make the side effect feel better or go away" (taking side effect medications).

The scales are listed above if they intend to measure patients' coping with their stressors including their general health-related problems. The scales measuring with the presence and or intensity of particular side effects of specific medications (e.g., anticancer medications, antipsychotics, or antiepileptics) are not discussed here because they were applicable only to patients with such diseases. These types of measures are briefly summarized in Table 2-1.

2.2 Summary of the literature review

As consistently reported in the coping literature, all scales in this review included at least two major types of coping, i.e., problem-focused coping and emotion-focused coping. Since this study emphasizes problem-focused coping with the reason noted earlier, the problem-focused coping items were examined cautiously. Of the scales, the SECope was particularly relevant to our study in that this questionnaire asked about patients' coping with specific *side effects* other than their coping responses to *an ongoing illness or the general health problem* which other scales asked about. The contents of the

items asking about coping responses to an ongoing illness or the general health problem seem to be too broad to be adopted for a new scale. However, the SECope included items applicable to a new scale, including “decide that the medication is not worth the side effect and stop taking it,” “reduce the dose of the medication that is causing the side effect,” “take less of the medication to see if the side effect is not so bad (smaller doses or less frequent),” “talk to your doctor or health care provider about the problem,” “try to get more information about the medication or side effect,” “take another medication to deal with the side effect,” “take a medication that will make the side effect feel better or go away,” “request a medication from your doctor to help the side effect,” and “talk to family, friends, loved ones about the problem.” These nine items were incorporated in the subscales such as nonadherence, information seeking, taking another medication to ameliorate the side effect, and social support seeking, but not in the positive emotion-focused coping subscale. Therefore, these items were reworded and adopted in the new scale.

Table 2-1. Scales to measure coping with side effects of specific medications[a,b]

Name	Purpose	Domains	Number of items
ASC-SR: Approaches to Schizophrenia Communication- Self-Report checklist	To measure antipsychotic drug side effects for use in clinical practice	n/r	17
C-PET: Clinical checklist for Patients with Endocrine Therapy	To measure occurrence of side effects associated with hormonal treatment of breast cancer	n/r	13
C-SAS: Chemotherapy Symptom Assessment Scale	To document side effects of chemotherapy	n/r	24
GASS: Glasgow Antipsychotic Side-effect Scale	To detect side effects of second generation antipsychotics	9 domains (sedation and CNS; cardiovascular; extrapyramidal; anticholinergic; GI; genitourinary; screening for DM; prolactinaemic; weight gain)	21
ICQ: Inhaled Corticosteroid Questionnaire	To measure patient-perceived side effects of inhaled corticosteroid	15 domains (voice problems; oropharynx problems; unpleasant taste; skin, hair, and nails; mood problems; taste disruption; perspiration; oropharyngeal itching; thirst; tiredness; oral candidiasis; facial edema; vision deterioration; dental deterioration; eye dryness)	57
LUNSERS: Liverpool University Neuroleptic Side Effect Rating Scale	To measure side effects of neuroleptic drugs	n/r	41
MEDS: Matson Evaluation of Drug Side effects	To evaluate identified side effects of psychoactive medications	9 domains (cardiovascular and hematologic; gastrointestinal; endocrine/genitourinary; eye/ear/nose/throat; skin/allergies/temperature; CNS-general; CNS-dystonia; CNS-parkinsonism/dyskinesia; CNS-akathesia)	90

MOSES: Monitoring of Side Effects System	To assess side effects of antipsychotics	8 domains (eyes/ears; gastrointestinal/mouth; neurologic/muscle; psychological/general; respiratory; skin; urinary; whole body)	73
MPQ: Medication Problems Questionnaire	To measure self-rated side effects of interferon drugs	n/r	21
MSEC: Medication Side Effect Checklist	To assess the severity of analgesic side effects	n/r	6
MTSOSD: Modified Transplant Symptom Occurrence and Symptom Distress	To assess symptom frequency and distress associated with triple drug therapy after transplantation	n/r	29
PNS: Peripheral Neuropathy Scale (aka FACT/GOG-Ntx subscale)	To measure peripheral neuropathy associated with chemotherapy	2 domains (hand neuropathy, foot neuropathy) and 2 items not included in domains	11
SEALS: Side Effect and Life Satisfaction	To measure subjective side effects of anti-epileptic medication	5 domains (cognition; dysphoria; temper; tiredness; worry)	38
SES-HP: Side effect scoring system for helicobacter pylori treatment regimens	To measure side effects of helicobacter pylori treatment regimens	n/r	9
UKU: Udvalg for Kliniske Undersogelse	To measure side effects of psychotropic drugs	4 domains (Psychic functions; neurological signs; autonomous side effects; other side effects)	48
WCQ: Worthing Chemotherapy Questionnaire	To document side effects of chemotherapy	6 domains (digestive system; mouth and nose; skin and hair; eyes; general physical health; moods and feelings)	75

[a] Adding several scales to the scales reported by Foster et al.'s study (Foster, van der Molen, Caeser, & Hannaford, 2008)

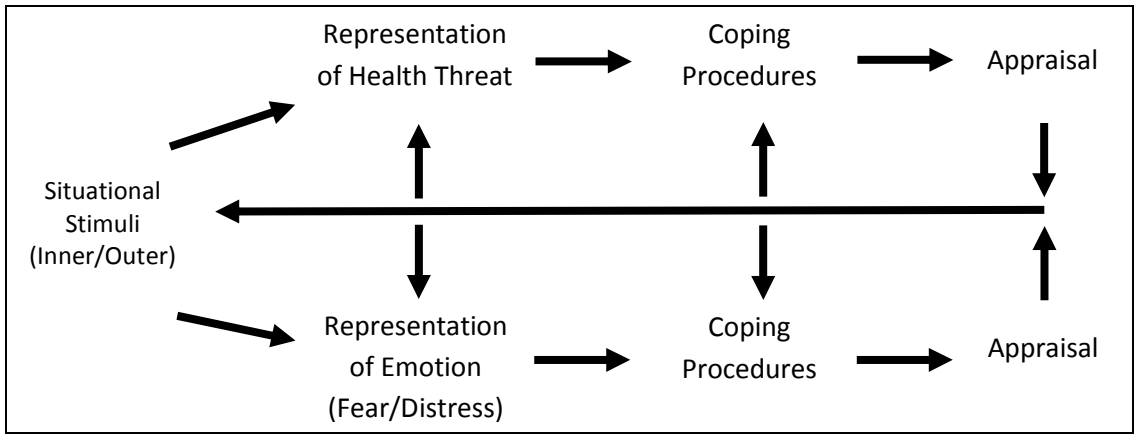
[b] Scales assessing only one individual symptom as an adverse event (e.g., tardive dyskinesia) were excluded. These scales include Abnormal Involuntary Movement Scale (AIMS), Akathisia Ratings of Movement Scale (ARMS), Barnes Akathisia Rating Scale (BARS), Dyskinesia Identification System Condensed User Scale (DISCUS), Extrapyramidal Symptom Rating Scale (ESRS), Hillside Akathisia Scale (HAS), Neurological Rating Scale (aka SimpsonAngus Scale (SAS)), Tardive Dyskinesia Rating Scale (TDRS), Texas Research Institute for Mental Sciences Tardive Dyskinesia Scale (TRIMS), and Withdrawal Emergent Symptoms Checklist (WES).

2.3 Theoretical framework

Self-Regulatory Model (SRM)

Leventhal et al. developed the common sense model of self-regulation to understand how people adapt to and manage specific health threats (Leventhal, Diefenbach, & Leventhal, 1992) (Figure 2-1). More specifically, these authors tried to identify individual's reactions during threat episodes to describe how the emotional process interacts with illness representations, and to explain the individual's processes for coping and appraising the outcomes of their attempts to self-regulate. In this theoretical model, an individual tries to make sense of a health threat such as a perceived ADP by developing emotional representations about the threat; the individual then uses these representations to guide his or her behavior to close the gap between current health status and desired health status. Thus, there are two underlying processes active in an individual who faces a health threat: the emotional representations and cognitive interpretation of the threat. Both of these perceptions give guidance for patients' coping behavior and appraisal of their management of the health threat.

Figure 2-1. Self-regulation model suggested by Leventhal et al. (1992)



Internal and external stimuli generate a cognitive interpretation of the threat and the emotional representations, leading to coping procedures and appraisal of outcomes.

In recent years, the Illness Perception Questionnaire (IPQ), a measure based on the SRM, has been used to measure illness perceptions (Kaptein et al., 2007). This questionnaire includes five domains and was extended with two more domains; it has been renamed as the Revised Illness Perception Questionnaire (IPQ-R) (Moss-Morris et al., 2002). More specifically, the revised version incorporated the subscales to assess emotional representations (e.g., anxiety and anger) and to assess the extent to which the illness makes sense to the individual.

The SRM can be useful in understanding how individuals formulate their appraisal of health threats such as an adverse problem from a medication. For this reason, this model has often been adopted to outline the perceptions of patients with schizophrenia (i.e., severe mental health difficulties) (Lobban, Barrowclough, & Jones, 2004; Lobban, Barrowclough, & Jones, 2005) and various chronic diseases (e.g., cardiac diseases) (Grace et al., 2005; Hirani, Pugsley, & Newman, 2006; Lane, Langman, Lip, & Nouwen, 2009). In particular, an ADP, like an illness, can be

perceived as a health threat; therefore, this model was also applied to outline patients' perception of ADPs in HIV (M. O. Johnson & Folkman, 2004) and HF (De Smedt, Haaijer-Ruskamp, Groenier, van der Meer, & Jaarsma, 2011).

The SRM guides this study since patients' handling of an ADP could be informed by the theoretical understanding of illness representation and coping, and outcome appraisal.

2.4 Operational definition of coping

According to the self-regulatory model, an individual encountering a stressor develops an emotional representation and interprets the contextual meaning of the stressor to proceed to the next underlying stages: coping procedures and appraisal. Appraisal refers to an individual's evaluation of the success or failure of the coping procedure. Coping procedure refers to an individual's behavioral or cognitive efforts to manage the stressor, and has two manifest types: active behavior (problem-focused) and regulation of distress (emotion-focused). Since this study highlighted problem-focused coping rather than emotional-focused coping for the reason noted earlier, a scale was developed focusing on behavioral aspects of coping rather than affective or cognitive coping. Patients' coping behaviors are thought to be most directly related to the effects of a perceived ADP on medication use, hence safety and effectiveness. Therefore, the definition of "coping" in this study is as a set of patient behaviors that respond to patients' perceptions of adverse drug problems, aiming to solve or manage the problem. A bank of questions (items) was developed to operationalize this definition and measure how patients cope with perceived ADPs.

Chapter 3 : RESEARCH METHODS

3.1 Selection of items

The content of the medication-problem coping scale (MPCS) was mostly based on the SECpoe questionnaire. Nine items in the MPCS were adopted from the SECope four subscales – nonadherence, information seeking, taking side effect medications, and seeking social support. Items in the positive emotion-focused coping subscale of the SECope were not included in the MPCS because this study highlighted problem-focused coping rather than emotional-focused coping for the reason noted previously. However, all adopted items were reworded, and the response options were changed from a 5-point scale to a dichotomous format (yes/no) in the MPCS because several items could not be answered using a polychotomous format (e.g., entirely stopped using the medication, continued to use the medication as prescribed in spite of the problem, got admitted to the hospital). Fourteen items were then added to the MPCS to fill in the content gaps. These items were

- tried to learn more about whether the problem was related to my medication
- continued to use the medication as prescribed in spite of the problem
- visited my physician or nurse to resolve the problem
- asked my physician or nurse to prescribe a different medication
- limited my activities or changed my daily routines
- sought out information that would help me resolve the problem

- tried to see if other people like me experienced the same problem I had
- took seek time or worked less than usual
- visited my pharmacist to resolve the problem
- used home remedy to treat the problem
- visited an emergency department or went to urgent care
- got admitted to the hospital
- used a non-prescription medication instead of using the medication
- used home remedy instead of using the medication.

The items were then reviewed by four pharmacy faculty, one medicine faculty, one clinical psychologist, and were modified according to their feedback. A total of 23 items were retained in the initial item pool and a pretest of the draft questionnaire was conducted with four subjects before administering it to patients in the field.

3.2 Study design

Data on coping behaviors were collected from patients in community pharmacies with a health-related problem that they attributed to their medication use. These community pharmacies are incorporated into the Minnesota Practice-Based Research Network (MN PBRN), an organization that combines community pharmacies with University faculty and a professional organization to help address societal, community, or professional questions related to medication use. For recruiting pharmacies to help our data collection from their patients, an email introducing the study (Appendix D) was sent to MN PBRN pharmacies. The email included our contact

information for pharmacists who wanted to participate in this study. Because there was no response from these pharmacists for two weeks after sending this email, three pharmacies (PRO pharmacy, Watertown pharmacy, and Setzer pharmacy) were directly contacted and asked permission to recruit patients in their practice sites after providing study objectives and a data collection plan. Since three pharmacies all allowed me to approach patients in their practice sites, patients waiting for their prescribed medication(s) in their sites were potential participants in the study. These patients were first asked about their willingness to participate in the study (Recruitment script is shown in Appendix E). If patients agreed to be involved in the study, they received a questionnaire completed with my assistance in answering the questions. The questionnaire consists of a few basic questions asking about number of medications being taken, purpose of taking medication(s), and whether they experienced medication-related ADP(s) during the past one year. If they had any perceived medication-related ADP(s), they were asked about medication to which they attribute their ADP, and whether they employed a coping response to their ADP, each presented by a separate item using a 'yes/no' response format. If patients experienced more than one ADP, they were asked to select the most bothersome ADP. The questions asking about an ADP-related medication and coping responses to ADP were not applicable to patients who did not experience medication-related ADP(s). However, demographic information was collected among patients who had not experienced ADP(s) but agreed to provide such information.

Because there was no precise rule to calculate sample size for IRT analyses, sample size in this study was consistent with general guidelines based on reported

experience and simulation studies. For the Rasch model, Linacre (1994) and Wright and Tennant (1996) recommended at least 30 responders to have 95% confidence that no item calibration parameter is more than 1 logit from its stable value; and about 100 subjects for 1/2 logit (Linacre, 1994; Wright & Tennant, 1996). Streiner and Norman (2008) also suggested 30 subjects as the minimum requirement for a one-parameter model with a dichotomous response option (Streiner & Norman, 2008). However, the sample size requirement should increase as the number of parameters increases. Therefore, the minimum number of respondents were determined as 100 for IRT analyses in this study.

3.3 Psychometric analyses

Evaluation of the assumptions of the IRT model

IRT entails three assumptions: unidimensionality of the latent trait, local independence of items, and monotonicity of the scale. Unidimensionality means that the scale is measuring only one latent trait (i.e., *a level of coping behaviors to perceived ADP* in this study); Local independence means that, conditioning on the latent trait being measured, the probability of endorsing a specific item is unrelated to the probability of answering any other item. That is, only the latent trait influences the probability of endorsing an item; Monotonicity means that the probability of endorsing a given item should increase monotonically with higher scores on the scale.

To investigate the dimensionality of the item set, confirmatory factor analysis (CFA) was conducted based on non-linear model using Mplus 6.1 in this study. The following fit criteria were used to determine whether items were unidimensional: the

Tucker-Lewis Index (TLI), the Comparative Fit Index (CFI), or the Root Mean Square Error of Approximation (RMSEA). The value of TLI and CFI > 0.90 and RMSEA < 0.10 were suggested to indicate reasonable fit (Browne & Cudeck, 1993). Local independence was evaluated by examining Chen & Thissen's LD X^2 statistic, computed by comparing the observed and expected frequencies between responses to each item and each of the other items, i.e. the association or correlation between items. Large values of standardized X^2 indicate a potential violation of local independence. Finally, item characteristic curves (ICCs) were investigated for each item to assess whether the probability of endorsing an item consistently increased as the level of the latent trait increased.

Estimating item parameters: Marginal maximum likelihood method (Bock & Aitkin, 1981)

Item parameters were estimated in the logistic metric using the marginal maximum likelihood (MML) method. The MML method assumes a specified distribution of the person parameter in the population (usually normal) and approximates that distribution by a quadrature procedure. For this reason, this method estimates item parameters first, and then estimates person parameters with the obtained item parameters. When estimating item parameters, it employs the expectation-maximization (E-M) algorithm: the expectation step determines the expected number of examinees in the specified distribution at each of the pre-specified quadrature points. Then, the expected proportion of examinees at each point that would endorse the item is determined. In the maximization step, item parameters are estimated by the maximum

likelihood method. Estimation is repeated until the sum of the absolute changes in item parameters becomes very small. When all item parameters are estimated, the likelihood of the data matrix is assessed to see if it meets the defined criteria. The E-M cycle is iterated until the likelihood of the data matrix satisfies the convergence criteria.

Item calibration

Items that met the IRT assumptions were calibrated using the one-parameter logistic (1PL) and two-parameter logistic (2PL) models respectively to determine which model is favored. A formal mathematical form of the model is

$$P_i(\theta_j|b_i) = 1/\{1+\exp[-Da_i(\theta_j-b_i)]\}$$

where a_i represents the discrimination parameter for item *i*, b_i is the difficulty parameter for item *i*, and D is a constant value of 1.0 (pure logistic) or 1.7 (logistic approximation to normal ogive). The 1PL model posits that all discrimination parameters are fixed and only difficulty parameters are allowed to vary. However, the 2PL model allows the discrimination parameters to vary across items as the difficulty parameters. Therefore, the discrimination parameter (a_i) in the 1PL model is constant in the above equation.

A discrimination parameter (a_i) indicates the rate of a change in probability of endorsing the item *i* with a 1 unit change in θ at its steepest point in IRFs. Discrimination represents the strength of the relationship between an item and the latent construct similar to the item-total correlation in classical test theory, which is usually expressed as point-biserial correlation:

$$a_i = \rho_i / [(1-\rho_i)^2]^{1/2}$$

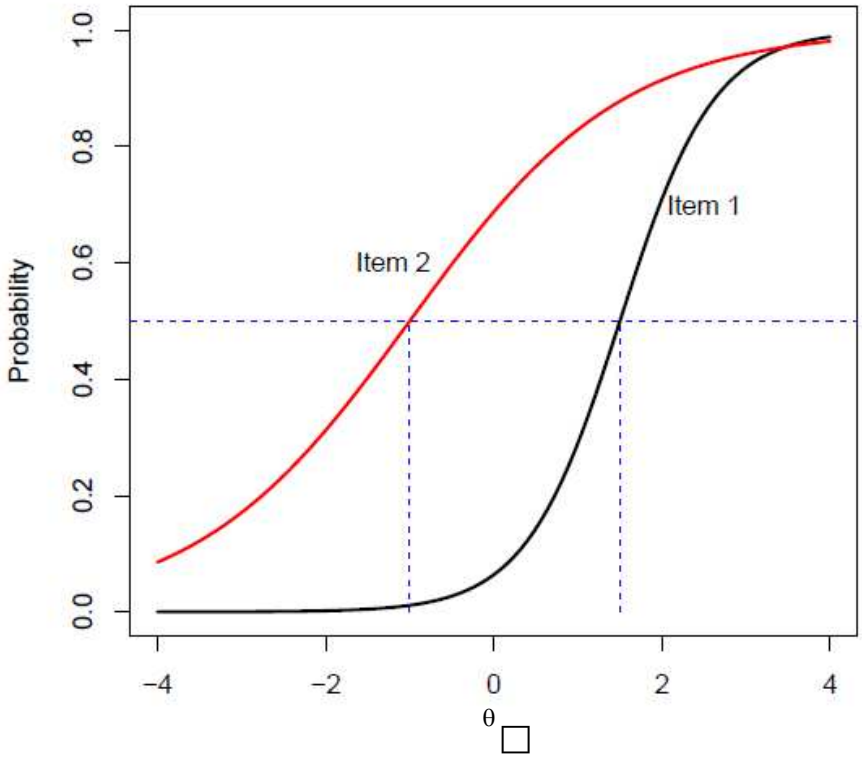
The difficulty parameter (b_i) reflects the coping level at which the probability of endorsing the item *i*, that is, a probability that responding to a "yes" option is equal to 0.5:

$$b_i = \Phi^{-1} (p_i / \rho_i)$$

where Φ^{-1} is the normal inverse function, p_i is the proportion of people who endorse the item *i*, and ρ_i is the point-biserial correlation of the item response with total score.

For example, Figure 3-1 below represents the hypothetical ICCs for two items. The ICCs show the relationship between the trait level and the probability of endorsing the items. Two items are monotonic, i.e., the probability of endorsing the item consistently increases as the trait level (θ) increases. Item 1 is a better discriminator of the trait than item 2 because the proportion of people endorsing the item changes relatively rapidly on item 1 as the trait level (θ) increases. The slope for item 2 is relatively flatter, indicating that it does not discriminate as well as item 1. For example, as a trait level (θ) increases from 0 to +2, the proportion people endorsing item 1 increases from 5% to 70%, while the proportion of endorsing item 2 increases only from 70% to 90%. The ICCs also indicate that item 1 is more difficult than item 2 because a trait level (θ) required to have 50% of probability of endorsing the item is further along the trait continuum for item 1 than item 2. That is, a trait level (θ) of -1 is required to have the probability of endorsing item 2, but a trait level (θ) is 1.5 to have the same probability of endorsing item 2.

Figure 3-1. Hypothetical item characteristic curves for two items



Item information function

Item information can be obtained from the item information function (IIF) defined as the ratio of the squared slope of the item response function (IRF) to the item variance at each θ value:

$$IIF_i \mid \theta = \{p_i'(\theta)\}^2 / p_i(\theta)q_i(\theta)$$

where $p_i'(\theta)$ is the first derivative of the item response function (IRF) with respect to θ and $q_i(\theta)$ is $1-p_i(\theta)$. This can be computed as follows for the 1PL and 2PL model, respectively (De Ayala, 2008):

$$\text{1PL: } IIF_i \mid \theta = p_i(\theta)q_i(\theta)$$

$$\text{2PL: } IIF_i \mid \theta = D^2 a_i^2 p_i(\theta)q_i(\theta)$$

The equations indicate that the amount of information is conditional on θ in the 1PL model and is proportional to a_i^2 in the 2PL model. Therefore, the height of IIF is associated with the discrimination of the item. That is, the better an item discriminates, the higher the IIF. In addition, the location of the IIF is associated with the item difficulty. After taking a derivative of these above equations, we can find a θ value that makes this derivative zero. The maximum information is obtained at this θ value. For the 1PL and 2PL model, this θ value is equal to $b_{i,}$ indicating that IIF reaches its peak at b_i.

By summing up item information for all items, test information is obtained. Alternatively, test information can be obtained from the test response function (TRF). In other words, the ratio of the squared slope of the TRF to its variance is defined as the test information function (TIF). TRF can be obtained either by summing the individual IRFs or by taking an average of all the IRFs. It indicates the "expected number correct" as a function of θ if IRFs are summed to compute TRF, or the "expected proportion correct" as a function of θ if IRFs are averaged to obtain TRF. Similar to item information, test information shows how well a test measures at each θ value; however, test information shows it at the test level, while item information is evaluated at each item level. TIFs display a θ value where a test has its maximum or substantial information along the whole θ continuum. The test can measure, most precisely, persons whose trait levels are around this θ value because the conditional test standard error of measurement (SEM) will be the lowest at this θ value. (The test SEM is the

reciprocal of the square root of the TIF.) Conversely, low TIF shows where a test has its largest SEM value and measures least precisely along the θ continuum.

Comparisons of the 1PL model to the 2PL model

To determine which model is preferred, the 1PL and 2PL model were compared by taking goodness-of-fit statistics, reliability of the estimated person scores, and standard error of measurement (SEM) into account. Goodness-of-fit to each model was assessed based on the deviance statistic (-2 log likelihood) and comparative fit measures such as Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC). The deviance statistics were used to examine if one model fit significantly better than the other model on the condition that one of the models was nested in the other. The model with the lower values of AIC and BIC indicated a better fit is preferred. In addition, a model with a higher reliability estimate is favored between the 1PL and 2PL model. Finally, the standard error of measurement and test information were investigated. A model with more information and less SEM over a range of the theta continuum is considered more desirable.

To assess an each item's fit to the model, an IRF diagnostic statistic was examined using the $S\text{-}X^2$ statistic suggested by Orlando and Thissen (Orlando & Thissen, 2000; Orlando & Thissen, 2003). The IRF of the individual item is considered to fit sufficiently if the observed proportion of responding 0 ("no") and 1 ("yes") match the model-expected proportions. However, great deviations of the observed proportions from the expectations indicate an item's poor fit. The statistically non-significant difference of the $S\text{-}X^2$ statistic suggests an adequate item fit. In addition, overall model-

data fit was evaluated using the M_2 goodness-of-fit statistic and its associated RMSEA value. The M_2 statistic, proposed by Maydeu-Olivares and Joe, is based on the one- and two-way marginal tables of the respondents classified by their response patterns (Maydeu-Olivares & Joe, 2006; Maydeu-Olivares & Joe, 2005). Adequate fit of the model to the data was indicated by non-significance of the M_2 statistic or the RMSEA value below 0.1.

Estimating the person parameters

The person parameter, i.e., each person's coping level (θ), was estimated using an expected a posteriori (EAP) method. Since this method adopts the Bayesian procedures, it modifies a likelihood function by a prior distribution to create a posterior distribution:

$$f(\theta|\square) = L(\square|\theta j)\, f(\theta j)$$

where $f(\theta|\square)$ is the posterior function, $L(\square|\theta j)$ is the likelihood function of the observations, and $f(\theta j)$ is the prior distribution.

EAP determines the θ estimates by computing the mean of the posterior distribution, given the observed response pattern. More specifically, the θ estimate is determined as the mean over quadrature points multiplied by the likelihood and the quadrature weight, i.e., the density of the prior distribution (Chen & Hou, 1997). EAP has some advantages over other estimating methods. First, EAP can be used to estimate for persons who get perfect scores or zero scores, which cannot be computed using the maximum likelihood estimation (MLE) method. In addition, EAP produces the lowest standard errors compared to MLE and maximum a posteriori (MAP), in

particular, in short-length tests (Wang & Vispoel, 1998). Because EAP does not involve an iterative process (e.g., Newton-Raphson) and employs the summation process, it is free from such concerns that an iteration is a time-consuming process and Newton-Raphson may not converge. However, the EAP estimates were not as accurate as MAP estimates when numerous items with high discriminations at all θ levels were missing (Wang & Vispoel, 1998). Since the EAP estimates are regressed toward the mean of the prior distribution, these estimates may not be accurate if the prior distribution is not appropriate. The size and direction of such bias depends on the location of the mean of the prior distribution. In this study, a normal distribution was assumed as a prior distribution.

In addition, a person's total score was estimated by summing individual scores from each item in an IRT-metric to transform the summed scores to a T-score metric where mean is equal to 50 and standard deviation is 10.

Differential item functioning (DIF)

Differential item functioning (DIF) is said to occur when individuals in one group respond differently to a certain item compared to individuals in the other group who possess the same level of the latent trait being measured. Therefore, difference in responses between these two groups is due to a group characteristic other than the latent trait. In IRT, DIF is considered to occur when the item response function differs for different groups. In other words, because the item response function is determined by the item parameters, items are evaluated for their DIF by comparing estimates of the item parameters between groups (Lord, 1977; Lord, 1980). In this study, DIF was

examined for all items between patients who perceived their ADP as moderate, small, or very small and those who perceived their ADP as big or very big. DIF was also evaluated between groups varying in demographics and health literacy levels: age (below the mean age (< 57) vs. equal to or above the mean age (≥ 57)), gender (male vs. female), education (some college or lower vs. college grad or higher), and health literacy level (low: not at all, a little bit, somewhat vs. high: quite a bit, extremely). To evaluate DIF, the Thissen, Steinberg, and Wainer (TSW) likelihood ratio test statistic implemented in IRTPRO was employed (De Ayala, 2008). Based on the TSW statistic which tests the null hypothesis of being no group differences in the item parameter estimates, the IRTPRO tests three null hypotheses: the estimated discrimination parameter is the same between the focal and reference group (H_0: $a_f = a_r$), the estimated intercept parameter (c = -a*b) conditional on the discrimination parameter is equal between two groups (H_0: $(c|a)_f = (c|a)_r$), and both the estimated discrimination and intercept conditional on the discrimination parameter are the same across the groups (H_0: $a_f = a_r$, $(c|a)_f = (c|a)_r$). To test these hypotheses, the TSW approach involves a three-step procedure. For example, to test the first hypothesis for item 1 (H_0: $a_f = a_r$), it fits the 2PL model to both groups with the proviso that item discrimination parameter estimates for all items, except for item 1, are the same across the groups. For step 2, it fits the 2PL model, but all item discrimination parameter estimates including those of item 1 are constrained to be the same across both groups this time. The final step involves a computation of TSW-ΔG^2:

$$\text{TSW-}\Delta G^2 = (-2LL_2) - (-2LL_1)$$

where $-2LL_1$ and $-2LL_2$ are the likelihood ratios from step 1 and step 2. TSW-ΔG^2 is distributed as a X^2 with two degrees of freedom since the discrimination and slope parameter estimates are both investigated simultaneously. A significant TSW-ΔG^2 indicates the presence of DIF, whereas a non significant TSW-ΔG^2 indicates no DIF for the item under consideration. This three-step process is continued for all the items on the scale, and for testing the other two hypotheses.

Development of a short-form of the scale

For efficient use of the constructed medication problem coping scale (MPCS), a short-form was developed by considering the information provided by each item and its contextual importance in a clinical setting. The most informative items were selected, and items' clinical importance was separately examined. The content of the final items in the short-form should cover the clinically meaningful coping behaviors comprehensively.

The IRT diagnostic tests and parameter estimations were conducted with the software IRTPRO 2.1 (IRTPRO guide 2.1, Scientific Software International).

3.4 Measures and predictions

Problem Intensity. To measure how much of a problem a participant perceived, the participant was asked to respond to the question "To what extent, was the problem (identified in the previous question) for you?" This item was rated on a 5-point scale where 1 = very small problem; 2 = small problem; 3 = moderate problem; 4 = big

problem; and 5 = very big problem. According to the responses to this item, respondents were divided into five groups. A hypothesis was then formulated that coping scores would be different between these groups. That is, patients' coping scores are expected to be relatively high when their ADP is perceived as comparatively big.

Health Literacy. Health literacy was defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health-related decisions" (Institute of Medicine, 2004). A previous study showed the usefulness of a single-item question for detecting inadequate health literacy by presenting its large area under the Receiver Operating Characteristic (ROC) curve of 0.74 (95% CI: 0.69 – 0.79) and 0.84 (95% CI: 0.79 – 0.89) based on the 2 most widely used health literacy assessment scales, the Short Test of Functional Health Literacy in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM) (Chew et al., 2008). The single item asks patients how confident they are to fill out health forms by themselves on a 5-point scale (0 = not at all; 1 = a little bit; 2 = somewhat; 3 = quite a bit; and 4 = extremely). Limited health literacy has been shown to be associated with poor health outcomes such as poor health knowledge, poor medication adherence, and poor control of chronic illness (Schillinger et al., 2002; Williams, Baker, Parker, & Nurss, 1998). To better understand associations between health literacy and health outcomes, the previous literature has reported four components of health literacy (Al Sayah, Majumdar, Williams, Robertson, & Johnson, 2013; Berkman, Davis, & McCormack, 2010; Nutbeam, 2008): functional, interactive, critical, and numeracy skills. Functional literacy refers to one's ability or skills to read written texts, understand and interpret

information in documents, and write and complete forms; Interactive literacy is one's ability or skills to speak and listen to information and actively participate in communication; Critical literacy refers to one's ability or skills to navigate the relevant systems (e.g., healthcare systems) to control situations; Numeracy literacy refers to one's ability or skills to conduct mathematical tasks. Among these diverse types of skills, the functional skill is expected to be possibly associated with a patient's coping behaviors of discussing an ADP with others. Also, this critical skill can be positively associated with a patient's information seeking behaviors in the scale. That is, if a patient is able to search the healthcare systems to manage the situation, the patient is expected to seek information to handle an ADP. Therefore, persons with a high level of health literacy were expected to possess a high coping level.

Coping Self-Efficacy (CSE). The CSE scale was designed to measure respondents' perceived self-efficacy to deal with psychological challenges or threats (Chesney, Neilands, Chambers, Taylor, & Folkman, 2006). The stem question is "When things aren't going well for you, or when you are having problems, how confident or certain are you that you can do the following?" and then the scale presents 13 items that tap three distinct dimensions: use problem-focused coping (6 items, alpha = 0.91), stop unpleasant emotions and thoughts (4 items, alpha = 0.91), and get support from friends and family (3 items, alpha = 0.80). Respondents are asked to rate their confidence with each statement on an 11-point scale, ranging from 0 = "cannot do at all" to 5 = "moderately certain can do" to 10 = "certain can do." In this study, the three items which had the highest factor loadings on the problem-focused coping subscale were

employed (i.e., “sort out what can be changed, and what cannot be changed,” “break an upsetting problem down into smaller parts,” and “make a plan of action and follow it when confronted with a problem.”). According to Albert Bandura, self-efficacy was defined as “one’s own capabilities to organize and execute the courses of action required to manage prospective situations (Bandura, 1997).” Since self-efficacy is conceptually related to beliefs about capabilities of conducting specific behaviors in particular situations (Schunk & Carbonari, 1984), it can affect a person’s coping behaviors when the person faces a problem with the purpose of managing and controlling the problem. This has been supported by the previous studies that showed relationships between self-efficacy and behavior change such as smoking cessation, weight control, or use of contraception (Chambliss & Murray, 1979; Gilchrist & Schinke, 1983; Nicki, Remington, & MacDonald, 1984). Therefore, this study hypothesized that persons with a higher coping level would possess a higher coping self-efficacy than those with a lower coping level.

Chapter 4 : RESULTS

This Chapter includes the main findings from the psychometric analyses and hypothesis testing of the study. More specifically, it presents an initial item pool, a description of the respondents and responses, confirmatory factor analysis results, IRT analysis results, a final item pool, and correlations between the coping level and other constructs.

4.1 Patient characteristics, reported ADPs, and ADP-related medications

A total of 140 patients (55 males, 85 females) who had experienced medication-related ADP(s) completed the questionnaire. Their ages ranged from 18 to 91 years old, with a mean age of 56.9 (SD = 15.4) and about 97% of them were White. Among 140 patients, three subjects did not answer the question asking about their medication-related ADP. Also, thirteen out of 140 patients did not respond to the question asking about the ADP-related medication. These non-respondents did not want to reveal their ADP or medication name for their privacy. Alternatively, some of them used multiple medications and did not know which medication was associated with their ADP. However, all 140 patients provided demographic information and answered 23 yes/no questions asking whether they used each coping strategy presented to them. These 140 patients were compared with 63 patients who did not experience of ADP(s) but provided demographic information and number of medications being taken (Table 4-1). The number of medication(s) was significantly higher in patients with ADP(s) (mean =

4.71, SD = 2.99) compared to those without ADP(s) (mean = 2.98, SD = 2.35) (t (150) = 4.33, p = .000). This indicates that chances of experiencing ADP(s) are higher in patients using more medications compared to those who take less medication(s). However, there was no significant difference in demographic characteristics (e.g., age, gender, race, education level, and working status) and the percent of those with health insurance and healthcare background between these two groups.

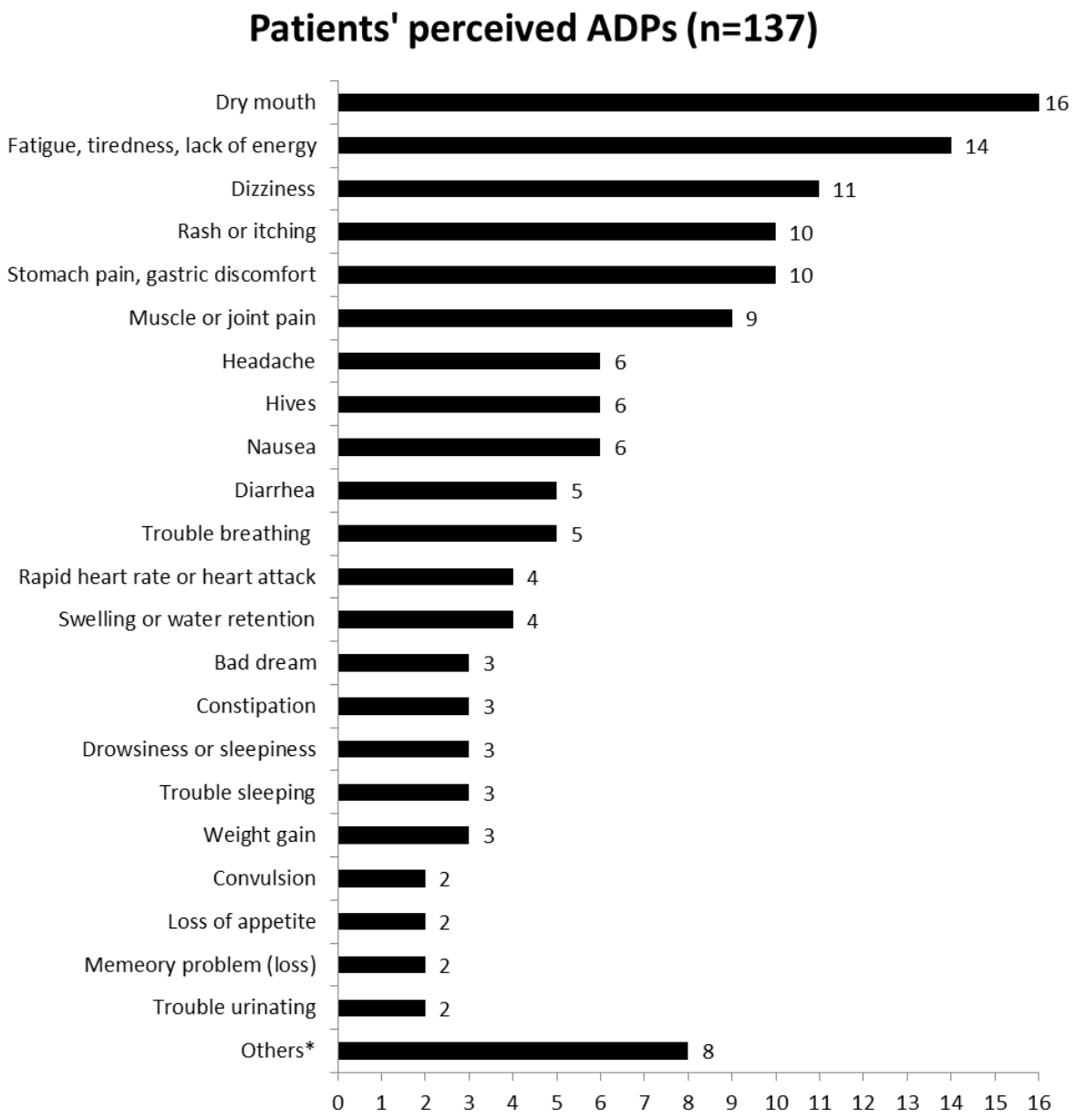
Table 4-1. Comparison of patients with an adverse drug problem (ADP) to patients without ADP*

	Patients with ADP (n=140)	Patients with no ADP (n=63)	t or X^2	Sig.
Number of medication use	4.71 (SD: 2.99), Range: 1-15	2.98 (SD: 2.35), Range: 1-11	t = 4.331	0.000
Age (yr)	56.86 (SD: 15.41), Range: 18-91	60.37 (SD: 18.73), Range: 21-89	t = 1.401	0.551
Female, n (%)	85 (60.7)	32 (50.8)	X^2 = 1.751	0.186
White, n (%)	136 (97.1)	62 (98.4)	X^2 = 0.292	0.589
College grad or more, n (%)	66 (48.2)	31 (50.0)	X^2 = 0.057	0.811
Currently working, n (%)	69 (50.4)	23 (36.5)	X^2 = 3.336	0.068
Health insurance, n (%)	139 (99.3)	60 (95.2)	X^2 = 3.685	0.055
Healthcare background, n (%)	29 (21.2)	10 (15.9)	X^2 = 0.771	0.380

* Differences between these two groups were examined using an independent t-test for continuous variables and chi-square analyses for categorical variables.

Patients' perceived ADPs are presented in Figure 4-1. A total of 30 different ADPs were reported by one hundred thirty seven patients. Overall the most frequently described ADP was a dry mouth (11.7%) followed by a fatigue/tiredness/lack of energy (10.2%). Eight different ADPs were reported by only a single patient. Those ADPs were anxiety, breast enlargement, cough/sore throat, hair loss, hallucination, increased appetite, altered taste, and twitching (facial). Respondents and ADPs were then categorized by the problem intensity they reported. Ten patients perceived their ADPs as very small; 24 as small; 44 as moderate; 32 as big; and 27 as very big. The ADP types and their reported frequency differed in each category. Although dizziness and dry mouth were the most frequently reported ADPs in patients who perceived their problem as *very small* or *small*, breathing problems and muscle/joint pain were the most common ADPs in those who considered their problem *very big*. A dry mouth problem was not stated in this group of patients while convulsion and rapid heart rate or heart attack were uniquely reported by these patients. The problems such as a fatigue/tiredness/lack of energy and dry mouth were the most frequently addressed among those who perceived their ADP(s) as *big*. Notably, a fatigue/tiredness/lack of energy problem was commonly reported in all categorized patient groups. However, the problem intensity varied from *very small* to *very big*, which suggests the importance of patients' perspectives in assessing the problem intensity and coping with this problem rather than others' perspectives.

Figure 4-1. Number of patients who perceived adverse drug problems (ADPs)



*Others: Eight different ADPs (anxiety, breast enlargement, cough/sore throat, hair loss, hallucination, increased appetite, taste problem, and twitching (facial problem)), each with a single response

Figure 4-2. Number of patients who perceived their adverse drug problem (ADP) as very small

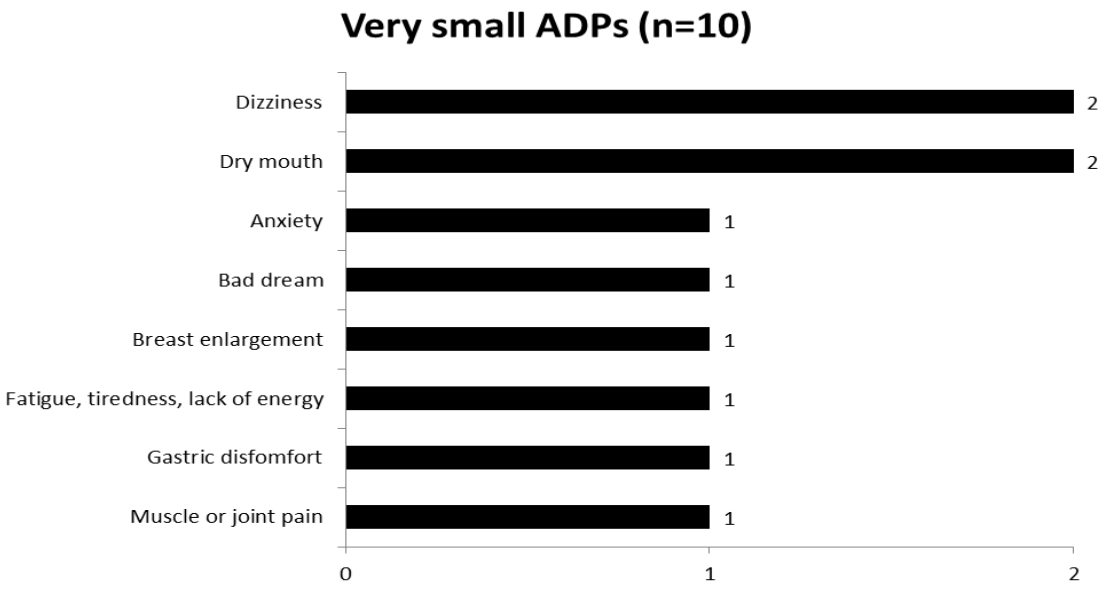


Figure 4-3. Number of patients who perceived their adverse drug problem (ADP) as small

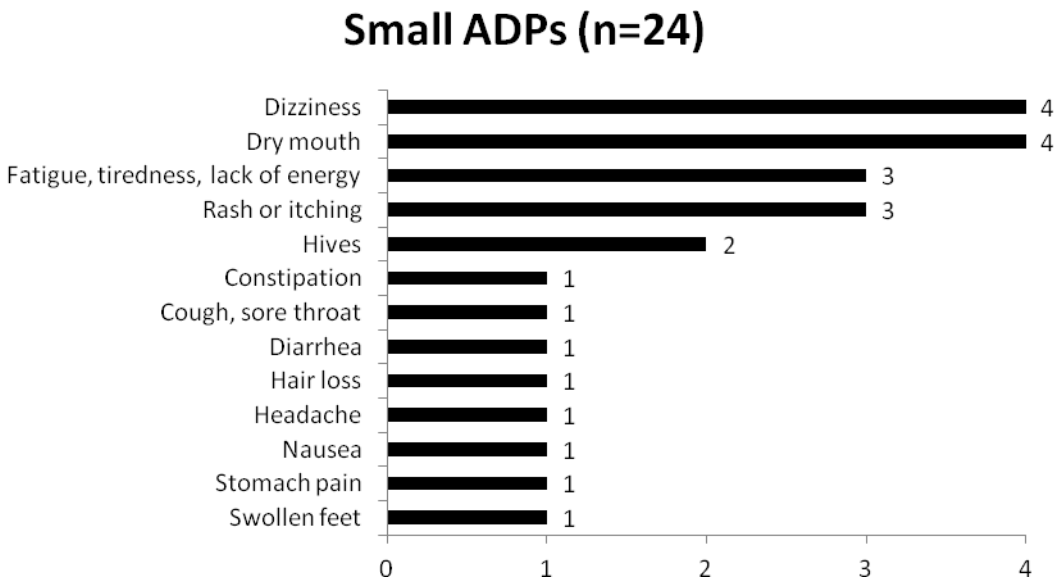


Figure 4-4. Number of patients who perceived their adverse drug problem (ADP) as moderate

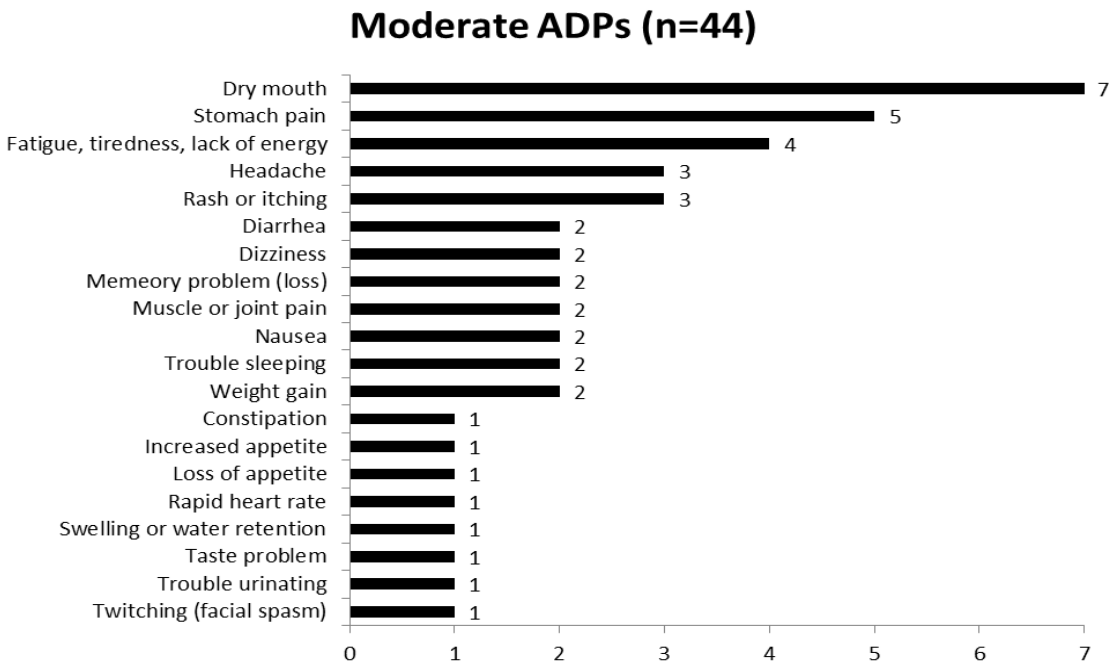


Figure 4-5. Number of patients who perceived their adverse drug problem (ADP) as big

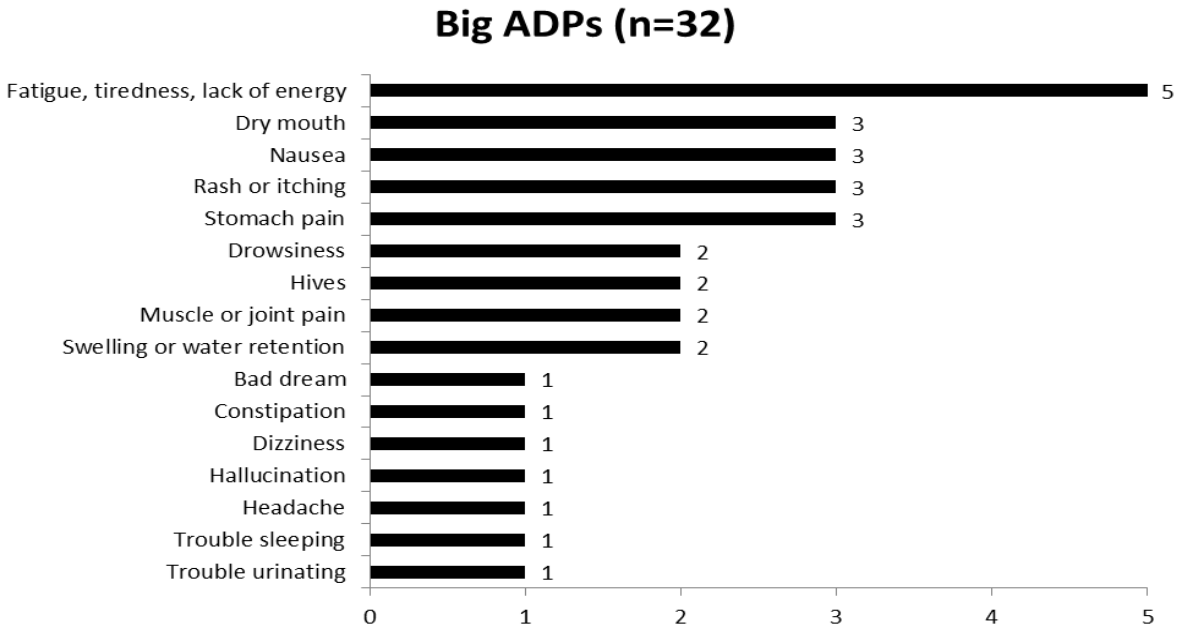


Figure 4-4. Number of patients who perceived their adverse drug problem (ADP) as very big

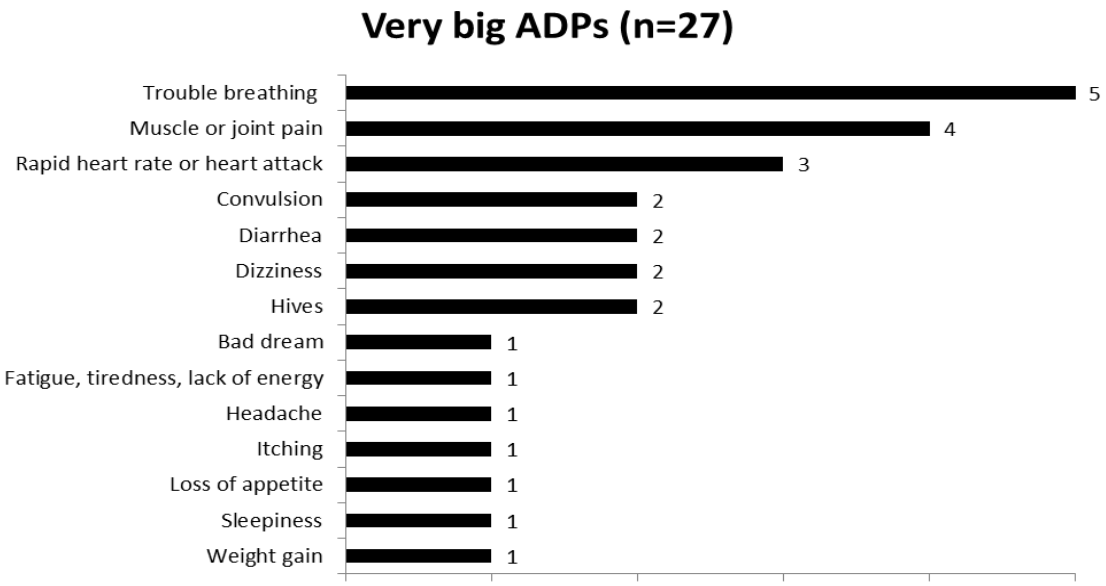


Table 4-2 shows the patients' various reasons for taking medication which were associated with their perceived ADPs. One hundred twenty seven patients answered a question asking about the name of their ADP-related medication while thirteen patients did not respond to this question for the reasons noted earlier. The medications for the treatment of heart disease and infection were most frequently reported as being associated with an ADP by this study sample. Antidepressants were also commonly identified as the ADP-associated medication. There were only two patients who attributed their ADPs to anticancer medications in this study sample. When patients reported their ADP and the medication that they designated as being associated with it, their reported ADPs were consistent with known side effects of the medication in almost all cases.

However, we did not examine if a patient's reason for taking medication was related to the patient's coping behaviors because this is beyond our study aims and scopes.

Table 4-2. Patients' reasons to take medications

Reason for medication use	Number of patients	%
Heart disease	28	22.0
Infection (e.g., AIDS, Lyme disease)	28	22.0
Depression or anxiety	20	15.7
Pain	10	7.9
Diabetes	9	7.1
Epilepsy or seizure	6	4.7
Hormone-related treatment	5	3.9
Schizophrenia	4	3.1
Benign Prostatic Hyperplasia (BPH)	3	2.4
Inflammation (e.g., Crohn’s disease, Rheumatic arthritis)	3	2.4
Cancer	2	1.6
Gastrointestinal disease	2	1.6
Osteoporosis	2	1.6
Overactive bladder	2	1.6
Asthma	1	0.8
Restless Legs Syndrome (RLS)	1	0.8
Immunosuppressant	1	0.8
Total	127	100

4.2 Item selection

A total of 23 items were initially included in the item pool. These items and the number of "yes" responses to each item are presented in Table 4-3. Patients' most frequently reported coping behavior was to discuss the problem with their physician or nurse. One hundred twelve respondents (80.0%) showed that they employed this discussion coping to deal with their ADP. Most of them (62.9%) also discussed it with their family or friends. In addition, more than 50% of patients employed the coping behaviors such as trying to learn if the problem was related to their medication use, or visiting their physician or nurse to fix the problem. However, only five patients reduced the dose of the medication and one patient used their medication less frequently without discussing it with their providers in response to their ADP. There were twenty-three patients who had visited emergency rooms (ERs) or been hospitalized because of their ADP.

Table 4-3. Frequencies of employing each coping strategy (n=140)*

Items	Number of "yes" responses, n (%)
To handle the medication-related problem identified, did you…	
Item 13: Discuss the problem with your physician or nurse?	112 (80.0%)
Item 11: Discuss the problem with your family or friends?	88 (62.9%)
Item 8: Try to learn more about if the problem is related to your medication?	78 (55.7%)
Item 2: Continue to use the medication as prescribed in spite of the problem?	73 (52.1%)
Item 21: Visit your physician or nurse to resolve the problem?	72 (51.4%)
Item 1: Entirely stop using the medication?	62 (44.3%)
Item 14: Ask your physician or nurse to prescribe a different medication?	60 (42.9%)
Item 7: Search for written information about the problem (on the internet, in a book, etc)?	57 (40.7%)
Item 15: Limit your activities or change your daily routines?	55 (39.3%)
Item 12: Discuss the problem with your pharmacist?	54 (38.6%)
Item 10: Seek out information that would help you resolve the problem?	49 (35.0%)
Item 9: Try to see if other people like you experienced the same problem you had?	41 (29.3%)
Item 17: Get another prescription medication to treat the problem?	32 (22.9%)
Item 18: Use a non-prescription medication to treat the problem?	26 (18.6%)
Item 16: Take sick time or work less than usual?	24 (17.1%)
Item 20: Visit your pharmacist to resolve the problem?	22 (15.7%)
Item 19: Use home remedy to treat the problem?	15 (10.7%)
Item 22: Visit an emergency department or go to urgent care?	13 (9.3%)
Item 23: Get admitted to the hospital?	10 (7.1%)
Item 4: Reduce the dose of the medication?	5 (3.6%)
Item 5: Use a non-prescription medication instead of using the medication?	5 (3.6%)
Item 6: Use home remedy instead of using the medication?	2 (1.4%)
Item 3: Use the medication less frequently?	1 (0.7%)

* Items are ordered by the frequencies of being employed.

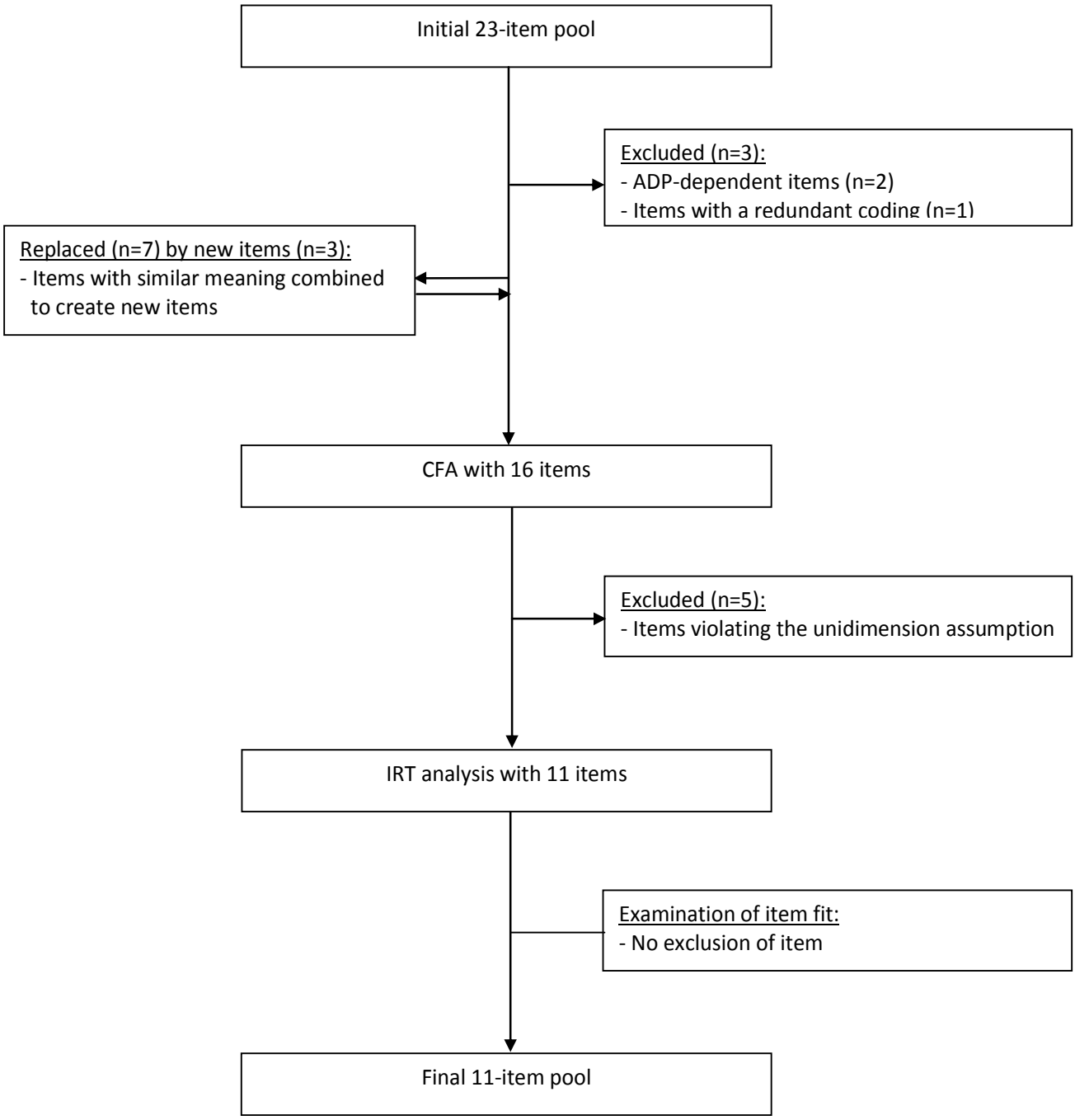
When conducting CFA to examine the unidimensionality assumption, only sixteen items were included from the initial 23-item pool after excluding three items and grouping similar items together (Figure 4-7). Two items were excluded because they were ADP-dependent and thus not applicable to all medication-related problems (items 5 and 6). There was no non-prescription medication or home remedy to replace the prescription medication for a certain disease (e.g., schizophrenia, cancer); thus, patients with such diseases were not able to answer item 5 ("used a non-prescription medication instead of using the medication.") and item 6 ("used home remedy instead of using the medication."), which was the reason why these items were eliminated in CFA. Moreover, item 2 ("continued to use the medication as prescribed in spite of the problem.") was excluded in CFA because patients' responses to this item were coded exactly the same as the coding for item 1 ("entirely stop using the medication.") when reverse-coding item 2 to conduct CFA. Also, the content of item 2 (i.e., continuation of using the medication as prescribed despite the problem) indicates that a patient did not cope with an ADP while this study focuses on how patients handled the problem on the assumption that they did cope. In addition, several items were grouped together to create a new item to reduce a patient's response burden by shortening the questionnaire while keeping the construct content covered by such items. For example, some patients were not able to respond to item 18 ("used a non-prescription medication to treat the problem.") and item 19 ("used home remedy to treat the problem.") for the same reason as items 5 and 6. However, instead of being removed in this case, these two items were combined with item 17 ("got another *prescription medication* to treat the problem.") to create a new item ("got another *medication or home remedy* to treat the problem.") to

keep their construct content. This new item replaced three items (item 17, 18, and 19) in CFA, coded as "1" ("yes" response) if any of these three items had a "yes" response, otherwise as "0" ("no" response). Moreover, some items were combined not to distinguish between healthcare providers which was separately termed as "pharmacist" or "physician or nurse" in the items. In assessing a patient's coping response to an ADP, it is more important to know whether the patient discussed with or visited a healthcare provider than whom the patient discussed with or visited. Therefore, a term "pharmacist" in item 12 and 20 and "physician or nurse" in item 13 and 21 were grouped together and replaced by a "healthcare provider" in the new items. Thus, two new items ("discussed the problem with my *healthcare provider*," and "visited my *healthcare provider* to resolve the problem.") were included in CFA replacing item 12 ("discussed the problem with my *pharmacist*."), item 13 ("discussed the problem with my *physician or nurse*."), item 20 ("visited my *pharmacist* to resolve the problem."), and item 21 ("visited my *physician or nurse* to resolve the problem.").

After removing three items (item 5, 6, and 2) and combining similar items together, nonlinear CFA was performed with a total of 16 remaining items. The initial CFA results with these items showed that some items were negatively or weakly correlated with other items, resulting in an inadequate model fit. Therefore, the most distinct item based on its weak or negative correlations with other items was first removed in the following CFA. Since the correlations between items and the fit indexes were still unsatisfactory, this procedure of eliminating such items was continued until all remaining items showed acceptable correlations with other items. When the five items (item 3, 4, 7, 8, and 9) were removed while leaving 11 items in CFA, the

correlations and fit indexes were reasonable. Although some correlations were very weak or very strong between these items, 95.5% of the correlations were in the range of 0.2 to 0.8 (Table 4-4). Goodness-of-fit indexes indicated that with the revised set of 11 items, a unidimensional model fit the data well (CFI = 0.950, TLI = 0.937, RMSEA = 0.099).

Figure 4-7. Item selection processes



ADP: adverse drug problem, IRT: item response theory

Table 4-4. Interitem polychoric (tetrachoric) correlation matrix

	Item 1	Item 10	Item 11	Item 12-13*	Item 14	Item 15	Item 16	Item 17-19*	Item 20-21*	Item 22	Item 23
Item 1											
Item 10	0.160										
Item 11	0.513	0.370									
Item 12-13*	0.625	0.414	0.287								
Item 14	0.614	0.380	0.485	0.716							
Item 15	0.261	0.328	0.507	0.210	0.470						
Item 16	0.504	0.457	0.575	0.526	0.714	0.872					
Item 17-19*	0.444	0.191	0.257	0.459	0.401	0.288	0.360				
Item 20-21*	0.433	0.550	0.364	0.802	0.738	0.560	0.676	0.491			
Item 22	0.692	0.268	0.623	0.368	0.583	0.515	0.740	0.763	0.700		
Item 23	0.715	0.202	0.562	0.300	0.726	0.669	0.708	0.616	0.643	0.865	

* Combined items due to their content similarities

4.3 Psychometric analyses

After confirming unidimensionality of the 11 items with reasonable fit indexes in CFA, the local independence assumption was examined for these items. As shown in Table 4-5, there was no considerable large value of standardized LD X^2 statistics (e.g., > 10) for any item. The largest value of standardized X^2 in the Table was 5.1, which indicates no items violated the local independence assumption.

Since these 11 items met the unidimensionality and local independence assumptions, they were renumbered and calibrated using the 1PL and the 2PL model. The estimated item parameters from these models are listed in Table 4-6 and Table 4-7, respectively. Results using the 1PL model showed that the discrimination parameter was fixed as 1.71 and the difficulty parameter varied from -1.42 to 2.13. The discrimination parameter obtained using the 2PL model ranged from 0.87 to 5.08 with a mean value of 2.36, indicating *moderate* to *very high* discriminating abilities of these items. Discrimination parameters ranging from 0.01 to 0.24 have been considered as *very low* discrimination, from 0.25 to 0.64 as *low*, from 0.65 to 1.34 as *moderate*, from 1.35 to 1.69 as *high*, larger or equal to 1.70 as *very high* (Baker, 2001). The range of the difficulty parameter estimates using the 2PL model (from -1.20 to 1.55) spanned a narrower range compared to the range of the estimates obtained using the 1PL model. Although there was no considerable difference in the estimated absolute values of the difficulty parameters between the 1PL model and the 2PL model, two items (item 5 and 8) were relatively located differently on these two models when ordered by their values of difficulty parameters. On the 1PL model, the difficulty parameter of item 5 was

estimated relatively highly compared to the estimated difficulty parameters of the other items.

Table 4-5. Marginal fit (X^2) and standardized LD X^2 statistics

	Item 1	Item 10	Item 11	Item 12-13*	Item 14	Item 15	Item 16	Item 17-19*	Item 20-21*	Item 22	Item 23
Item 1											
Item 10	0.2										
Item 11	0.3	-0.2									
Item 12-13*	-0.5	-0.7	0.5								
Item 14	-0.4	-0.7	-0.7	-0.6							
Item 15	0.4	-0.6	0.5	3.0	-0.6						
Item 16	-0.6	-0.6	-0.3	-	-0.7	5.1					
Item 17-19*	-0.4	-0.5	-0.6	-0.7	-0.5	-0.6	-0.2				
Item 20-21*	0.5	0.4	0.1	-0.2	-0.7	-0.7	-0.6	-0.7			
Item 22	-0.4	-0.1	0.2	-	-	-0.6	-0.6	1.7	-		
Item 23	0.1	0.6	-	-	-	-0.5	-0.1	-0.5	-	-0.7	

* Combined items due to their content similarities

Table 4-6. Item parameter estimates and fit statistics using the one-parameter logistic (1PL) model*

Items	Item parameters				$S\text{-}X^2$ fit index		
	a	SE	*b*	SE	X^2	*df*	*p*
To handle the medication-related problem identified, did you…							
Item 4: Discuss the problem with your healthcare provider?	1.712	0.204	-1.422	0.207	2.499	3	0.476
Item 3: Discuss the problem with your family or friends?	1.712	0.204	-0.473	0.149	7.644	6	0.267
Item 9: Visit your healthcare provider to resolve the problem?	1.712	0.204	-0.142	0.144	5.143	5	0.400
Item 8: Get another medication or home remedy to treat the problem?	1.712	0.204	0.159	0.147	9.526	6	0.146
Item 1: Entirely stop using the medication?	1.712	0.204	0.184	0.147	5.224	6	0.517
Item 5: Ask your physician or nurse to prescribe a different medication?	1.712	0.204	0.235	0.149	6.356	5	0.275
Item 6: Limit your activities or change your daily routines?	1.712	0.204	0.364	0.154	5.630	6	0.467
Item 2: Seek out information that would help you resolve the problem?	1.712	0.204	0.524	0.163	23.084	6	0.0008
Item 7: Take sick time or work less than usual?	1.712	0.204	1.339	0.219	10.804	6	0.094
Item 10: Visit an emergency department or go to urgent care?	1.712	0.204	1.907	0.281	8.131	4	0.087
Item 11: Get admitted to the hospital?	1.712	0.204	2.129	0.309	4.701	3	0.196

* Items are ordered by their values of difficulty parameters. *a*: discrimination parameter, *b*: difficulty parameter.

Table 4-7. Item parameter estimates and fit statistics using the two-parameter logistic (2PL) model*

Items	Item parameters				$S\text{-}X^2$ fit index		
	a	SE	*b*	SE	X^2	*df*	*p*
To handle the medication-related problem identified, did you…							
Item 4: Discuss the problem with your healthcare provider?	2.746	0.906	-1.197	0.214	0.776	2	0.679
Item 3: Discuss the problem with your family or friends?	1.133	0.297	-0.586	0.234	5.176	6	0.523
Item 9: Visit your healthcare provider to resolve the problem?	2.980	0.819	-0.111	0.142	1.869	4	0.760
Item 5: Ask your physician or nurse to prescribe a different medication?	2.594	0.633	0.212	0.156	4.128	5	0.532
Item 1: Entirely stop using the medication?	1.485	0.348	0.214	0.182	4.141	6	0.658
Item 8: Get another medication or home remedy to treat the problem?	1.113	0.284	0.223	0.199	2.738	7	0.908
Item 6: Limit your activities or change your daily routines?	1.324	0.335	0.436	0.192	3.670	6	0.722
Item 2: Seek out information that would help you resolve the problem?	0.870	0.252	0.823	0.300	9.054	7	0.248
Item 7: Take sick time or work less than usual?	2.880	1.262	1.111	0.157	7.224	4	0.124
Item 10: Visit an emergency department or go to urgent care?	3.800	1.696	1.460	0.193	2.831	2	0.244
Item 11: Get admitted to the hospital?	5.079	1.083	1.549	0.143	1.101	2	0.577

* Items are ordered by their values of difficulty parameters. *a*: discrimination parameter, *b*: difficulty parameter.

When items were ordered by their values of difficulty parameters, the location of item 5 was ranked as the sixth from the lowest on the 1PL model. However, this item was located as the fourth from the lowest on the 2PL model due to its relatively low estimated value of difficulty parameter. This item positioned differently on two models because the discrimination was fixed as 1.71 for the 1PL model, whereas it was estimated as 2.59 for the 2PL model. In addition, item 8 had a lower difficulty value than item 1 for the 1PL model, which was not the case for the 2PL model. When calibrating using the 2PL model, the value of the difficulty parameter of item 8 (0.22) was slightly higher than that of item 1 (0.21). To handle these inconsistencies between two models and decide a better model, the item fit to each model was examined. When calibrating using the 1PL model, the $S\text{-}X^2$ statistic showed statistical non-significance for all items but for item 2 ($S\text{-}X^2(6) = 23.1$, $p < 0.001$). However, all items showed an adequate item fit indicated by statistical non-significance of the $S\text{-}X^2$ statistic for the 2PL model. Therefore, the estimations of the item parameters obtained using the 2PL model were considered more reasonable.

In addition to the comparison at this item-level, the 1PL and the 2PL models were compared at the model-level to determine which model is preferred. First, model-data fit was assessed using the deviance statistic (-2 log likelihood) and comparative fit measures such as AIC and BIC (Table 4-8). The deviance statistic (-2 log likelihood) for the 1PL and the 2PL model were reported as 1478.76 ($df = 54$) and 1437.14 ($df = 44$), respectively. The chi-squared difference test was highly significant ($X^2(41.61, 10)$, $p < 0.0001$) indicating that the 2PL model provided a better fit to the item responses compared to the 1PL model. This result was supported by the information–theoretic fit index (AIC) and the RMSEA value, all of which favored the 2PL model. However, the

values of the BIC were almost the same in these two models, which made comparisons difficult based solely on this fit measure. Second, reliability of the estimated scores was examined for each model. Consistent with the previous results, the 2PL model was preferred with a higher value of score reliability estimate (0.82) compared to that of the 1PL model (0.79).

Table 4-8. Comparisons between the one-parameter logistic (1PL) and two-parameter logistic (2PL) model

		1PL	2PL
Fit	-2LL	1478.755 (df = 54)	1437.144 (df=44)
	AIC	1502.755	1481.144
	BIC	1538.055	1545.860
	RMSEA	0.08	0.06
Reliability	Marginal reliability for response pattern score	0.79	0.82

Finally, the standard error of measurement and test information was investigated for each model (Figures 4-8, 4-9 and Tables 4-9, 4-10). The 2PL model had much more information and much lower SEM over most of the coping behavior range. The 1PL model had slightly more information and lower SEM only when the coping level ranged from -2.8 to -2.0 and from 2.2 to 2.8. The relative efficiency index (REI) of the 2PL model over 1PL was shown in Figure 4-10. The coping level around 0.4, where the 1PL model can measure the coping level most precisely along the theta continuum, was even more precisely measured by the 2PL model. That is, the 2PL model had more information, less measurement error, and therefore better precision even where the coping level was most precisely measured by the 1PL model. Those whose coping level was around 1.6 were most precisely measured by the 2PL model. All of these findings suggested that the 2PL model was preferred than the 1PL model.

Figure 4-11displays the item response function and item information function for each item using the 2PL model and Figure 4-12 presents total response function using 2PL.

Figure 4-8. Standard error of measurement (SEM) for the one-parameter logistic (1PL) and two-parameter logistic (2PL) model

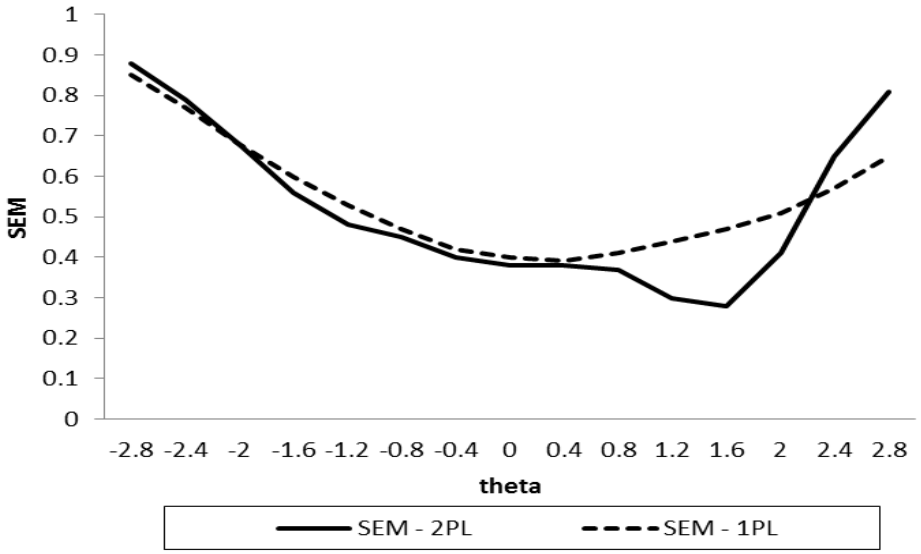


Figure 4-9. Test information for the one-parameter logistic (1PL) and two-parameter logistic (2PL) model

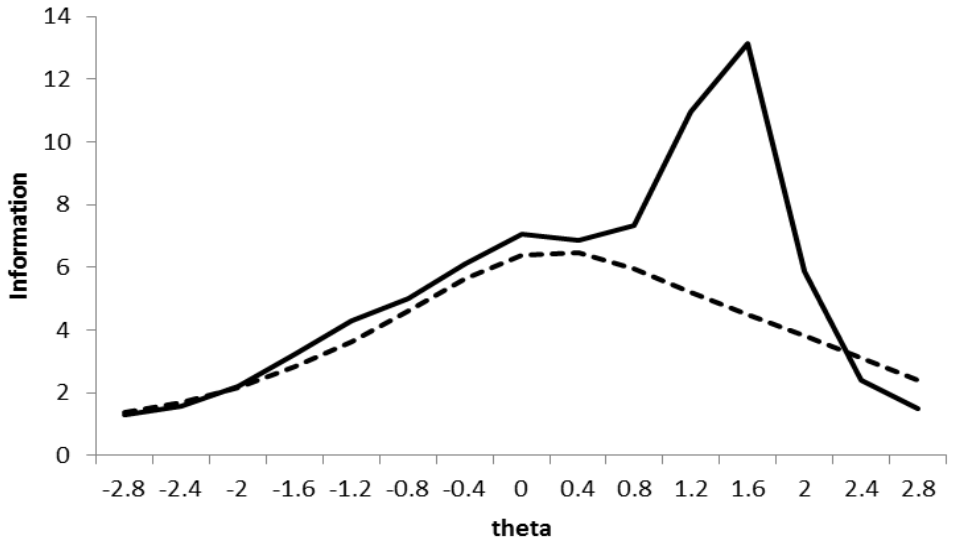


Figure 4-10. Relative Efficiency Index (REI)

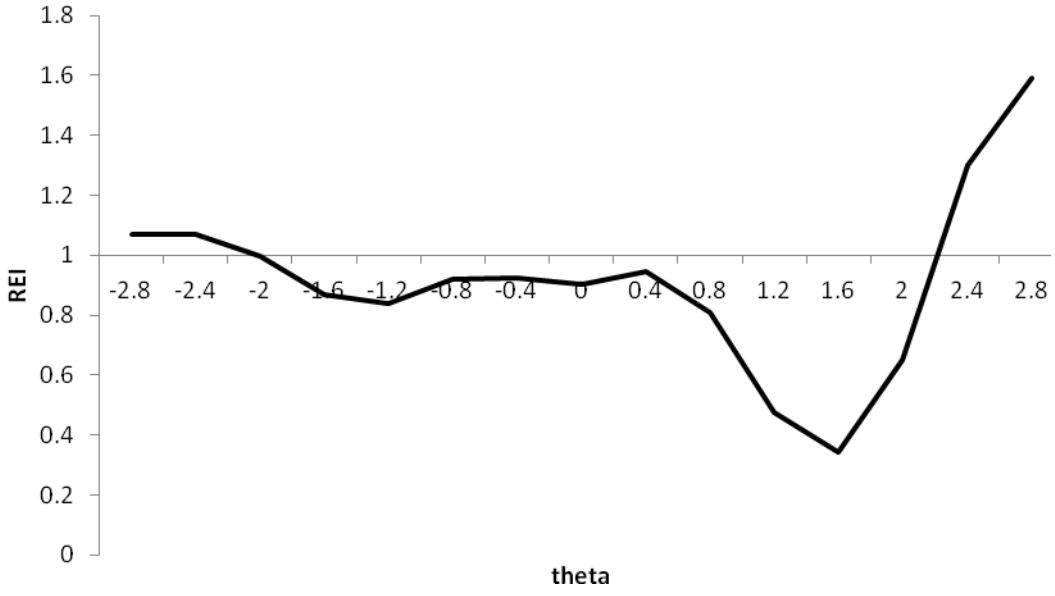


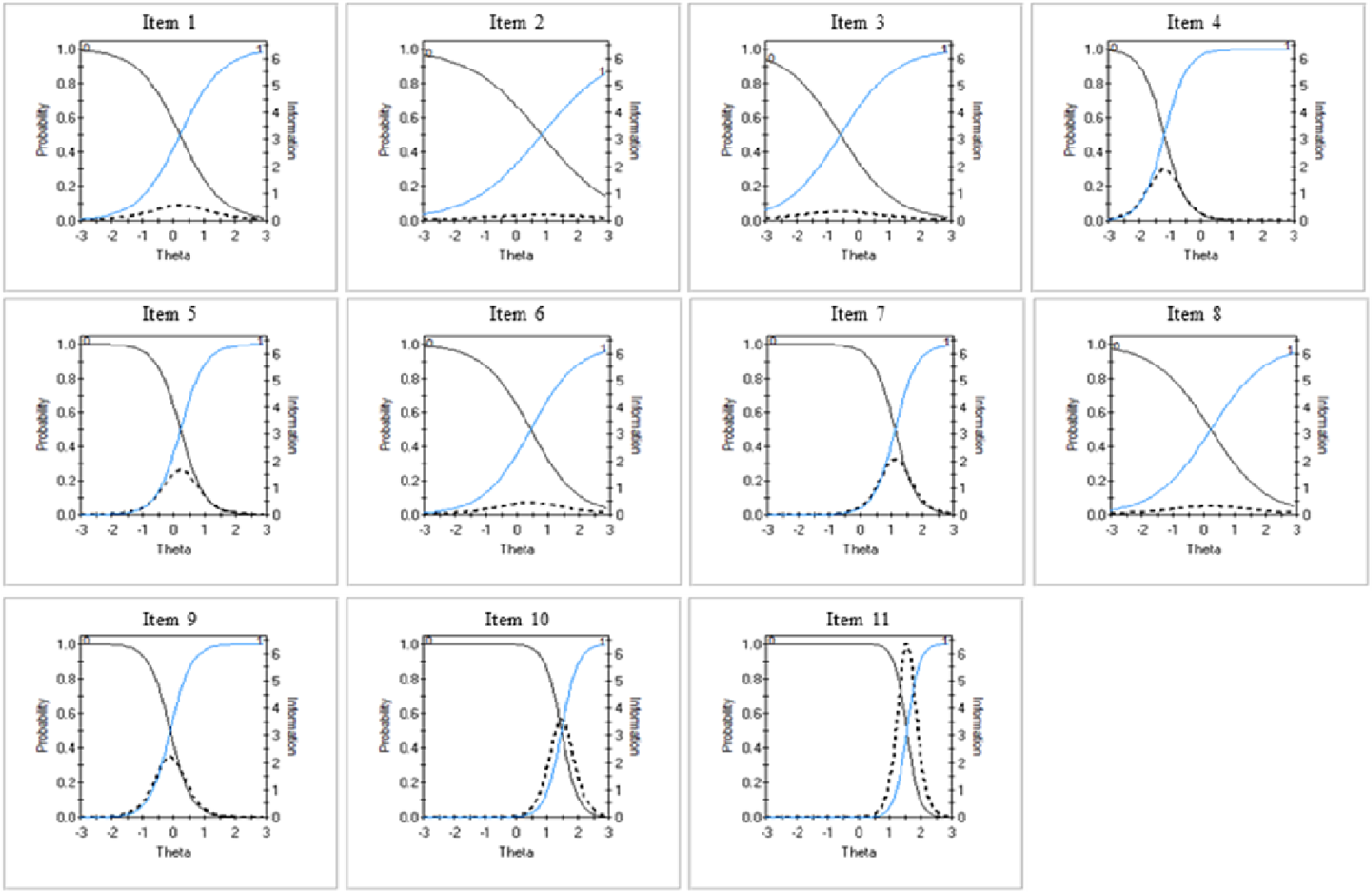
Table 4-9. Item information and test information measured using the one-parameter logistic (1PL) model

Item	Theta														
	-2.8	-2.4	-2.0	-1.6	-1.2	-0.8	-0.4	0	0.4	0.8	1.2	1.6	2.0	2.4	2.8
Item 1	0.02	0.03	0.07	0.13	0.23	0.39	0.58	0.71	0.71	0.56	0.37	0.22	0.12	0.06	0.03
Item 2	0.01	0.02	0.04	0.07	0.14	0.25	0.41	0.60	0.72	0.69	0.53	0.35	0.20	0.11	0.06
Item 3	0.05	0.10	0.19	0.32	0.51	0.68	0.73	0.62	0.44	0.27	0.15	0.08	0.04	0.02	0.01
Item 4	0.23	0.39	0.58	0.72	0.71	0.56	0.37	0.22	0.12	0.06	0.03	0.02	0.01	0.00	0.00
Item 5	0.02	0.03	0.06	0.12	0.21	0.36	0.55	0.70	0.72	0.58	0.40	0.24	0.13	0.07	0.04
Item 6	0.01	0.03	0.05	0.09	0.18	0.31	0.49	0.67	0.73	0.64	0.46	0.28	0.16	0.08	0.04
Item 7	0.00	0.00	0.01	0.02	0.04	0.07	0.14	0.24	0.41	0.60	0.72	0.70	0.54	0.35	0.21
Item 8	0.02	0.04	0.07	0.13	0.24	0.40	0.59	0.72	0.70	0.55	0.36	0.21	0.12	0.06	0.03
Item 9	0.03	0.06	0.11	0.21	0.35	0.54	0.70	0.72	0.60	0.41	0.24	0.13	0.07	0.04	0.02
Item 10	0.00	0.00	0.00	0.01	0.01	0.03	0.05	0.10	0.19	0.33	0.52	0.68	0.73	0.62	0.43
Item 11	0.00	0.00	0.00	0.00	0.01	0.02	0.04	0.07	0.14	0.25	0.41	0.60	0.72	0.69	0.54
Test information	1.39	1.70	2.18	2.82	3.62	4.61	5.65	6.39	6.47	5.94	5.20	4.51	3.84	3.11	2.40
Expected SE	0.85	0.77	0.68	0.60	0.53	0.47	0.42	0.40	0.39	0.41	0.44	0.47	0.51	0.57	0.65

Table 4-10. Item information and test information measured the two-parameter logistic (2PL) model

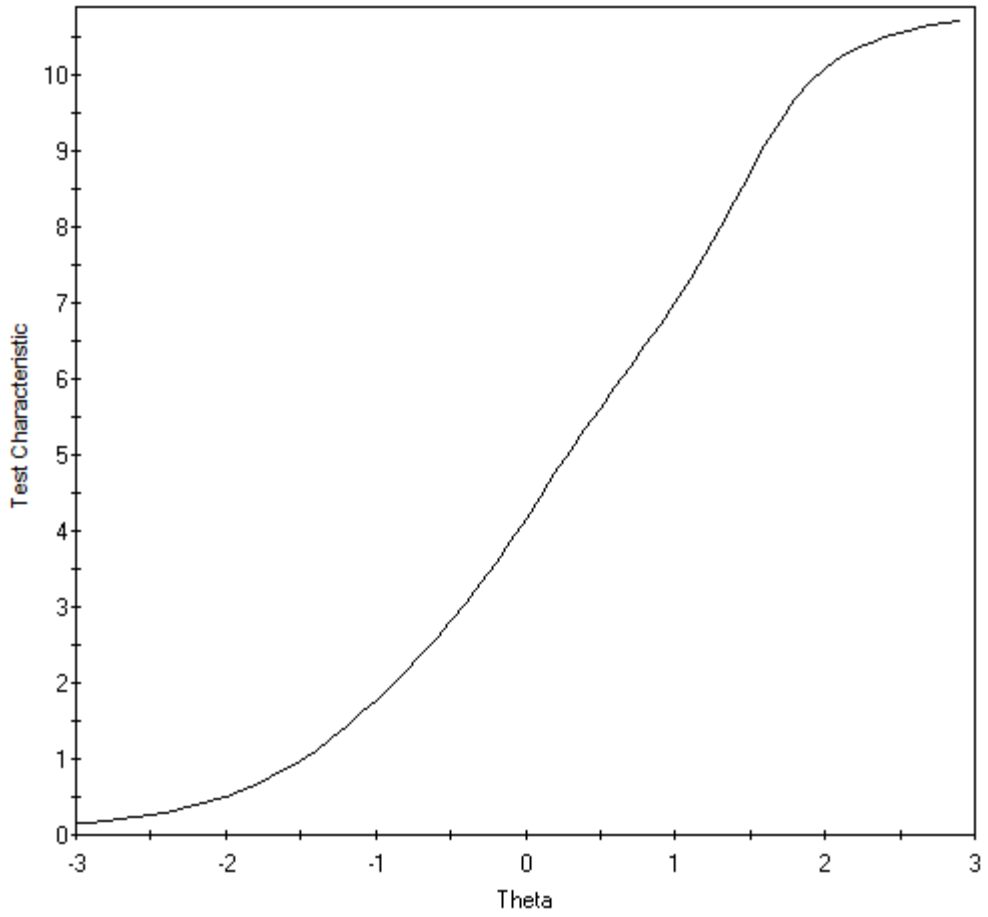
Item	Theta														
	-2.8	-2.4	-2.0	-1.6	-1.2	-0.8	-0.4	0	0.4	0.8	1.2	1.6	2.0	2.4	2.8
Item 1	0.02	0.04	0.08	0.13	0.21	0.33	0.45	0.54	0.54	0.46	0.34	0.22	0.14	0.08	0.05
Item 2	0.03	0.04	0.06	0.07	0.09	0.12	0.14	0.17	0.18	0.19	0.18	0.17	0.15	0.12	0.10
Item 3	0.09	0.13	0.18	0.23	0.29	0.32	0.32	0.29	0.24	0.18	0.13	0.09	0.06	0.04	0.03
Item 5	0.09	0.26	0.67	1.41	1.88	1.42	0.68	0.26	0.09	0.03	0.01	0.00	0.00	0.00	0.00
Item 6	0.00	0.01	0.02	0.06	0.16	0.42	0.95	1.56	1.59	0.99	0.45	0.17	0.06	0.02	0.01
Item 7	0.02	0.04	0.06	0.10	0.16	0.24	0.33	0.40	0.44	0.41	0.34	0.25	0.17	0.11	0.07
Item 8	0.00	0.00	0.00	0.00	0.01	0.03	0.10	0.31	0.84	1.71	2.04	1.31	0.55	0.19	0.06
Item 9	0.04	0.06	0.09	0.13	0.18	0.23	0.28	0.30	0.31	0.28	0.23	0.18	0.13	0.09	0.06
Item 10	0.00	0.01	0.03	0.10	0.32	0.89	1.85	2.16	1.31	0.52	0.17	0.05	0.02	0.00	0.00
Item 11	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.06	0.25	1.01	2.86	3.36	1.45	0.38	0.09
Item 12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.07	0.55	3.20	6.34	2.15	0.33	0.04
Test information	1.30	1.59	2.19	3.24	4.31	5.01	6.12	7.06	6.85	7.33	10.96	13.16	5.89	2.39	1.51
Expected SE	0.88	0.79	0.68	0.56	0.48	0.45	0.40	0.38	0.38	0.37	0.30	0.28	0.41	0.65	0.81

Figure 4-11. Item response function and item information function measured using the two-parameter logistic (2PL) model



Blue line represents item response function (IRF); Black line represents 1-IRF; Black dotted line indicates item information function (IIF).

Figure 4-12. Test response function (TRF) measured using the two-parameter logistic (2PL) model



Test response function (TRF) is the sum of the individual item response function (IRF). TRF indicates the expected number of endorsing items as a function of theta.

4.4 Differential item functioning (DIF)

Table 4-11and 4-12 provide DIF statistics and parameter estimates for different problem intensity groups. Three items (items 4, 7, and 10) showed significant X^2 results, which may indicate the presence of DIF. However, the significant results in these items stemmed from unreliably large estimates of discrimination parameter in any of two groups rather than their differential functioning between two groups. The unreliable estimates of parameters (e.g., 26.40, 30.07, and 45.52) were obtained because of response categories with very few observations (i.e., strongly skewed distributions) for these items. Items with sparse cell distributions have generally been known to be problematic in obtaining reliable estimates of parameters. Therefore, DIF for these three items needs to be reexamined in large samples after obtaining adequate estimates of parameters.

Three Items with significant X^2 results in investigating demographic DIFs (gender DIF, education DIF, age DIF) and health literacy level DIF had the same problem (Table 4-13, 4-14. 4-15, 4-16, 4-17, 4-18, 4-19, and 4-20). That is, some parameters of these items were estimated unreliably high in a subgroup due to very few observations in a response category. Such items include items 4, 10, and 11 for demographic DIFs and items 1, 6, and 7 for health literacy DIF. DIF for these items should also be reinvestigated when each response category in the items has enough observations to obtain reliable parameter estimates.

Table 4-11. Problem intensity differential item functioning (DIF) statistics

Item	Moderate, small, or very small (n=81)		Big or very big (n=59)		Total X^2	*df*	*p*	X_a^2	*df*	*p*	$X_{c\|a}^2$	*df*	*P*
	"No" response, n (%)	"Yes" response, n (%)	"No" response, n (%)	"Yes" response, n (%)									
Item 1	61 (75.3)	20 (24.7)	17 (28.8)	42 (71.2)	1.4	2	0.492	0.6	1	0.424	0.8	1	0.378
Item 2	62 (76.5)	19 (23.5)	29 (49.2)	30 (50.8)	0.9	2	0.644	0.8	1	0.360	0.0	1	0.840
Item 3	45 (55.6)	36 (44.4)	7 (11.9)	52 (88.1)	6.0	2	0.051	0.6	1	0.450	5.4	1	0.020
Item 4	18 (22.2)	63 (77.8)	4 (6.8)	55 (93.2)	101.5	2	0.0001	81.4	1	0.0001	20.2	1	0.0001
Item 5	60 (74.1)	21 (25.9)	20 (33.9)	39 (66.1)	1.2	2	0.542	0.4	1	0.512	0.8	1	0.374
Item 6	65 (80.2)	16 (19.8)	20 (33.9)	39 (66.1)	3.9	2	0.145	0.4	1	0.539	3.5	1	0.062
Item 7	77 (95.1)	4 (4.9)	39 (66.1)	20 (33.9)	84.6	2	0.0001	12.6	1	0.0004	72.0	1	0.0001
Item 8	58 (71.6)	23 (28.4)	19 (32.2)	40 (67.8)	0.8	2	0.656	0.3	1	0.580	0.5	1	0.465
Item 9	53 (65.4)	28 (34.6)	12 (20.3)	47 (79.7)	3.7	2	0.155	1.4	1	0.244	2.4	1	0.123
Item 10	79 (97.5)	2 (2.5)	48 (81.4)	11 (18.6)	113.7	2	0.0001	100.3	1	0.0001	13.4	1	0.0003
Item 11	80 (98.8)	1 (1.2)	50 (84.7)	9 (15.3)	0.2	2	0.883	0.2	1	0.639	0.0	1	0.866

Table 4-12. Item parameter estimates for different problem intensity groups

Items	Moderate, small, or very small				Big or very big			
	a	SE	*c*	SE	*a*	SE	*c*	SE
To handle the medication-related problem identified, did you…								
Item 1: Entirely stop using the medication?	1.36	0.54	-1.39	0.46	0.79	0.46	-0.36	0.74
Item 2: Seek out information that would help you resolve the problem?	0.44	0.36	-1.20	0.31	0.96	0.45	-1.60	0.82
Item 3: Discuss the problem with your family or friends?	0.35	0.30	-0.21	0.23	0.85	0.60	0.73	0.87
Item 4: Discuss the problem with your healthcare provider?	45.52	4.50	34.84	4.52	2.62	1.53	-0.24	1.47
Item 5: Ask your physician or nurse to prescribe a different medication?	3.68	2.13	-2.38	1.35	2.19	0.79	-2.70	1.19
Item 6: Limit your activities or change your daily routines?	0.48	0.35	-1.44	0.31	0.84	0.45	-0.69	0.79
Item 7: Take sick time or work less than usual?	30.07	7.96	-43.96	4.34	1.58	1.05	-3.58	2.02
Item 8: Get another medication or home remedy to treat the problem?	0.64	0.36	-0.97	0.32	0.95	0.42	-0.77	0.65
Item 9: Visit your healthcare provider to resolve the problem?	2.20	0.88	-0.99	0.54	4.17	1.44	-3.91	1.45
Item 10: Visit an emergency department or go to urgent care?	26.40	2.20	-45.30	5.07	2.94	0.81	-7.68	1.78
Item 11: Get admitted to the hospital?	25.40	43.53	-48.55	327.24	4.96	0.91	-13.03	1.84

a: discrimination parameter, *c*: - *a*b* (*b*: difficulty parameter).

Table 4-13. Gender differential item functioning (DIF) statistics

Item	Male (n=55)		Female (n=85)		Total X^2	*df*	*p*	X_a^2	*df*	*p*	$X_{c\|a}^2$	*df*	*P*
	"No" response, n (%)	"Yes" response, n (%)	"No" response, n (%)	"Yes" response, n (%)									
Item 1	31 (56.4)	24 (43.6)	47 (55.3)	38 (44.7)	2.3	2	0.324	2.3	1	0.135	0.0	1	0.911
Item 2	35 (63.6)	20 (36.4)	56 (65.9)	29 (34.1)	2.0	2	0.360	2.0	1	0.158	0.1	1	0.805
Item 3	21 (38.2)	34 (61.8)	31 (36.5)	54 (63.5)	0.4	2	0.825	0.3	1	0.608	0.1	1	0.728
Item 4	10 (18.2)	45 (81.8)	12 (14.1)	73 (85.9)	59.1	2	0.0001	22.8	1	0.0001	36.3	1	0.0001
Item 5	27 (49.1)	28 (50.9)	53 (62.4)	32 (37.6)	3.0	2	0.227	0.8	1	0.361	2.1	1	0.144
Item 6	35 (63.6)	20 (36.4)	50 (58.8)	35 (41.2)	2.2	2	0.326	1.4	1	0.243	0.9	1	0.349
Item 7	45 (81.8)	10 (18.2)	71 (83.5)	14 (16.5)	0.5	2	0.779	0.4	1	0.503	0.1	1	0.822
Item 8	30 (54.5)	25 (45.5)	47 (55.3)	38 (44.7)	0.0	2	0.996	0.0	1	0.934	0.0	1	0.965
Item 9	23 (41.8)	32 (58.2)	42 (49.4)	43 (50.6)	0.8	2	0.686	0.1	1	0.778	0.7	1	0.412
Item 10	51 (92.7)	4 (7.3)	76 (89.4)	9 (10.6)	38.0	2	0.0001	36.7	1	0.0001	1.3	1	0.262
Item 11	53 (96.4)	2 (3.6)	77 (90.6)	8 (9.4)	9.8	2	0.008	0.5	1	0.486	9.3	1	0.002

Table 4-14. Item parameter estimates for different gender groups

Items	Male				Female			
	a	SE	*c*	SE	*a*	SE	*c*	SE
To handle the medication-related problem identified, did you…								
Item 1: Entirely stop using the medication?	0.94	0.40	-0.29	0.30	2.00	0.57	-0.29	0.35
Item 2: Seek out information that would help you resolve the problem?	1.48	0.60	-0.76	0.53	0.56	0.26	-0.69	0.24
Item 3: Discuss the problem with your family or friends?	1.29	0.52	0.65	0.35	0.97	0.34	0.72	0.28
Item 4: Discuss the problem with your healthcare provider?	1.67	0.78	2.19	0.61	33.00	6.54	40.88	4.99
Item 5: Ask your physician or nurse to prescribe a different medication?	2.08	0.77	0.08	0.53	3.23	0.99	-1.13	0.53
Item 6: Limit your activities or change your daily routines?	2.20	1.04	-0.93	0.52	0.93	0.29	-0.40	0.25
Item 7: Take sick time or work less than usual?	4.17	2.67	-3.96	1.94	2.29	0.81	-2.92	0.70
Item 8: Get another medication or home remedy to treat the problem?	0.99	0.42	-0.21	0.30	1.04	0.32	-0.23	0.25
Item 9: Visit your healthcare provider to resolve the problem?	2.87	1.44	0.71	0.53	2.41	0.74	0.15	0.38
Item 10: Visit an emergency department or go to urgent care?	28.16	4.06	-40.98	15.08	2.66	1.11	-4.18	1.15
Item 11: Get admitted to the hospital?	24.94	21.07	-44.90	8.22	9.97	3.89	-14.11	5.56

a: discrimination parameter, *c*: - *a*b* (*b*: difficulty parameter).

Table 4-15. Education differential item functioning (DIF) statistics

Item	Some college or lower (n=71)		College grad or higher (n=66)		Total X^2	*df*	*p*	X_a^2	*df*	*p*	$X_{c\|a}^2$	*df*	*P*
	"No" response, n (%)	"Yes" response, n (%)	"No" response, n (%)	"Yes" response, n (%)									
Item 1	37 (52.1)	34 (47.9)	39 (59.1)	27 (40.9)	1.0	2	0.598	1.0	1	0.322	0.0	1	0.827
Item 2	52 (73.2)	19 (26.8)	37 (56.1)	29 (43.9)	4.6	2	0.099	0.0	1	0.974	4.6	1	0.032
Item 3	29 (40.8)	42 (59.2)	23 (34.8)	43 (65.2)	1.6	2	0.458	0.0	1	0.862	1.5	1	0.217
Item 4	9 (12.7)	62 (87.3)	13 (19.7)	53 (80.3)	0.6	2	0.727	0.5	1	0.471	0.1	1	0.732
Item 5	39 (54.9)	32 (45.1)	40 (60.6)	26 (39.4)	0.1	2	0.963	0.1	1	0.813	0.0	1	0.888
Item 6	40 (56.3)	31 (43.7)	43 (65.2)	23 (34.8)	0.2	2	0.926	0.1	1	0.795	0.1	1	0.769
Item 7	58 (81.7)	13 (18.3)	55 (83.3)	11 (16.7)	0.4	2	0.838	0.2	1	0.657	0.2	1	0.694
Item 8	38 (53.5)	33 (46.5)	39 (59.1)	27 (40.9)	1.0	2	0.615	1.0	1	0.324	0.0	1	0.986
Item 9	29 (40.8)	42 (59.2)	35 (53.0)	31 (47.0)	2.5	2	0.291	2.4	1	0.119	0.0	1	0.858
Item 10	62 (87.3)	9 (12.7)	62 (93.9)	4 (6.1)	57.7	2	0.0001	11.7	1	0.0006	46.0	1	0.0001
Item 11	63 (88.7)	8 (11.3)	64 (97.0)	2 (3.0)	5.8	2	0.056	5.6	1	0.019	0.2	1	0.651

Table 4-16. Item parameter estimates for different education level groups

Items	Some college or lower				College grad or higher			
	a	SE	*c*	SE	*a*	SE	*c*	SE
To handle the medication-related problem identified, did you…								
Item 1: Entirely stop using the medication?	1.18	0.40	-0.10	0.31	1.99	0.72	-0.09	0.66
Item 2: Seek out information that would help you resolve the problem?	1.13	0.42	-1.25	0.36	1.15	0.52	-0.02	0.46
Item 3: Discuss the problem with your family or friends?	1.23	0.44	0.49	0.32	1.12	0.47	1.05	0.42
Item 4: Discuss the problem with your healthcare provider?	1.78	1.28	2.83	1.15	6.41	6.30	6.97	6.53
Item 5: Ask your physician or nurse to prescribe a different medication?	2.86	1.25	-0.35	0.58	2.50	0.84	-0.17	0.73
Item 6: Limit your activities or change your daily routines?	1.40	0.57	-0.33	0.38	1.21	0.50	-0.49	0.47
Item 7: Take sick time or work less than usual?	3.50	2.16	-3.55	2.14	2.41	1.13	-2.18	0.91
Item 8: Get another medication or home remedy to treat the problem?	0.91	0.36	-0.16	0.29	1.53	0.51	-0.13	0.50
Item 9: Visit your healthcare provider to resolve the problem?	12.36	6.28	3.20	2.86	2.44	0.86	0.39	0.68
Item 10: Visit an emergency department or go to urgent care?	3.18	1.75	-4.20	1.83	32.73	8.46	-39.53	4.29
Item 11: Get admitted to the hospital?	11.46	3.47	-14.30	4.60	2.37	1.69	-4.79	2.15

a: discrimination parameter, *c*: - *a*b* (*b*: difficulty parameter).

Table 4-17. Age differential item functioning (DIF) statistics

Item	Aged below 57 (n=64)		Aged equal to or over 57 (n=76)		Total X^2	*df*	*p*	X_a^2	*df*	*p*	$X_{c\|a}^2$	*df*	*p*
	"No" response, n (%)	"Yes" response, n (%)	"No" response, n (%)	"Yes" response, n (%)									
Item 1	33 (51.6)	31 (48.4)	45 (59.2)	31 (40.8)	0.3	2	0.882	0.0	1	0.834	0.2	1	0.649
Item 2	43 (67.2)	21 (32.8)	48 (63.2)	28 (36.8)	0.7	2	0.723	0.1	1	0.771	0.6	1	0.452
Item 3	22 (34.4)	42 (65.6)	30 (39.5)	46 (60.5)	0.0	2	0.981	0.0	1	0.925	0.0	1	0.864
Item 4	9 (14.1)	55 (85.9)	13 (17.1)	63 (82.9)	10.0	2	0.007	9.1	1	0.003	0.9	1	0.340
Item 5	36 (56.3)	28 (43.8)	44 (57.9)	32 (42.1)	0.5	2	0.769	0.5	1	0.498	0.1	1	0.798
Item 6	33 (51.6)	31 (48.4)	52 (68.4)	24 (31.6)	3.8	2	0.153	2.2	1	0.142	1.6	1	0.207
Item 7	51 (79.7)	13 (20.3)	65 (85.5)	11 (14.5)	0.3	2	0.862	0.1	1	0.802	0.2	1	0.630
Item 8	32 (50.0)	32 (50.0)	45 (59.2)	31 (40.8)	0.6	2	0.751	0.1	1	0.792	0.5	1	0.478
Item 9	31 (48.4)	33 (51.6)	34 (44.7)	42 (55.3)	0.9	2	0.639	0.6	1	0.455	0.3	1	0.562
Item 10	57 (89.1)	7 (10.9)	70 (92.1)	6 (7.9)	0.1	2	0.957	0.0	1	0.843	0.0	1	0.826
Item 11	60 (93.8)	4 (6.3)	70 (92.1)	6 (7.9)	0.3	2	0.875	0.0	1	0.932	0.3	1	0.610

Table 4-18. Item parameter estimates for different age groups

Items	Age < 57				Age ≥ 57			
	a	SE	*c*	SE	*a*	SE	*c*	SE
To handle the medication-related problem identified, did you…								
Item 1: Entirely stop using the medication?	1.43	0.55	-0.08	0.38	1.29	0.44	-0.30	0.34
Item 2: Seek out information that would help you resolve the problem?	0.79	0.37	-0.81	0.32	0.93	0.33	-0.50	0.29
Item 3: Discuss the problem with your family or friends?	1.06	0.48	0.80	0.35	1.01	0.35	0.71	0.35
Item 4: Discuss the problem with your healthcare provider?	18.14	5.36	19.60	5.83	1.86	0.69	2.88	0.76
Item 5: Ask your physician or nurse to prescribe a different medication?	2.12	0.80	-0.41	0.54	3.07	1.14	-0.24	0.65
Item 6: Limit your activities or change your daily routines?	0.83	0.35	-0.07	0.30	1.82	0.57	-0.96	0.49
Item 7: Take sick time or work less than usual?	2.44	0.99	-2.50	0.92	3.32	3.35	-3.78	3.19
Item 8: Get another medication or home remedy to treat the problem?	1.07	0.41	0.01	0.34	0.93	0.32	-0.30	0.28
Item 9: Visit your healthcare provider to resolve the problem?	2.21	0.84	0.13	0.55	5.47	4.28	1.78	1.65
Item 10: Visit an emergency department or go to urgent care?	6.18	16.96	-7.96	18.95	2.81	1.29	-4.63	1.36
Item 11: Get admitted to the hospital?	3.88	3.23	-6.62	4.15	4.44	5.70	-6.66	7.67

a: discrimination parameter, *c*: - *a***b* (*b*: difficulty parameter).

Table 4-19. Health literacy level differential item functioning (DIF) statistics

Item	Low (n=27)		High (n=109)		Total X^2	*df*	*p*	X_a^2	*df*	*p*	$X_{c\|a}^2$	*df*	*P*
	"No" response, n (%)	"Yes" response, n (%)	"No" response, n (%)	"Yes" response, n (%)									
Item 1	12 (44.4)	15 (55.6)	63 (57.8)	46 (42.2)	6.0	2	0.050	4.8	1	0.028	1.2	1	0.279
Item 2	21 (77.8)	6 (22.2)	67 (61.5)	42 (38.5)	1.6	2	0.447	0.2	1	0.661	1.4	1	0.234
Item 3	12 (44.4)	15 (55.6)	40 (36.7)	69 (63.3)	0.1	2	0.965	0.0	1	0.859	0.0	1	0.844
Item 4	4 (14.8)	23 (85.2)	17 (15.6)	92 (84.4)	2.0	2	0.373	1.7	1	0.187	0.2	1	0.631
Item 5	18 (66.7)	9 (33.3)	60 (55.0)	49 (45.0)	1.6	2	0.452	1.5	1	0.218	0.1	1	0.798
Item 6	17 (63.0)	10 (37.0)	65 (59.6)	44 (40.4)	17.0	2	0.0002	16.1	1	0.0001	1.0	1	0.327
Item 7	24 (88.9)	3 (11.1)	88 (80.7)	21 (19.3)	19.5	2	0.0001	10.4	1	0.001	9.1	1	0.003
Item 8	12 (44.4)	15 (55.6)	64 (58.7)	45 (41.3)	2.8	2	0.244	2.6	1	0.109	0.3	1	0.616
Item 9	12 (44.4)	15 (55.6)	51 (46.8)	58 (53.2)	1.6	2	0.460	0.9	1	0.336	0.6	1	0.429
Item 10	27 (100.0)	0 (0.0)	96 (88.1)	13 (11.9)	-	-	-	-	-	-	-	-	-
Item 11	26 (96.3)	1 (3.7)	100 (91.7)	9 (8.3)	0.2	2	0.928	0.0	1	0.950	0.1	1	0.702

Table 4-20. Item parameter estimates for different health literacy level groups

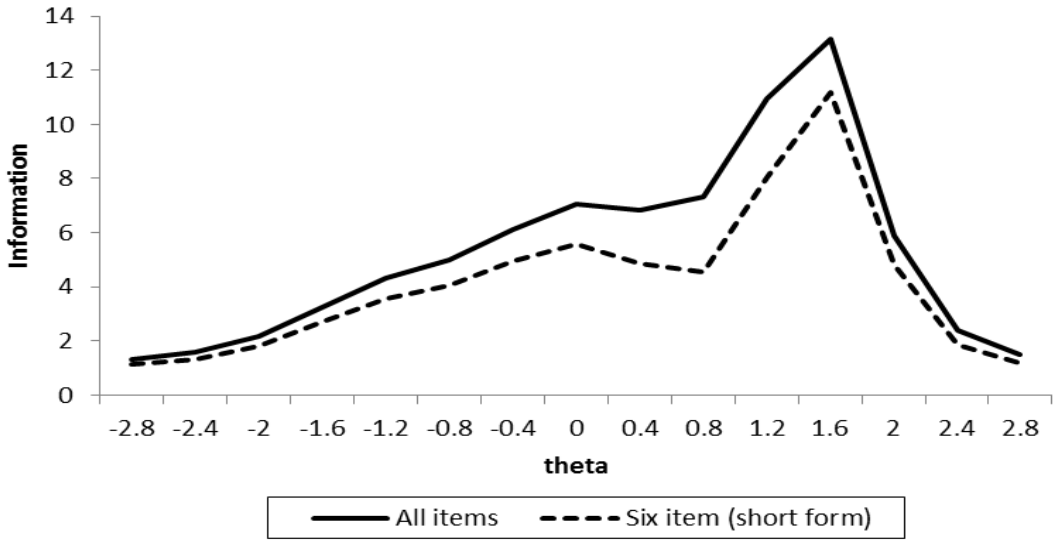
Items	Low				High			
	a	SE	*c*	SE	*a*	SE	*c*	SE
To handle the medication-related problem identified, did you…								
Item 1: Entirely stop using the medication?	-0.01	0.45	0.06	0.36	1.35	0.42	-0.88	0.44
Item 2: Seek out information that would help you resolve the problem?	0.76	0.63	-1.38	0.53	0.47	0.17	-0.64	0.24
Item 3: Discuss the problem with your family or friends?	0.94	0.66	0.55	0.47	0.82	0.23	0.63	0.29
Item 4: Discuss the problem with your practitioner?	0.13	0.63	1.65	0.49	1.18	0.49	2.67	0.81
Item 5: Ask your physician or nurse to prescribe a different medication?	0.77	0.58	-0.67	0.45	1.96	0.77	-0.91	0.61
Item 6: Limit your activities or change your daily routines?	31.02	7.61	-10.87	7.54	0.50	0.16	-0.56	0.24
Item 7: Take sick time or work less than usual?	14.52	3.99	-18.98	3.84	1.10	1.19	-1.99	1.14
Item 8: Get another medication or home remedy to treat the problem?	0.06	0.43	0.33	0.36	1.10	0.49	-0.39	0.62
Item 9: Visit your practitioner to resolve the problem?	9.41	7.73	1.15	3.35	1.83	1.45	0.53	1.12
Item 10: Visit an emergency department or go to urgent care?	-	-	-	-	-	-	-	-
Item 11: Get admitted to the hospital?	18.91	13.01	-34.89	26.14	20.88	28.34	-43.55	17.45

a: discrimination parameter, *c*: - *a*b* (*b*: difficulty parameter).

4.5 Construction of a short-form

A short-form was constructed by considering both the content of items and their psychometric properties. First, the most informative seven items (items 1, 4, 5, 7, 9, 10, and 11) were selected solely from a measurement perspective. These items contributed approximately 85% of the whole information covered by the scale, indicating that they provided relatively greater utility to the scale. Next, items were selected by their content from a clinical perspective regardless of their measurement properties. Nine items (items 1, 4, 5, 6, 7, 8, 9, 10, and 11), which could provide clinically important content, were selected. Because seven of the nine items were also included in the first selection, they were candidates to be included in the short-form. However, item 7 ("took sick time or worked less than usual") seemed to be rather incongruous with the other six items in that only this item did not involve any medication or healthcare provider(s) as patients' coping behaviors in its content. Therefore, this item was no longer considered, remaining six items final short-form. Items in this short-form covered the majority (about 79%) of the whole information and exhibited a wide span across the whole coping range (Figure 4-13).

Figure 4-13. Test information on the 11 item pool and the 6-item short-form



4.6 Person scores and T-score metric

Using a person's response patterns, the coping scores were estimated in an IRT-metric. Table 4-21 and Figure 4-14 show a distribution of the EAP estimates of person scores which ranged from -1.67 to 2.15 with a mean of 0 and SD of 0.91. Since normal distribution was used as a prior distribution, the estimated EAP scores were toward zero.

To improve interpretations of the scores, the scores were transformed into a T-score metric (mean = 50, SD = 10) using a person's summed scores. Table 4-22 shows conversions from summed scores to T scores. Using the conversion table, a total score of 6, for example, is converted to a T-score of 55 with a standard error of 4. Therefore, the 95% confidence interval for this observed score ranges from 47.2 (= 55-1.96*4) to 62.8 (= 55+1.96*4). From the converted T-scores, patients' coping level can be compared to the reference group which is the calibration sample in this study. A patient with a coping

score of 60, for example, indicates that this patient coping level is one standard deviation higher than the mean of the calibration population.

However, the converted T-scores may not be reliable because sample size in our study is not enough to be representative of the general population.

Table 4-21. Frequencies of the expected a posteriori (EAP) estimates of person scores

Estimated coping scores ($\hat{\theta}$)	Number of patients
$\hat{\theta} < -2.0$	0
$-2.0 \leq \hat{\theta} < -1.5$	8
$-1.5 \leq \hat{\theta} < -1.0$	12
$-1.0 \leq \hat{\theta} < -0.5$	27
$-0.5 \leq \hat{\theta} < 0$	24
$0 \leq \hat{\theta} < 0.5$	31
$0.5 \leq \hat{\theta} < 1.0$	21
$1.0 \leq \hat{\theta} < 1.5$	11
$1.5 \leq \hat{\theta} < 2.0$	5
$2.0 \leq \hat{\theta} < 2.5$	1
$2.5 \leq \hat{\theta}$	0

Figure 4-14. Distribution of the expected a posteriori (EAP) estimates of person scores

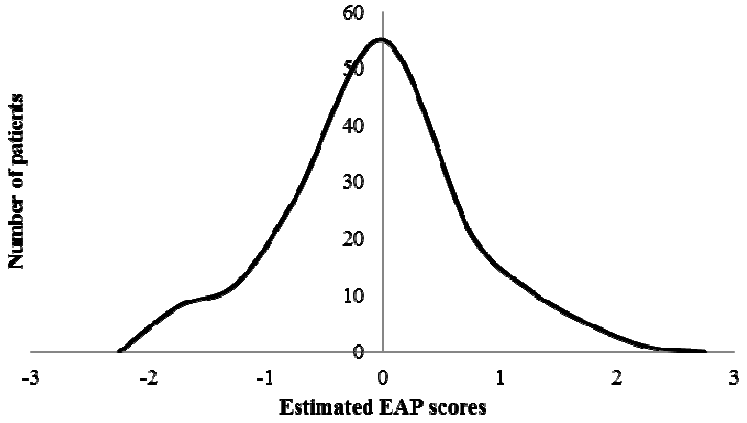


Table 4-22. Summed score to scale score conversion table*

Summed score	Scaled score (T)	Standard error
0	33	6
1	39	5
2	43	5
3	46	4
4	49	4
5	52	4
6	55	4
7	58	4
8	61	4
9	64	4
10	68	4
11	72	5

* Scale scores are on a T-score scale. The values of standard deviation are reported as conditional standard error of measurement.

4.7 Relationship between medication-problem coping scale and other constructs

Correlations between this coping scale and other constructs were examined to assess convergent validity. First, as predicted, the coping scale was significantly correlated in a positive direction with problem scale ($r = 0.646$, $p < 0.000$). The mean coping scores for each group were shown in Table 4-23 and Figure 4-15. They suggest that coping scores (θ) were significantly higher in patients who perceived their problem as being larger. That is, patients reporting their ADP as large showed higher coping scores than those who perceived their ADP as small.

Before evaluating the correlations between the coping level and health literacy level, a patient's coping score (θ) was transformed into an exponential form (i.e., exp(θ)) because the homoscedasticity assumption was violated for the raw θ scores. Therefore, the correlations between them were appraised after this assumption was met with the transformed exponential scores. Results showed that patients with a high level of health literacy did not possess a significantly high coping level ($r = 0.127$, $p = 0.141$). To examine correlations between the exponential coping scores and health literacy levels in more detail, their relationships were graphically investigated (Figure 4-16). To investigate whether patients' information seeking behavior is associated with their health literacy level, we compared patients' health literacy levels between patients who sought out information and those who did not. As expected, health literacy levels for patients who sought out information to resolve their ADP were significantly higher compared to those who did not (X^2 (4, $N = 136$) = 10.51, $p = 0.033$). This indicates that individuals

with higher confidence for their health literacy are more likely to seek out information as a way of handling their ADP.

Table 4-23. Mean coping scores for different problem intensity groups

Problem Scale	N	Mean coping score
Very small	10	-1.038
Small	27	-0.499
Moderate	44	-0.312
Big	32	0.366
Very big	27	0.955
Total	140	0

Figure 4-15. Mean coping scores for different problem intensity groups

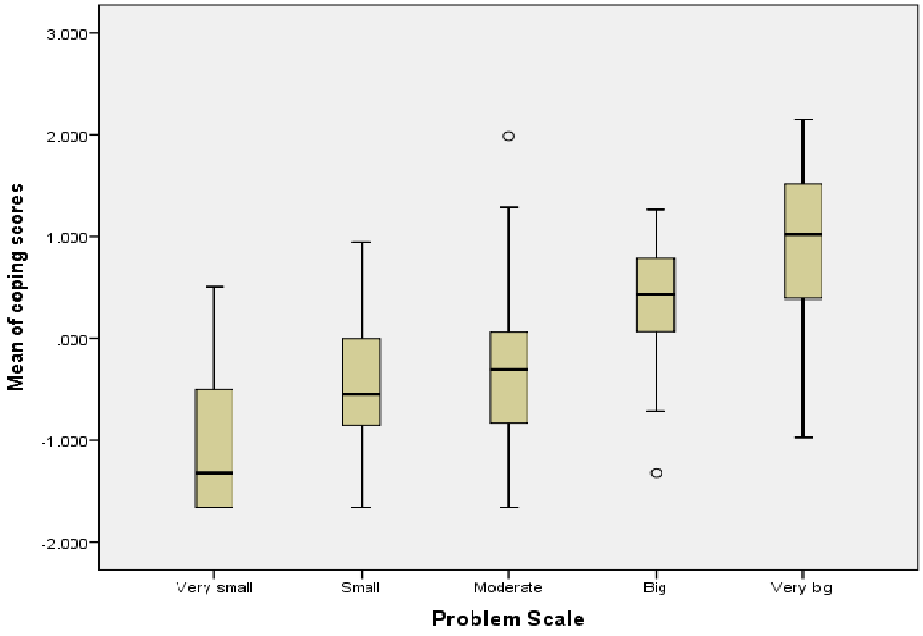
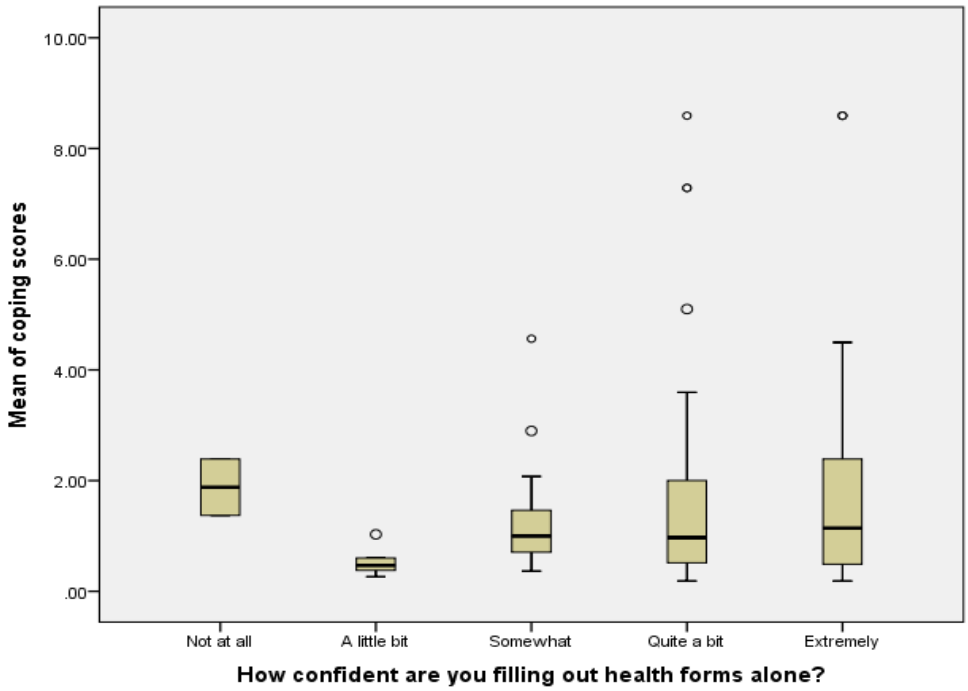
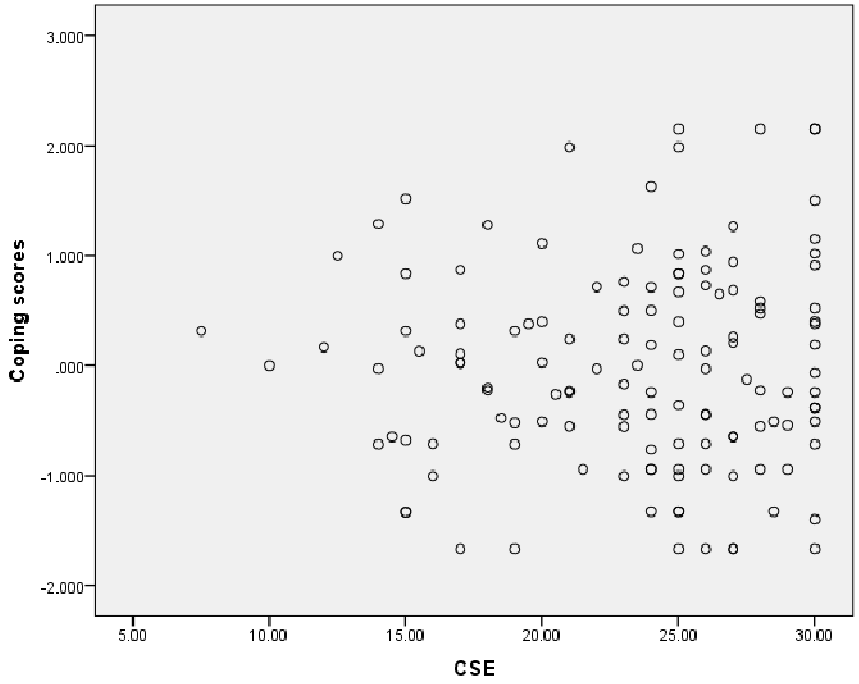


Figure 4-16. Relationships between coping scores and health literacy levels



Finally, relationships between the coping scale and coping self-efficacy were investigated as shown in the Figure 4-17. Although positive correlation between patients' coping self-efficacy and coping levels (θ) was hypothesized, this correlation was unexpectedly very weak ($r = 0.029$, $p = 0.744$). That is, patients' ADP-coping levels were not or little correlated with their levels of coping self-efficacy. However, we observed the presence of ceiling effects (i.e., substantial scores were at or near the highest possible score) in our sample. Because of ceiling effects, only partial information about the scores of patients scoring at the ceiling was available, which might limit the ability to distinguish true differences between patients scoring at the highest in the CSE scale. Alternatively, patients may cope with their ADP using a different mechanism as they do when facing other general problems. Because coping self-efficacy was measured for handling general problems and not specific to adverse drug problems, patients' coping levels in response to their ADP were not necessarily related to their levels of coping self-efficacy. In other words, patient's coping may be very specific to the characteristics of task or situation.

Figure 4-17. Relationships between the coping scale and coping self-efficacy



Chapter 5 : DISCUSSION

5.1 Summary of study results

The present study developed a medication-problem coping scale to measure patients' coping responses to their perceived ADP using item response theory. The developed scale is brief and easy to administer for clinicians to receive patients' immediate feedback on their coping behaviors. Patients' coping behaviors would be measured precisely by applying items with good discriminating abilities and varying difficulty levels.

Results of model comparison showed that the 2PL model was favored over 1PL based on its better fit to the item response patterns, more reliable θ score estimates, and less standard error of measurement over the coping continuum. The final 11-item pool, which was calibrated using the 2PL model, demonstrated adequate psychometric properties including unidimensionality, local independence, and acceptable fit statistics. DIF was examined for items in the final pool between patients who perceive the problem intensity differently and between different groups in demographics and health literacy levels. Items with significant X^2 results stemmed from their unreliable parameter estimates due to very few observations in the response categories rather than their differential functioning for different groups. For these items, DIF should be reexamined with a much larger sample to obtain reliable parameter estimates for these items that are infrequently endorsed.

The coping scores were computed based on IRT response patterns using a Bayesian approach, an expected a posterior (EAP) method. Alternatively, the overall coping scores were obtained by summing individual item scores to convert the summed scores to T-scores. Using such norm-based scores, an individual's coping level can be quickly and conveniently interpreted. However, a further study with large sample size in diverse clinical settings is recommended to produce more stabilized respondents' scores and T-scores. This will allow comparison of patients' coping status with a more global reference group (e.g., the general clinical population) than the calibration sample in this study.

A short-form was constructed with six items selected based on their amount of information and content representation. All items in the short-form exhibited *high* or *very high* discrimination parameter estimates. This 6-item short-form provided the majority of the test information, suggesting its comprehensive coverage along the coping trait continuum. The short-form will be used to reduce patients' burden and save clinicians' time in various settings. However, if it is required to measure a coping trait more precisely, the whole 11-item pool should be administered to produce a more precise score.

Convergent validity was assessed by testing *a priori* hypotheses about expected correlations between the coping levels and other related measures. First, coping levels (θ scores) were compared between groups who perceived their problem intensity differently. As expected, respondents reporting their ADP as relatively large had rather higher coping levels compared with those who perceived their ADP as small, supporting convergent validity. These findings broadly suggest that the medication

problem coping item banks are able to detect changes in perceived problem intensity. Contrary to expectations, patients' coping levels were not significantly correlated with their health literacy levels. However, health literacy levels were higher in patients who sought out information as a coping behavior than those who did not. This indicates associations particularly between critical health literacy and information-seeking behavior as a way of coping. Because of the critical literacy component, which was defined as high level of cognitive and social skills required to access, understand, and evaluate information on the determinants of health, and to use this information to control situations (WHO), health literacy has expanded its conceptual meaning to include information-seeking, along with a multitude of other imperative abilities and skills to make health-related decisions. Our results empirically supported this conceptualization of health literacy.

Finally, there was unexpectedly little or no relationship between patients' coping levels and their coping self-efficacy. However, ceiling effects should be noted when interpreting this result. The true relationship between them might be weakened because of the limited ability to distinguish true differences between patients scoring at the highest levels in the CSE scale. Using all six items rather than three items of the problem-focused CSE scale might overcome this problem. Alternatively, there might be little or no relationship between them aside from ceiling effects. That is, a patient's coping level was not necessarily high even though their coping self-efficacy for handling the general problems was high. This suggests that patients' coping seemed to vary depending on the situations. For example, when a patient faces a medication-related problem as this study, the patient may think that this situation requires

practitioner's interventions and less actively cope with this problem even though their coping self-efficacy is high. This is a different situation compared to several cases shown in the previous studies where patients can control the problems on their own by changing their behaviors such as a smoking cessation, weight control, or use of contraception. For this reason, the importance of understanding an encountered specific situation should be noted in assessing an individual's coping. As Maes et al. stated in a review of coping with chronic illness, "only studies that take into account characteristics of the stressor can lead to a full understanding or the coping process and its success" (Zeidner & Endler, 1996) .

5.2 Study limitations

Several limitations of this study should be noted. First, the use of a non-probability sample collected only from the community pharmacies and small sample size limits the degree to which study results can be generalized. It is not certain how much respondents in this study perceive ADPs and respond to them differently compared to patients in other clinical setting (e.g., hospital or nursing facility). Patients where their access to practitioners is easily made may answer differently to the questionnaire. They might more frequently endorse the items that involve an interaction with practitioners as a coping strategy compared to this study sample. This would result in different parameter estimates for such items. In addition, parameters in IRT are estimated more accurately with large sample sizes. With small sample sizes, a simple model which allows only a difficulty parameter to vary (e.g., 1PL) is known to be

adequate. For example, Linacre suggested a sample size of more than 30 or 50 for the simple Rasch model to be 95% or 99% confident that no item parameter is more than 1 logit from its stable value (Linacre, 1994). However, larger sample sizes are required as the model becomes complex with more parameter estimates. In this study with a sample size of 140, items fit the 2PL model better than the 1PL model. However, a future study with larger sample size can produce more stable parameter estimates. It also allows cross-validation with independent sets of data in model comparisons. Second, a causality assessment on the relationship between patients' perceived ADPs and their coping was not conducted; thus, there is a possibility that the problems perceived by patients are incorrectly attributed to their medication use. They may in fact result from other causes, such as the disease itself or their diet. However, the ultimate purpose of this study is to identify health problems that patients perceive and to improve their medication management after communicating with clinician once patients are recognized as having ADPs. In this sense, the true unknown origin of the problems is not a big concern if this scale is used as intended. Finally, since only problem-focused coping was highlighted in a new measure, the suitability of this measure for patients who mostly employ emotion-focused coping is questionable. For example, this scale may not be applicable to patients with a high level of negative symptoms in schizophrenia who are known to use most emotion-related coping and less problem-focused coping in response to stressors (Wiedl, 1992). Further study that includes items related to emotion-focused coping would enable investigation of this coping type in such population.

5.3 Strengths of study

To my knowledge, this is the first study that developed a medication problem coping scale using item response theory (IRT). As a novel technique, this theory has gaining its prominence in the development and evaluation of a variety of health-related measures. The scale developers take advantages of using IRT because it provides more precise measures with fewer items, and improves efficiency by minimizing the number of items required to obtain a desired degree of precision. Therefore, in this study, a scale was developed using IRT to provide more precise measures across the full spectrum of patients' coping ranges, with less respondent burden. In addition, patients' coping with perceived ADP is measured based on the patients' perspectives. Over the past 40 years, the paradigm in healthcare has shifted, placing patients from passive recipients of treatment to active players in the process of care. In the new paradigm, the influence of patients' perspectives in health-related decisions has grown in importance. This change notwithstanding, patients' experience of ADPs has been evaluated from the clinicians' perspective to date. Notably, there is a considerable discrepancy between patients' perceived ADPs and physicians' evaluations of ADPs. In addition, clinicians may not even be aware of the patients' perceived ADPs. Using a newly developed scale, patients can report their coping strategies when they perceive ADPs. This is the most precise way of measuring them, particularly when patients' self-reports do not correspond to those drawn from clinical measures. The outcome of this study is the practical scale that clinicians can use in their patient population to receive patients' immediate feedback on their coping with perceived ADP. In particular, it can serve as a screening device for further formal assessment of ADPs and a guidance to develop a future intervention.

Clinicians will be able to provide appropriated interventions tailored to the individual who suffer from an ADP. After receiving practitioners' assistance on the ADP, patients are able to achieve safe medication use by improving ADP management.

5.4 Future research

Future research will involve further validation of the MPCS item banks. Validity can be evaluated by comparing information about a patient's responses to ADPs obtained from the patient's medical records (e.g., whether a patient discontinued the ADP-related medication, discussed the ADP with a healthcare provider, asked a healthcare provider to prescribe a different medication due to the ADP, visited a healthcare provider to resolve the ADP, visited an emergency department or urgent care, or was hospitalized) with such information from MPCS. Consensus between them made by experts will support validity. If validity of the MPCS is evidenced, its utility, as a screening device or a case identification tool, can be investigated in clinical settings. The MPCS was developed to suggest a coping level that was associated with the ADP intensity. This implies that patients with a high coping level are more likely to perceive their ADP as large. Therefore, healthcare providers can have opportunities to provide interventions to their patient with a high coping level using information from the MPCS. Such information includes whether the patient is still using the problem-related medication, discussed the problem with a healthcare provider already, or went to a hospital to treat the problem. If a healthcare provider finds out that his or her patient who perceived the ADP as large still uses an ADP-related medication, the healthcare

provider can discuss about discontinuing and changing the medication with the patient. Alternatively, the healthcare provider can ask the details about the ADP that a patient experienced unless the patient has discussed it yet, and develop a next treatment plan.

Conclusions

State of the art IRT methods were employed to develop a reliable and valid medication-problem coping scale and its brief version (Appendix F and G). This new measure of how patients cope with ADPs warrants further research to establish its clinical utility. The final item bank and its short-form should be applied to large samples in diverse clinical settings to evaluate their usefulness. Further research is needed to test the validity and accuracy for identifying clinically significant adverse drug problems.

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Appendices

Appendix A. Study questionnaire

Part I: Problems from Medication Use

Screening questions:

1. Have you used any prescribed medication(s) on a regular basis?

□ Yes

□ No → If you will use the prescription(s) you are picking up today, may I call you if about a month to ask about any problem that is associated with medication use?

□ Yes (Phone #:) □ No → **Thank you!**

2. (If yes) How many medications do you take? _____

3. In the last year, have you had any new medication-related problems or have any of your health problems become worse because of your medication(s)?

□ Yes

□ No → **Go to Part II**

(If yes) Please pick the most bothersome problem and describe it briefly. Which medication was the most associated with this problem?

_____

4. When you experienced the problem, how long did the problem last? _____

5. How often have you experienced this problem while using this medication?

_____

6. To what extent, was this a problem for you?

□ Very small problem □ Small problem □ Moderate problem □ Big problem □ Very big problem

To handle the medication-related problem identified in the previous question #3, did you…

1. Entirely stop using the medication?	□ Yes	□ No
2. Continue to use the medication as prescribed in spite of the problem?	□ Yes	□ No
3. Use the medication less frequently?	□ Yes	□ No
4. Reduce the dose of the medication?	□ Yes	□ No
5. Use a non-prescription medication instead of using the medication?	□ Yes	□ No
6. Use home remedy instead of using the medication?	□ Yes	□ No
7. Search for written information about the problem (on the internet, in a book, etc)?	□ Yes	□ No
8. Try to learn more about if the problem is related to your medication?	□ Yes	□ No
9. Try to see if other people like you experienced the same problem you had?	□ Yes	□ No
10. Seek out information that would help you resolve the problem?	□ Yes	□ No
11. Discuss the problem with your family or friends?	□ Yes	□ No
12. Discuss the problem with your pharmacist?	□ Yes	□ No
13. Discuss the problem with your physician or nurse?	□ Yes	□ No
14. Ask your physician or nurse to prescribe a different medication?	□ Yes	□ No
15. Limit your activities or change your daily routines?	□ Yes	□ No
16. Take sick time or work less than usual?	□ Yes	□ No
17. Get another prescription medication to treat the problem?	□ Yes	□ No
18. Use a non-prescription medication to treat the problem?	□ Yes	□ No
19. Use home remedy to treat the problem?	□ Yes	□ No
20. Go to visit your pharmacist to resolve the problem?	□ Yes	□ No
21. Go to visit your physician or nurse to resolve the problem?	□ Yes	□ No
22. Visit an emergency department or go to urgent care?	□ Yes	□ No
23. Get admitted to the hospital?	□ Yes	□ No

24. How satisfied are you with how the medication problem was handled?

□ Very unsatisfied □ Unsatisfied □ Neither unsatisfied nor satisfied □ Satisfied □ Very satisfied

Part II: Information About you

1. Gender: □ Male □ Female

2. Age: _____

3. Which best describes your race:
□ White
□ Black or African-American
□ American Indian or Alaska Native
□ Asian
□ Native-Hawaiian or other Pacific Islander
□ Hispanic or Latino
□ Other, describe: _____

4. Do you have somebody who lives with you to help you use your medication(s)? □ Yes □ No

5. What is your employment status?
□ Currently employed
□ Currently unemployed
□ Retired
□ Other, describe: _____

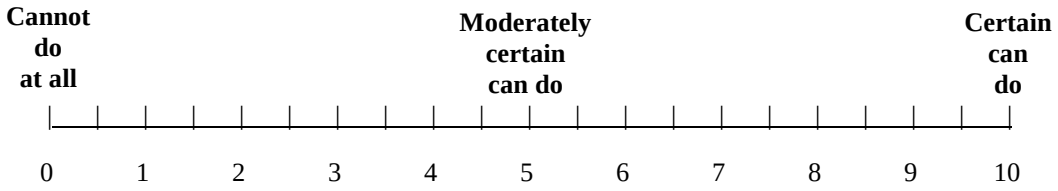
6. What is your highest level of education?
□ High School
□ Some college
□ College graduate
□ Post graduate

7. Do you have a health insurance? □ Yes □ No

8. Do you have a healthcare background? □ Yes □ No

9. How confident are you filling out health forms by yourself?
□ Not at all □ A little bit □ Somewhat □ Quite a bit □ Extremely

For each of the following items, write a number from 0 – 10, using the scale below.



When things aren't going well for you, how confident are you that you can:

10. Sort out what can be changed, and what cannot be changed. _____

11. Break an upsetting problem down into smaller parts. _____

12. Make a plan of action and follow it when confronted with a problem. _____

Appendix B. IRB application: Consent form

CONSENT FORM

Development of an instrument to assess patient's coping responses to perceived adverse drug problems (ADPs) using item response theory (IRT)

You are invited to be in a research study of experience of adverse drug problems (ADPs) and coping responses to such problems. You were selected as a possible participant because you have taken one or more medication(s), and experienced a health-related problem that you attribute to your medication use. We ask that you read this form and ask any questions you may have before agreeing to be in the study.
This study is being conducted by Taehwan Park, PhD candidate, Social and Administrative Pharmacy at the University of Minnesota.

Background Information

The purpose of this study is to examine patients' experience of a health-related problem after starting taking a medication and how they decide to handle such a problem. This study involves no medicines or invasive procedures. All participants will continue their usual medical care. We only ask a few basic questions about a health-related problem that you attribute to your medication use, and about 20 questions about how you coped with such problem.

Procedures:

If you agree to be in this study, you will receive a questionnaire which is expected to be completed. The questionnaire consists of a few basic questions asking about your experience of a health-related problem, and about twenty questions asking about frequency of what you did to cope with such a problem. That is, each question will show each possible coping behavior and you can check how often you actually behaved in that way among the five response categories (i.e., never, rarely, sometimes, often, and very often). It will not take longer than 10 minutes. If a question is not clear or the meaning of a question is not understandable, please feel free to ask me.

Risks and Benefits of being in the Study

There is no expected risk and benefit to you as a participant in this study. However, if you feel any discomfort or embarrassment for any reason while answering the question, you are free to deny answering it.

Compensation:

There are no costs involved in participating in this study. You will not be paid for your participation.

Confidentiality:

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality.

Voluntary Nature of the Study:
Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:
Taehwan Park is the researcher responsible for conducting this study. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact me at parkx672@umn.edu or (213) 200 0314. You may also contact my advisor, Dr. Ronald S Hadsall at [redacted].

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455; (612) 625-1650.

Appendix C. IRB approval

From: irb@umn.edu
To: parkx672@umn.edu
Subject: 1204E12567 - PI Park - IRB - Exempt Study Notification
Date: Mon, 16 Apr 2012

TO : [redacted], parkx672@umn.edu,

The IRB: Human Subjects Committee determined that the referenced study is exempt from review under federal guidelines 45 CFR Part 46.101(b) category #2 SURVEYS/INTERVIEWS; STANDARDIZED EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR.

Study Number: 1204E12567

Principal Investigator: Taehwan Park

Title(s): Development of an instrument to assess patient's coping responses to perceived adverse drug problems (ADPs) using item response theory (IRT)

This e-mail confirmation is your official University of Minnesota RSPP notification of exemption from full committee review. You will not receive a hard copy or letter. This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

The study number above is assigned to your research. That number and the title of your study must be used in all communication with the IRB office.
Research that involves observation can be approved under this category without obtaining consent.

SURVEY OR INTERVIEW RESEARCH APPROVED AS EXEMPT UNDER THIS CATEGORY IS LIMITED TO ADULT SUBJECTS.

This exemption is valid for five years from the date of this correspondence and will be filed inactive at that time. You will receive a notification prior to inactivation. If this research will extend beyond five years, you must submit a new application to the IRB before the study's expiration date.

Upon receipt of this email, you may begin your research. If you have questions, please call the IRB office at (612) 626-5654.
You may go to the View Completed section of eResearch Central at http://eresearch.umn.edu/ to view further details on your study.

The IRB wishes you success with this research.

Appendix D. Project introduction to Minnesota Pharmacy PBRN

To whom it may concern,
You are invited to participate in a research study of patients' experiences of adverse drug problems (ADPs) and coping responses to such problems. I am writing as the principal investigator of this research project from the University of Minnesota, and you were selected because your pharmacy is incorporated in the Minnesota practice-based research network (PBRN). Your participation is very much needed as we begin to collect data. Please read this over and let us know if you are able to participate in this study using contact information below.

Study Information
The purpose of this study is to examine patients' experiences of ADP after taking medication and how they decide to handle such an identified problem. This study is based on a questionnaire/interview conducted by me (Taehwan Park), and involves no medicines or invasive procedures. We ask a few basic questions about an ADP that your patient's experienced and attribute to their medication use. This study and the protocol have been approved by the University of Minnesota's Institutional Review Board (IRB) (Study number: 1204E12567).

Procedures:
If you allow this study to be conducted in your pharmacy, your patients will be asked about their willingness to participate in this study. A patient is eligible if he or she has any health-related problem that they attribute to their medication use. If a patient agrees to be involved in this study, he or she will receive a questionnaire or participate in an interview. The questionnaire consists of a few basic questions asking about experiences with the health-related problem, and about twenty yes/no questions asking whether patients used each coping strategy. It will not take longer than 15 minutes per patient. I will assist each patient in answering the questions. There are no expected risks or benefits to the participants in this study, and they are free to choose not to participate in the study or answer any question during their participation.

Time period of the Study:
We will start to collect data from your patients contingent on your decision. It will continue until we can obtain 200 responses from the participating pharmacies incorporated in the Minnesota PBRN - including your pharmacy if you chose to participate. We do not anticipate data collection taking longer than 10 days in your pharmacy. Participation in this study is voluntary and you can withdraw your participation at any time. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota or the Minnesota PBRN. There is no compensation for or costs involved in participating in this study. However, we would like to acknowledge you in the dissertation or any future publication from the study as a token of our appreciation. A copy of results and tested instrument will be available upon your request.

Contacts and Questions:

Taehwan Park is the researcher responsible for conducting this study under the guidance of his advisor, Ronald S Hadsall. If you have any question or want to see a copy of questionnaire or IRB approval prior to participation, please contact me at parkx672@umn.edu or (213) 200 0314 or my advisor at [redacted]. You may also contact a director of graduate studies, Dr. Jon C Schommer at [redacted].

Thank you.

Appendix E. Participant recruitment script

Recruitment script

Hello, my name is Taehwan Park and I am a graduate student at the University of Minnesota College of Pharmacy. I am doing a research project of investigating individual's experience on drug-related problems. I'd like to know if you are willing to participate in this study. If you agree to participate, I will ask you to complete a questionnaire which consists of about twenty main questions. They are asking about your drug-related problem and how you handled it. This will take about 10 minutes at most. Would you be willing to participate?

(If a subject does not want to participate,) Thank you.

(If a subject agrees to participate,) Thank you very much for your participation. Now I will get you a questionnaire which you can complete. If any question is not clear or the meaning of a question is not understandable, please feel free to ask me.

Do you have any question before we start?

Appendix F. Medication Problem Coping Scale (MPCS) Items

MEDICATION PROBLEM COPING SCALE (MPCS)

In the last year, have you had any side effect or have any of your health problems become worse because of your prescribed medication(s)?

□ No □ Yes

If "**No**", you have completed this questionnaire. If "**Yes**", please specify this problem you experienced and answer the following questions below. (If you have more than one problem, please select the most bothersome problem.)

Problem:_____

There are many different ways to deal with side effect problems. Here are some strategies that people use to handle such problems. Please indicate whether you used each strategy to hadle **the problem you specified above**.

To handle the problem you identified, did you…

1. entirely stop using the medication?	□ No	□ Yes
2. seek out information that would help you resolve the problem?	□ No	□ Yes
3. discuss the problem with your family of friends?	□ No	□ Yes
4. discuss the problem with your healthcare provider?	□ No	□ Yes
5. ask your physician or nurse to prescribe a different medication?	□ No	□ Yes
6. limit your activities or change your daily routines?	□ No	□ Yes
7. take sick time or work less than usual?	□ No	□ Yes
8. get another medication or home remedy to treat the problem?	□ No	□ Yes
9. visit your healthcare provider to resolve the problem?	□ No	□ Yes
10. visit an emergency department or go to urgent care?	□ No	□ Yes
11. get admitted to the hospital?	□ No	□ Yes

Thank you!

Appendix G. Brief Medication Problem Coping Scale (BMPCS) items

BRIEF MEDICATION PROBLEM COPING SCALE (BMPCS)

In the last year, have you had any side effect or have any of your health problems become worse because of your prescribed medication(s)?

□ No □ Yes

If "**No**", you have completed this questionnaire. If "**Yes**", please specify this problem you experienced and answer the following questions below. (If you have more than one problem, please select the most bothersome problem.)

Problem:_____

There are many different ways to deal with side effect problems. Here are some strategies that people use to handle such problems. Please indicate whether you used each strategy to hadle **the problem you specified above**.

To handle the problem you identified, did you…

1. entirely stop using the medication?	□ No	□ Yes
2. discuss the problem with your healthcare provider?	□ No	□ Yes
3. ask your physician or nurse to prescribe a different medication?	□ No	□ Yes
4. visit your healthcare provider to resolve the problem?	□ No	□ Yes
5. visit an emergency department or go to urgent care?	□ No	□ Yes
6. get admitted to the hospital?	□ No	□ Yes

Thank you!