

## MEDICATION-THERAPY-RELATED QUALITY OF LIFE MEASUREMENT USING THE PATIENT-GENERATED INDEX: A PILOT STUDY

PHANTIPA SAKTHONG\*<sup>1</sup>, RUNGPECH SAKULBUMRUNGSIL<sup>2</sup>, WIN WINIT-WATJANA<sup>3</sup>

<sup>1</sup>Department of Pharmacy Practice, <sup>2</sup>Department of Social and Administrative Pharmacy, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand, <sup>3</sup>Department of Pharmacy Practice, College of Clinical Pharmacy, University of Dammam, Dammam, Saudi Arabia. Email: phantipa.s@chula.ac.th; psakthong@gmail.com

Received: 19 Apr 2013, Revised and Accepted: 22 May 2013

### ABSTRACT

The study aimed to measure medication-therapy-related quality of life (MTRQoL) using the individualized approach – Patient-generated Index (PGI). Twenty-five patients were identified at the Medication Therapy Management Clinic of the Faculty of Pharmaceutical Sciences, Chulalongkorn University in Bangkok between September 2010 and March 2011. The PGI method included three steps: 1) select five domains affected by taking medication from the list of 24 domains; 2) rate each of the selected five domains on a scale ranging from 0 (the worst status) to 100 (the best status); and 3) distribute 10 points across the different selected domains patients wished to improve. Weighted scores were summed up across the domains to create a 0-1 index, with higher scores indicating a better MTRQoL. The results showed patients' mean age was 56.9±13.5 years and 52% were female. The MTRQoL index score was 0.57±0.24. Top 5 selected domains (≥50%) were getting medication information, fear of medication side-effects, security/safety in life, medication dependence, and pain/discomfort. The MTRQoL measurement using the PGI proved to be useful. Drug therapy reduced patients' QoL by 40% from their normal lives. The most affected MTRQoL domains identified will be beneficial for the development of a future questionnaire.

**Keywords:** Medication-related quality of life, Individualized quality of life, Pharmaceutical care, Patient-generated Index, Thailand.

### INTRODUCTION

Health-related quality of life (HRQoL) is a patient's subjective perception of the impact of disease and treatment on physical, psychological and social functioning[1]. Assessing HRQoL is an important step of the medication therapy review of medication therapy management (MTM)[2]. However, most widely used HRQoL measures, such as the Short-Form Health Survey (SF-36), are not sensitive enough to detect the impacts of pharmacist's interventions or pharmaceutical care (PC) on a patient's life[3-8]. Thus, Murawski and colleagues developed a questionnaire to specifically assess the impact of pharmaceutical therapy on quality of life[9]. Nevertheless, it has not been widely employed. Additionally, the translated Swedish version was found to have poor validity, as the respondents did not understand its questions and introduction and it also had redundant items[10].

Two approaches to measuring HRQoL include standardized questionnaires (e.g. SF-36) and individualized approaches namely the Patient Generated Index (PGI)[11]. The PGI approach helps individual patients to identify their own impact domains and give a weight to each domain themselves, whereas most standardized instruments provide predetermined items, each of which carries the same weight for all patients. Most standardized approaches therefore assess health status rather than HRQoL, which specifically evaluate the impact of disease and treatment. This is one of the main reasons why the tools are not sensitive enough to assess the impact of providing PC[3-8]. Thus, this study was intended to use the PGI to measure the specific impact of medication-therapy-related quality of life (MTRQoL) on a patient's life, which has never been investigated before.

### MATERIALS AND METHODS

#### Patients and Procedures

This is a cross-sectional study, as part of the pilot project for the development of patient-centered pharmaceutical care, of which objectives were to explore patients' medication experiences and MTRQoL. A convenience sample was identified at the Medication Therapy Management (MTM) Clinic run by pharmacists of the Faculty of Pharmaceutical Sciences, Chulalongkorn University in Bangkok from September 2010 to March 2011. Of the 34 patients approached by the pharmacists, 25 (74%) were included in the study. The eligible criteria included adults aged over 20, taking

medicines continuously for at least three months, understanding the Thai language with no cognitive impairments, and willing to participate in the study. After the patients provided written informed consent, they were interviewed face-to-face by the first investigator (PS) in a consultation room of the MTM clinic. Each interview took about 1 – 2 hours and all patients received 200 baht (US\$6.5) as an incentive. This study was approved by the Ethics Committee of the Faculty of Pharmaceutical Sciences at Chulalongkorn University.

#### Study Instrument

The Patient-generated Index (PGI) was utilized. It included three steps: 1) choose five domains (could be fewer or more than 5) affected by taking medications from the list of impact domains (see Appendix); 2) rate each domain selected on the scale ranging from 0 (the worst possible) to 100 (the best possible); and 3) distribute 10 points across the chosen domains patients wanted to improve[11]. It is however unnecessary to give points to every domain, but all points need to add up to make 10 in total. The MTRQoL index was the sum of multiplication products, i.e. the domain ratings of step 2 by the corresponding domain weights in step 3. Examples of patients' MTRQoL index scores are demonstrated in Tables 1 – 3. The index score was between 0 and 1, with higher scores indicating a higher MTRQoL.

The list of 24 domains impacted by medication use, as detailed in Appendix, was developed using two generic HRQoL measures, i.e. WHOQoL-BREF (11 domains)[12] and EuroQoL (5 domains)[13], literature relating to medication experiences (6 domains)[9],[14-15], and patients' nominations during interviews (2 domains). The list mainly covers domains from the WHOQoL-BREF, since it was a large-scale study conducted in 15 countries around the world including Thailand and its domains are highly reliable.

#### Data analysis

All data were entered into PASW Statistics 17 (SPSS-IBM Co., Chicago, IL) and descriptive statistics was used to analyze patient characteristics and MTRQoL data. Percentages and frequencies were calculated for categorical variables, but the means, standard deviations (SD), medians, and range (minimum-maximum) were for continuous variables.

## RESULTS

### Patient characteristics

Of 25 patients, the mean age was 56.9±13.5 years (range: 24 - 79) and 52% were female. Half of them were married and most patients had finished at least college levels. The most common diseases were hypertension (84%), hyperlipidemia (52%), and diabetes (16%). The average number of diseases and daily medications was 2.4±1.0 and 4.6±2.6, respectively.

### Medication-therapy-related quality of life

Three examples of patients' medication-therapy-related quality of life (MTRQoL) evaluations were considered noteworthy. The first measurement for a female patient aged 67 is summarized in Table 1. The patient was taking cilastazol for her cerebrovascular disease. This medication made her feel dizzy, thereby affecting her walking or mobility (rated 65/100 and weighted 3/10). She also felt insecure about her life; she feared when she left her house, she might have an accident (rated 65/100 and weighted 3/10). This affected visiting her mom every week (activities with the family), probably because she dared not go out (rated 65/100 and weighted 1/10). This medication was quite expensive (US\$ 100/month) (rated 60/100 and weighted 1/10). She was also worried about the drug side-effects (rated 40/100 and weighted 2/10). Overall, her MTRQoL index score was 0.60.

The second example of MTRQoL measurement for a male patient at the age of 61 is shown in Table 2. This patient suffered from hypertension and had been taking antihypertensive drugs for 10 years. Every time he took his medicines he was afraid of the side-effects and did not want to take them. He rated the 'stress/fear/concern of drug side-effects' domain as 0/100, indicating he feared for the adverse effects the most. The reason why he still took his medication was that he wanted to please his doctor, as he was once an employee at the hospital. After discussing with the pharmacist, he felt better and understood more about his medicines. As a result, he put the three selected domains, i.e. stress/fear/concern of medication side-effects, getting medication information, and value in life, as 100% (the best possible). He responded that he was happier and not worried about taking his medications after the pharmacist clearly explained his treatment. He was more convinced about medication intake and no longer feared for the adverse effects. Moreover, he was satisfied with his access to medication use due to his previous work at the hospital (rated 100/100). However, he felt he would still depend on medicines for the rest of his life (rated 0/100); he needed this domain to be improved the most (8/10), followed by value in life (2/10). His MTRQoL score was 0.2, but if he had not received MTM from the pharmacist, his score would have been only 0.1.

**Table 1: Medication-therapy-related quality of life (MTRQoL) of a 67-year-old female patient**

Please select 5 domains of life affected by taking your medication (both positive and negative impacts)	Rating of 5 selected domains on the 0-100 scale with anchors 'as good' and 'as bad' as could possibly be.	Suppose you have 10 points. Please distribute the 10 points to any selected domains for improvement. It is unnecessary to give the points to every domain but the sum must be 10 points.
1. Walking/mobility	65/100	3/10
2. Stress/fear/concern of medication side-effects	40/100	2/10
3. Activities with family	65/100	1/10
4. Security/safety in life	65/100	3/10
5. Financial status	60/100	1/10
<b>MTRQoL index score = (0.65×0.3)+(0.40×0.2)+(0.65×0.1)+(0.65×0.3)+(0.60×0.1) = 0.60</b>		

**Table 2: Medication-therapy-related quality of life (MTRQoL) of a 61-year-old male patient**

Selected impact domain	Rating score	Distribution of 10 points
1. Stress/fear/concern of medication side effects	100/100 (rated 0/100 before talking with the pharmacist)	0/10
2. Medication dependence	0/100	8/10
3. Availability/access to medications	100/100	0/10
4. Getting medication information	100/100 (rated 40/100 before talking with the pharmacist)	0/10
5. Value in life	100/100 (rated 50/100 before talking with the pharmacist)	2/10
MTRQoL index score before talking with pharmacist = (0×0)+(0×0.8)+(1.0×0)+(0.4×0)+(0.5×0.2) = 0.1		
MTRQoL index score after talking with pharmacist = (1.0×0)+(0×0.8)+(1.0×0)+(1.0×0)+(1.0×0.2) = 0.2		

Table 3 presents the last example of MTRQoL assessment for a 24-year-old female patient. She received enalapril, an antihypertensive drug, for one year by the time of the interview. During the past year, she had also developed a dry cough but was initially not aware of it being the drug adverse effect. Since she studied and worked part-time, she thought that her study and hard work made her susceptible to a cold. She went to the same hospital to treat her illness a few times over the one-year period. After that, she suspected her cough might be caused by enalapril, so she visited the MTM Clinic to ask about it. After she learnt that enalapril was causing her cough, she returned to see her doctor to change it to another antihypertensive drug. As for her MTRQoL, she was satisfied with the effectiveness of the new antihypertensive drug (rated 100/100) but felt negative about obtaining medicine information from healthcare providers in the past (rated 0/100).

In addition, she thought that taking an antihypertensive drug caused her more at risk of falling due to hypotension (i.e. rated mobility as 60/100). Moreover, she felt that her life had to rely on medication use and perceived it as a burden that her mother needed to remind her of taking medication from time to time; both domains were rated 50/100. Among the five selected domains, she preferred only the 'getting medication information' domain to be improved by giving all 10 points. Consequently, her MTRQoL score increased from 0.00 to 0.85 after receiving medicine information and pharmaceutical care from the pharmacist (85/100).

As shown in Table 4, for all 25 patients the average MTRQoL index score was 0.57±0.24 (range: 0.00-0.83). Five mostly selected domains were getting medication information (64%), stress/fear/concern of medication side-effects (56%), security/safety in life (52%), medication dependence (48%) and pain/discomfort (40%).

**Table 3: Medication-therapy-related quality of life (MTRQoL) of a 24-year-old female patient**

Selected impact domain	Rating score	Distribution of 10 points
1. Walking/mobility	60/100	0/10
2. Happiness/satisfaction with medication use	100/100	0/10
3. Medication dependence	50/100	0/10
4. Getting medication information	0/100 (rated 85/100 after talking with the pharmacist)	10/10
5. Feeling burdened with taking medications	50/100	0/10
MTRQoL index score before talking with pharmacist = $(0.6 \times 0) + (1 \times 0) + (0.5 \times 0) + (0 \times 1) + (0.50 \times 0) = 0.00$		
MTRQoL index score after talking with pharmacist = $(0.6 \times 0) + (1 \times 0) + (0.5 \times 0) + (0.85 \times 1) + (0.5 \times 0) = 0.85$		

**Table 4: Impact domains selected by patients (N = 25).**

Selected Domain	Number of patients (%)
1. Getting medication information	16 (64)
2. Stress/fear/concern of medication side effects	14 (56)
3. Security/safety in life	13 (52)
4. Medication dependence	12 (48)
5. Pain/discomfort	10 (40)
6. Happiness/satisfaction with medication use	8 (32)
7. Value in life	6 (24)
8. Diarrhea/constipation	6 (24)
9. Walking/mobility	4 (16)
10. Paid work	3 (12)
11. Availability/access to medications	3 (12)
12. Financial status	2 (8)
13. Convenience/difficulty of medication use	2 (8)
14. Energy	2 (8)
15. Leisure activities	2 (8)
16. Feeling burdened with taking medications	2 (8)
17. Body image	2 (8)
18. Sleep	2 (8)
19. Appetite	1 (4)
20. Activities with family	1 (4)
21. Personal relations with friends/others in society	1 (4)

## DISCUSSION

This was the first study that applied the Patient-generated Index (PGI), which is an individualized HRQoL approach, to measuring the specific impact of medication therapy on a patient's life. The mean MTRQoL index score was approximately 0.6 that implies taking medications decreases the patients' HRQoL by 40% from their normal or healthy lives. Moreover, the most important domains in life chosen by most patients (>50%) were involved in the provision of medicine information and psychological issues relating to medication use, e.g. concerns about adverse drug effects, medicine dependence, feeling insecure in life, etc.

Generally, the main purposes of HRQoL measurements are to evaluate the outcomes of treatment or interventions for patient care. This study demonstrates that the MTRQoL assessment could help healthcare professionals identify and resolve drug-related problems (DRPs) from a patient's perspective. As can be seen from the first example, the female patient experienced the medication side-effect (i.e. dizziness). At first, she told the physician about the adverse effect, but he replied he had given her the minimum drug dose and could not do more. After her physician knew about her MTRQoL or how the medication side-effect impacted on her daily life, he reduced her medication dose by half. Aside from that, from the second example the pharmacist could identify the patient's DRPs: he tried to avoid taking medications owing to his perceptions of the side effects and less efficacy. Thus, after his problems were identified and medicine information was provided, he felt more comfortable and less scared about his medicine in take. This slightly improved his MTRQoL from 0.1 to 0.2.

Furthermore, from the third example the patient suffered from the medication side-effect (i.e. dry cough) for one year although she had visited the hospital throughout the year. She felt very bad for not being told about the side-effect, thus rating the 'getting medication information' domain as '0' and gave the weight 100% to improve it.

This made her overall MTRQoL score '0'. However, after receiving medicine information from the pharmacist, she was happier and rated the getting medication information as 0.85. This raised her MTRQoL to 0.85. On the whole, although there is no standardized MTRQoL tool nowadays, the PGI approach can be applied to evaluate MTRQoL as the outcome of pharmacist's interventions.

Regarding the most impact domains, the result of this study are consistent with other studies in that medication side-effects and medication dependence are two issues of great concern by most patients[9,15]. Slightly different from other evidences is that the majority of patients in this study(64%) were not satisfied with medication information obtained from healthcare providers as mentioned in the examples. Cipolle and his colleagues[14] asserted that patient understanding of drug therapy is one of four drug-related needs including understanding, effectiveness, safety, and convenience. Current evidence has also pointed out that educating and counseling patients about their medicines could improve their medication adherence[16], knowledge and attitude towards the medication use[17]. Thus, pharmaceutical care providers should focus more on patient's understanding of their medications in terms of efficacy and safety.

## CONCLUSION

Medication therapy is likely to reduce patients' quality of life by 40% from their healthy lives. The medication-therapy-related quality of life (MTRQoL) measurement using the Patient-generated Index (PGI) method enables healthcare practitioners to identify and resolve drug-related problems, and to evaluate the outcomes of pharmaceutical care provision. This preliminary study also identified domains that are mostly affected by medication use. These domains will be useful for the development of a future MTRQoL questionnaire. Since this study was a pilot project conducting in only 25 patients, a large-scale study is required to explore further about MTRQoL in various patient groups.

## ACKNOWLEDGEMENTS

This study was funded by a grant from the Ratchadapiseksompoj Fund of Chulalongkorn University. The authors also wish to thank the patients for their valuable information. A part of the study was presented as a poster at the 18<sup>th</sup> Annual Conference of International Society of Quality of Life Research in Denver, USA, during October 26-29, 2011.

## REFERENCES

- Bungay KM, Boyer JG, Steinwald AB, Ware JE. Health-related quality of life: An overview. In: Bootman JL, Townsend RJ, McGhan WF, editors. Principle of pharmacoconomics. 2<sup>nd</sup> ed. Cincinnati (OH): Wharvey Whitney Books Company;1996. p.128-48.
- American Pharmacists Association and the National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: Core elements of an MTM service model (version 2.0). J Am Pharm Assoc 2008;48(3):341-53.
- MachadoM, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part II: systemic review and meta-analysis in hypertension management. Ann Pharmacother 2007;41(11):1770-80.
- Machado M, Nassor N, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part III: systematic review and meta-analysis in hyperlipidemia management. Ann Pharmacother 2008;42(9):1195-07.
- McLean WM, MacKeigen LD. When does pharmaceutical care impact health outcomes? A comparison of community pharmacy-based studies of pharmaceutical care for patients with asthma. Ann Pharmacother 2005;39(4):625-31.
- DesplenterFAM, Simoens S, Laekeman G. The impact of informing psychiatric patients about their medications: a systemic review. Pharm World Sci 2006; 28(6):329-41.
- HanlonJT, Lindblad CI, Gray SL. Can clinical pharmacy services have a positive impact on drug-related problems and health outcomes in community-based older adults? Am J Geriatr Pharmacother 2004;2(1):3-13.
- MaloneDC, Carter BL, Billups SJ, Valuck RJ, Barnette DJ, Sintek CD, et al. Can clinical pharmacists affect SF-36 scores in veterans at high risk for medication-related problems? Med Care 2001;39(2):113-22.
- Murawski MM, BentleyJP. Pharmaceutical therapy-related quality of life: Conceptual development. J Soc Admin Pharm 2001;18:2-14.
- RenbergT, Lindblad AK, Tulley MP. Testing the validity of a translated pharmaceutical therapy-related quality of life instrument, using qualitative 'think aloud' methodology. J Clin Pharm Ther 2008;33(3):279-87.
- RutaD, GarrattA, Leng M, Russel IT, MacDonald LM. A new approach to the measurement of quality of life: The patient generated index. Med Care 1994;32(11): 1109-26.
- WHOQOL Group. Development of the World Health Organization WHOQOL-BREF quality of life assessment. Psychol Med 1998;28(3):551-8.
- Dolan P, Gudex C, Kind P, Williams A. A social tariff for EuroQOL: results from a UK general population survey. Discussion Paper No. 138, Center for Health Economics, University of York. 1995.
- Cipolle RJ, Strand LM, Morley PC, editors. Pharmaceutical care practice: the clinician's guide. 2<sup>nd</sup> ed. New York: McGraw-Hill;2004.
- Shoemaker SJ, Ramalho de Oliveira D. Understanding the meaning of medications for patients: The medication experience. Pharm World Sci 2008;30(1):86-91.
- Santhosh YL, Naveen MR. Mediation adherence behavior in chronic diseases like asthma and diabetes. Int J Pharm PharmSci 2011; 3(3):238-40.
- Reema T, Adepu R, Sabin T. Impact of pharmacist intervention on knowledge, attitude and practice (KAP) of patients with chronic obstructive pulmonary disease. Int J Pharm PharmSci 2010; 2(4):54-7.