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Distress and health-related quality of life in Indonesian type 2 diabetes mellitus outpatients

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General Introduction

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GENERAL INTRODUCTION

The number of people with type 2 Diabetes Mellitus (T2DM) in Indonesia is increasing annually. Based on data from the IDF (International Diabetes Federation), in the last decade, the number has risen significantly from seven million in 2009 [1] to ten million at the end of 2017 [2]. Research by the Indonesian Ministry of Health supported this phenomenon by comparing the data in 2007 and 2013 [3]. The increasing number of people with T2DM, in turn, has impacted health care costs. As an illustration, in 2010, the costs going through the Indonesian state-owned health insurance company known as BPJS/Badan Penyelenggara Jaminan Sosial (the Social Security Administrative Agency) reached more than 138 billion Rupiah [4]. To respond to this situation, one attempt that can be made is to enhance the study of pharmacoeconomics to analyse the situation using various techniques, for example, cost-utility analysis (CUA) [5]. CUAs can help to identify cost-effective options for health care, for example, in T2DM. There are two main components that go into a CUA: costs and Quality of Life (QoL) data. This thesis aims to focus on the latter.

What is Quality of Life (QoL) and Health-Related Quality of Life (HRQoL)?

Many organizations have different ideas about QoL. The World Health Organization (WHO) has divided QoL into six inter-related domains. These are physical, psychological, level of independence, social relationships, environment, and spirituality/religion/personal beliefs [6]. Furthermore, the European Quality of Life (EuroQoL) Group Research Foundation argues that QoL consists of five dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, to be measured with the EQ-5D instrument [7,8]. Additionally, it should be realized that health-related quality of life (HRQoL) refers specifically to a part of QoL [9] that concerns how health affects QoL [10]. As such, HRQoL can be considered a self-perceived health status reported by T2DM outpatients/participants [10].

Why is it necessary to perform an assessment of health-related quality of life in type 2 diabetes?

People with T2DM are forced to accept many consequences. One of them is feeling challenged with the day-to-day demands of T2DM management, for example, being obliged to keep up with the therapy, selecting healthy food and doing regular exercise [11]. Also, those with T2DM must make time to check their blood-sugar level regularly [11]. Furthermore, a T2DM patient has to be prepared to face the social stigma surrounding diabetes or other diabetes-related stigmas [12]. A systematic review [12] reported that diabetes-related stigmas not only result in negative consequences on psychological well-being but also on self-care and clinical outcomes. To detect and potentially minimize those negative consequences, assessment of HRQoL needs to be done regularly and continuously. Notably, the results of these regular assessments can be used as a basis for selecting clinical and psychological interventions.

In Indonesia, there are some publications available on the assessment of HRQoL on T2DM, but these mainly focus on the island of Java [13–18]. This is likely to be because hospital data management in Java is better than many regions in Eastern Indonesia. Also, the population of Java is larger than that of the other four main islands in Indonesia, and the density of healthcare services and professionals is centered mainly in Java. We took participants from Java as well as Sulawesi since, in the last five years, the three provinces with the highest

percentage of T2DM patients in Indonesia were from the island of Sulawesi, namely: Central Sulawesi, North Sulawesi, and South Sulawesi [3].

In this general introduction, we searched in PubMed and Google Scholar, as well as sent emails to three HRQoL researchers in Indonesia to identify research on the subject matter concerning Indonesian T2DM patients. Two objectives of this literature review were:

i. to identify the type of instruments to be used to assess HRQoL in Indonesian T2DM patients; and
ii. to investigate T2DM-specific predictors for HRQoL.

By using the keywords "diabetes AND quality of life AND Indonesia," we found 14 studies, including national and international publications.

Type of instruments to be used to assess HRQoL in Indonesian T2DM

Five of the 14 identified studies were multi-country studies in Asia, which reported the relationship between using the correct type of insulin and HRQoL [19–23]. These studies used the EQ-5D [24] instrument, but there was no detailed report on the influence of T2DM on the five domains in this instrument (mobility, self-care, usual activities, pain/discomfort and depression/anxiety) [24]. Five studies [13–17] used the Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ) [25], two studies [26,27] used WHOQoL-BREF [28], and one study [18] used Diabetes-specific QoL diabetes 39 (D-39) [29]. Furthermore, one study of 1875 diabetic patients (98% T2DM) [30] used the WHO-Wellbeing Index (WHO-5) [31] for the measurement of HRQoL. In summary, studies on HRQoL and in particular the use of EQ-5D [24] as an instrument for assessing QoL in Indonesian T2DM patients are still rare.

Predictors of health-related quality of life of people with diabetes in Indonesia

Besides identifying the type of instruments used, we also reviewed the predictors of HRQoL in Indonesian T2DM from these 14 studies. We divided these predictors into four main groups; i.e., socio-demographic characteristics, clinical conditions, psychological aspects, and social environment (Figure 1). Socio-demographic data was self-reported by the research participants, whereas most of the clinical conditions were gathered from the hospital databases where the research took place. Related to the psychological aspects, three studies [15,16,18] analyzed the relationship between adherence and HRQoL and one study [26] evaluated the relationship between knowledge of T2DM and HRQoL. Furthermore, the social aspect predictors were identified based on the review of social support compared with HRQoL.

Clinical conditions

Four of the 14 studies specifically investigated and indeed revealed that T2DM complications could result in a negative effect on HRQoL [17,18,26,30]. Andayani *et al* stated that the HRQoL score in Indonesian T2DM declined along with an increase in the number and types of T2DM complications suffered [17]. Amelia mentioned that T2DM complications have a huge impact on HRQoL, mainly in the domain of sexual activity [26]. These statements were strengthened by the research by Alfian *et al* [18] who also stated that sexual behaviour was one of the HRQoL domains which were most influenced by T2DM and complications. Soewondo *et al* [30] reported that 60% of participants (n = 1785) in their study suffered at least one type of T2DM complication, dominated by neuropathy and retinopathy at 64% and 42%, respectively. McCall
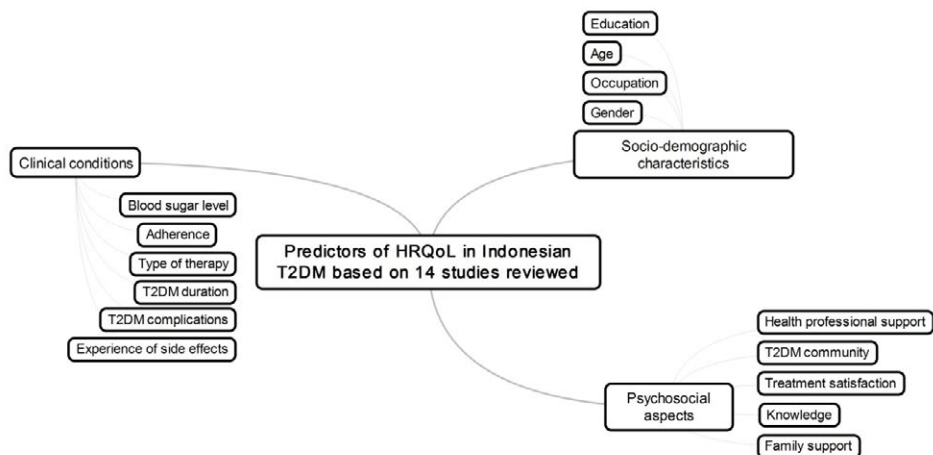
Figure 1. Outline of Introduction

also supported the statement by Soewondo *et al* that in almost 60% of T2DM patients in Indonesia, the disease is accompanied by T2DM complications [32].

Perwitasari *et al* [16] conducted research on 88 participants by dividing them into three groups: monotherapy (group A), a combination of sulfonylurea and metformin (group B), and a combination of oral and insulin (group C). The HRQoL scores in group A were better in satisfaction and treatment satisfaction. Group B showed better scores in physical function and mental health. Meanwhile, the participants in group C showed higher HRQoL scores in four domains: energy, health pressure, treatment effectiveness, and symptom frequency. On average, although there was no significant statistical difference, the participants in group C had the better HRQoL. Soewondo *et al* reported that almost 40% of the participants in the study stated that "I am very worried about having to start on insulin" [21].

Soewondo *et al* [30] stated that the level of glycemic control of Indonesian T2DM patients could be categorized based upon the duration of suffering from T2DM. In this study, the average level of HbA1c of the T2DM patients in Indonesia increased along with the patients' duration of having the disease. The average level of HbA1c in the participants having had T2DM for less than one year was 7.8%, while in the group of participants having had T2DM for more than ten years, the average HbA1c-level was 8.5%. Table 1 presents the relationship between glycemic control and T2DM duration.

Furthermore, it was found that most T2DM patients only visited a health facility once the T2DM got worse or they had T2DM complications [32]. Restinia *et al* categorized the participants in their study into three groups based on T2DM duration: Group A: 1–5 years, Group B: 6–10 years and group C participants with a T2DM duration of ≥10 years [14]. The analysis showed that the HRQoL levels of participants in group A were better compared to B and C in physical function, energy, and frequency of symptoms [14].

Perwitasari *et al* [16] reported that during the process of data collection some participants complained about the side effects of T2DM therapy they were undergoing (treatment duration 4.92 ± 4.08 years).

Table 1. Association between glycemic control based on Indonesian T2DM duration
(reproduced with permission from Prof. Pradana Soewondo provided by email)

| Glycemic controls | T2DM duration in years | | | | | | | | p-value |
| | < 1 | | 1 – 5 | | >5 – 10 | | > 10 | | |
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	
HbA1c (%)	44	7.8 ± 1.7	545	7.7 ± 1.9	450	8.4 ± 2	563	8.5 ± 2	<.0001
Fasting blood glucose (mg/dL)	42	139 ± 47	521	137 ± 48	397	146 ± 51	502	149 ± 53	<.0001
Post Prandial blood glucose (mg/dL)	43	198 ± 76	490	198 ± 81	377	214 ± 85	460	216 ± 81	.003
Random blood glucose (mg/dL)	10	182 ± 62	129	193 ± 78	97	198 ± 73	164	209 ± 81	.322

In addition, the participants were also afraid of the long-term adverse impact of the therapy. Alfian *et al* [18] added the correlation between the information of the therapy particularly the side effect of medicines and the increase of adherence with HRQoL.

Adherence to T2DM therapy is one of the things that can have a significant impact on HRQoL. Hence, it requires programs that can help to increase the adherence of T2DM patients [18]. In Indonesian T2DM patients, both males and the elderly showed a better level of adherence [13,15,16]. Other factors impacting on adherence include accuracy in the provision of T2DM therapy [15,16,18], understanding of the benefits of adherence [18], and experience of the occurrence of the side effects of the therapy[13]. Alfian *et al* [18] assessed the correlation between adherence and five HRQoL domains, including energy and mobility, T2DM control, anxiety and worry, social overload, and sexual behaviour. The result of the study analysis showed that sexual behaviour was the most disturbed domain in the group without any adherence to their T2DM therapy followed by the domain of energy and mobility [18].

Socio-demographic characteristics
Most of these studies on HRQoL in Indonesian T2DM patients involved a majority of patients over 50 years of age [13–18,27,30]. Another study carried out in North Sumatra in 2015 primarily concerned the age group of 36–45 (30%) followed by those of 45–55 years old (27%) [26]. Interestingly, a more recent report has shown that more cases of T2DM were found in younger people [33]. The Indonesian Ministry of Health also reported that, based on the analysis of diabetes reports in Indonesia from 2007 to 2013, many new cases of T2DM were found in the 15–20 years age group [3]. In line with the previous report, McCall (2016) also reported that the age of new Indonesian T2DM patients is rapidly decreasing [32].

From the 14 published articles on HRQoL in Indonesian T2DM patients, six indicated that the majority of participants were female [13–16,18,30], two articles stated the opposite [17,27], while one article did not differentiate the participants involved with respect to gender [19–23,26]. In relation to this, the Indonesian Ministry of Health reported that until 2013, there was no significant difference in people that suffered from T2DM in Indonesia based on sex, both in urban and rural areas [3]. Perwitasari and Urbayatun stated that HRQoL of male participants was better than that of females [15]. Research conducted by Restinia *et al* [14] on 31 male participants and 52 female participants showed that the level of HRQoL in male participants was better in the domains of health distress, mental health, and satisfaction. This may indicate that the male participants were better in controlling their psychological condition than the females [14].

Restinia *et al* [14] analyzed HRQoL of Indonesian T2DM patients based on employment status. The result of this research showed that, of eight domains of HRQoL in the DQLCTQ instrument, the unemployed group was better regarding physical function, energy, satisfaction, and treatment flexibility. Yet, obviously, the employed group showed higher scores in health distress, mental health, treatment satisfaction and frequency of symptoms [14].

Four studies [13,15,16,18], with 75–87% of participants having a maximum educational level of higher secondary school, showed a close relationship between educational level and daily attitude towards T2DM therapy management, for example, being more aware of the importance of adherence to T2DM therapy, with corresponding impacts on HRQoL. Another study stated that a high educational level might bring enhanced awareness, thus minimizing the risk of occurrence of T2DM complications [17]. Also, research on 90 T2DM participants in the Haji Adam Malik Hospital in Medan showed that the higher the educational level, the better the ability to absorb T2DM knowledge [26]. In general, the participants in this study with at minimum a diploma-level education had the better T2DM knowledge, for example, they were aware of the importance of monthly T2DM checks and regularly visited the relevant health facilities [26]. Participants who had their routine T2DM checkups at health facilities were in better condition than those who did not visit the health facilities regularly [26].

Psychosocial aspects

Support from a health professional can be in the form of the provision of T2DM knowledge when the patients visit health facilities. Knowledge can be given to the patients by providing sufficient consultation time and by the additional information that can be given by the pharmacist when giving the medicine to the patients [16]. Perwitasari *et al* stated that good communication between the patients and health professionals could help to increase the adherence of the patient; thus, it can improve their HRQoL [16]. We only found one study from Medan in North Sumatra that investigated the correlation between the level of T2DM knowledge and HRQoL. The results of this research stated that better HRQoL could be acquired by increasing one's knowledge of T2DM. Notably, a positive contribution towards the patients' knowledge could be in the way physicians communicate various aspects of the disease with their patients during the consultation [26].

Since 2010, the BPJS has introduced Prolanis (chronic disease management program) [4]. Prolanis also has a T2DM community in which the members can meet and share their experiences on T2DM with other members and obtain education from a general practitioner (GP) or a consulting resident of internal medicine [34]. Besides this, Prolanis also organizes weekly exercise programs that can be joined by all the members as well as a regular observation of blood sugar levels once a month. In the beginning, the Prolanis program was only focused on T2DM, but today it is also being used for hypertension. The number of members joining has increased from year to year: in 2010 the number of Prolanis members was 1,702, and at the end of 2013, the number had increased to 100,302, also reaching more parts of Indonesia [4]. One study [27], conducted in Yogyakarta, analyzed two specific groups of participants. The first group (n = 30) was referred to as the intervention group in which the participants joined a CBIA-DM (community-based interactive approach to diabetes mellitus) program. The second group was referred to as the control group, with participants only receiving

standard care from a physician when the participants visited a hospital. The results of the research showed that the participants with the CBIA-DM intervention had significantly better HRQoL compared to the control group (p = <.05).

Satisfaction can be viewed from several angles. Various studies analyzed the level of satisfaction of the participants in relation to the therapy they were undergoing. In Indonesian T2DM patients, the group of participants with insulin therapy showed better HRQoL scores compared to other types of therapies [16,19–23]. Another type of satisfaction was related to the accessibility of health facilities, also warranting careful consideration. Such accessibility could include the distance from the house of patients with T2DM to the healthcare service center [15], or other facilities to acquire the therapy.

In conclusion, based on a review of 14 studies, it can be concluded that to date, HRQoL research in Indonesia is mostly on Java Island, and in a secondary care setting. From this review, it was also found that compared to males, the females had a lower HRQoL, and T2DM patients with higher education had a better HRQoL compared with participants with lower education.

THESIS OBJECTIVES AND THESIS CHAPTERS

With the scarcity of studies available and the limited scope covered, further development of HRQoL research in Indonesia is urgently needed. The initial step that can be taken concerns the consideration of several instruments for the assessment of HRQoL, such as the EQ-5D that has been widely used to assess utility score (EQ-5D index score) and seems to have a preference in European Health Technology Assessments (HTAs) [24]. EQ-5D index score in Indonesian

T2DM patients are important as they are one of the critical components in the CUAs and modelling studies in Pharmacoeconomics. Furthermore, it might be worthwhile to combine EQ-5D with other instruments that more specifically measure the psychological state of T2DM patients. One such instrument could, for example, be the diabetes distress scale (DDS), with diabetes distress (DD) screening being included in the guidelines for T2DM in various countries [35,36]. Notably, this is not yet the case in Indonesia. Also, to enrich the data, and alongside quantitative studies, psychological studies using qualitative methods can provide further detailed comprehension and simultaneously empower T2DM outpatients in their understanding of and aspirations for better and adequately scientific evidence-based treatment of T2DM. The thesis is structured as follows:

Chapter 2 concerns the translation, revision, and validation of the Diabetes Distress Scale (DDS) for Indonesian T2DM outpatients with various types of complications. This chapter explains the method of translating and validating the instruments based on international standards.

Chapter 3 outlines how Indonesian T2DM outpatients cope with DD. It is a qualitative study to understand more about the phenomenon of DD in Indonesia. In this chapter, we describe a number of important aspects felt by T2DM-outpatients in one of the primary health care services in Surabaya.

Chapter 4 shows factors influencing DD in Indonesian T2DM outpatients, with a comparison between primary and secondary care. This chapter presents a quantitative description of DD-related to the socio-demographic and clinical conditions in Indonesian T2DM outpatients.

Chapter 5 aims to examine the specific measurement properties and scoring of the

Indonesian version of the EQ-5D with 3 levels (EQ-5D-3L) for answering compared to the EQ-5D with 5 levels (EQ-5D-5L) in T2DM outpatients.

Chapter 6 analyzes the EQ-5D index scores in Indonesian T2DM outpatients. In this chapter, we present the list of EQ-5D index scores in Indonesian T2DM outpatients that can be used as a reference in CUAs in Indonesia. The list is based on socio-demographic characteristics and clinical conditions of participants. Furthermore, we also subsequently investigate the association between those variables.

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