THE ASSOCIATION BETWEEN MEDICATION REGIMEN COMPLEXITY, TREATMENT SATISFACTION AND MEDICATION ADHERENCE AMONG MALAYSIAN OLDER ADULT OUTPATIENTS IN SULTAN AHMAD SHAH MEDICAL CENTRE@IIUM (SASMEC@IIUM)

BY

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A thesis submitted in fulfilment of the requirement for the degree Master of Science in Pharmaceutical Sciences (Pharmacy Practice).

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ABSTRACT

In 2022, Malaysia has become an ageing nation, where older adults make up about 7.3% of the national population. Older adults constitute the majority of medicine consumers. However, there is a scarcity of research examining the factors influencing medication non-adherence among the Malaysian older adults. This research aimed to explore the association between medication regimen complexity (MRC), treatment satisfaction and medication adherence within this population. A cross-sectional study was conducted in the outpatient settings of Sultan Ahmad Shah Medical Centre@IIUM, from February to September 2023. The study utilised three assessment tools: Medication Regimen Complexity Index (MRCI), Malay Treatment Satisfaction for Medication Version II (M-TSQM v.II), and Malaysia Medication Adherence Assessment Tool (MyMAAT). The research applied multivariate linear and logistic regression models to determine the predictors of MRC, treatment satisfaction and medication adherence. Additionally, mediation analysis was implemented to assess the mediating role of treatment satisfaction for the association between MRC and non-adherence. Initially, a cross-cultural adaptation of M-TSQM v.II was conducted and it included translation, validation, and reliability testing of the questionnaire. For the cross-cultural adaptation of M-TSQM v.II, the study achieved excellent content validity, with high scores for "Relevance" and good scores for "Clarity". Reliability testing of constructs demonstrated good internal consistency, with all Cronbach's α values of each domain exceeding 0.7. Convergent validity was established with Average Variance Extracted (AVE) values of ≥0.5 for every construct. Construct validity, assessed through confirmatory factor analysis (CFA), indicated a robust model fit with favourable fitness indexes. M-TSQM v.II is valid, reliable and psychometrically sound for the Malaysian older adult population. The study included 429 patients with a mean age of 71.98 ± 5.5, and 51.0% (n=217) were non-adherent to their medications. The average total score for MRC was 17.38 ± 7.07, while overall treatment satisfaction, assessed across four domains in TSQM v.II (Effectiveness, Side Effects, Convenience, and General Satisfaction), scored an average of 73.91 ± 15.23. Multivariate logistic regression analysis identified four significant determinants associated with non-adherence: MRC, overall treatment satisfaction, partially self-managed medication, and fully managed medication by caregivers. Furthermore, multivariate linear regression analysis revealed three significant determinants influencing treatment satisfaction: MRC, Charlson Comorbidity Index (CCI), and self-managed medication. Additionally, a mediation analysis unveiled the partial mediating role of treatment satisfaction in the association between MRC and non-adherence. In conclusion, the leading factors contributing to non-adherence among Malaysian older adult have been identified in this study, which signifies the greater need for evaluation of regimen simplification, the patient-centred approach based on their satisfaction and involvement of caregivers in medication management to strengthen geriatric healthcare system in Malaysia.

ملخص البحث

في عام 2022، وصلت ماليزيا بالفعل إلى مرتبة الدولة المتقدمة في السن، حيث تشكل حوالي 7.3% من سكان الدولة. ومع ذلك، هناك ندرة في الأبحاث التي تدرس العوامل المؤثرة على عدم الالتزام بالأدوية بين كبار السن الماليزيين. يهدف هذا البحث إلى استكشاف العلاقة بين تعقيد نظام الدواء (MRC)، والرضا عن العلاج والالتزام بالأدوية بين هذه الفئة من السكان.تم إجراء دراسة مقطعية في العيادات الخارجية لمستشفى تعليمي في باهانج، ماليزيا، في الفترة من فبراير إلى أغسطس 2023. استخدمت الدراسة ثلاث أدوات تقييم: مؤشر تعقيد نظام الدواء (MRCI) ، ورضا العلاج باللغة الماليزية للإصدار الثاني (M -TSQM v.II) وأداة تقييم الالتزام بالأدوية الماليزية (MyMAAT) ، طبق البحث نماذج الانحدار الخطي واللوجستي متعددة المتغيرات لتحديد تنبؤات الرضا عن العلاج والالتزام بالأدوية. بالإضافة إلى ذلك، تم تنفيذ تحليل الوساطة لتقييم دور الوساطة لرضا العلاج للارتباط بين MRC وعدم الالتزام.في البداية، تم إجراء تعديل عبر الثقافات لـ M-TSQM v.II وشمل الترجمة والتحقق واختبار موثوقية الاستبيان.شملت الدراسة 429 مريضاً بمتوسط عمر 71.98 ± 5.5، و51.0% (العدد = 217) كانوا غير ملتزمين بأدويتهم.كان متوسط الدرجات الإجمالية لـ MRC 17.38 ± 7.07، في حين سجل الرضا العام عن العلاج، والذي تم تقييمه عبر أربعة مجالات في TSQM v.II (الفعالية والآثار الجانبية والراحة والرضا العام)، متوسطًا قدره 73.91 ± 15.23. حدد تحليل الانحدار اللوجستي متعدد المتغيرات أربعة محددات مهمة مرتبطة بعدم الالتزام: MRC (AOR = 1.179، p = 0.002)، والرضا العام عن العلاج (AOR = 0.847، p <0.001)، الأدوية المدارة ذاتيًا جزئيًا (AOR = 2.675، p = 0.011)، والأدوية المدارة بالكامل بواسطة مقدمي الرعاية (= AOR 8.436، p = 0.004).علاوة على ذلك، كشف تحليل الانحدار الخطي متعدد المتغيرات عن ثلاثة محددات مهمة تؤثر على الرضا عن العلاج: MRC (β = -1.395، p <0.001)، CCI (β = -0.746، p = 0.009) =، والأدوية المدارة ذاتيًا (β = 5.554، p = 0.006). بالإضافة إلى ذلك، كشف تحليل الوساطة عن دور الوساطة الجزئي للرضا عن العلاج في العلاقة بين MRC وعدم الالتزام.بالنسبة للتكيف بين الثقافات لـ M-TSQM v.II، حققت الدراسة صلاحية محتوى ممتازة، مع درجات عالية لـ "الملاءمة" (متوسط S-CVI/UA = 1.00، I-CVI = 1.00) ودرجات جيدة لـ "الوضوح" " (يعني S-CVI/UA = 0.45، I-CVI = 0.88).أظهر اختبار موثوقية التركيبات اتساقًا داخليًا جيدًا، حيث تجاوزت قيم كرونباخ α 0.7 للفعالية 0.84) (=E، والآثار

الجانبية (SE =0.92)، والراحة (C = 0.87)، والرضا العام (GS = 0.88). تم إنشاء صلاحية متقاربة بقيم متوسط التباين المستخرج (AVE) البالغة .50.5 لـ (0.74) E و(0.82) SE و C (0.70) و(0.78) GS.أشارت صلاحية البناء، التي تم تقييمها من خلال تحليل العوامل التأكيدية (CFA)، إلى نموذج قوي يتناسب مع مؤشرات اللياقة الملائمة: GFI ،2.122 = (<5.0)χ2/df ،RMSEA (<0.08) = 0.051 ،0.969 = (>0.9)، و0.988 = (>0.9) CFI. يعتبر M-TSQM v.II صالحًا وموثوقًا وسليمًا من الناحية النفسية لكبار السن الماليزيين. إن MRC والرضا عن العلاج وعدم قدرة المرضى على إدارة الأدوية هي العوامل المحددة لعدم الالتزام. تعد MRC وCCI والأدوية التي تتم إدارتها ذاتيًا من العوامل المهمة التي تحدد رضا المريض. وأخيرا، توسط الرضا عن العلاج جزئيا العلاقة بين مركز موارد المهاجرين وعدم الالتزام.

APPROVAL PAGE

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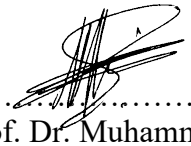

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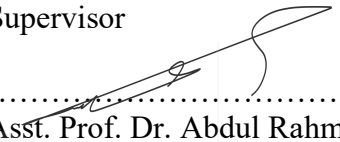

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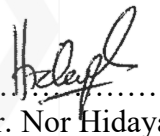

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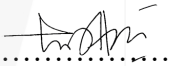

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DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

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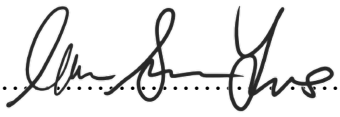
Signature…  …… Date…27/6/24…….

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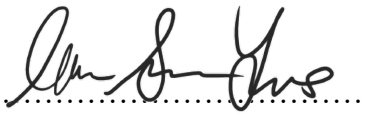

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This thesis is profoundly dedicated to my tenacious support system – my wife, parents, family and supervisors for being the driving force behind my academic journey. Your encouragement has been my great inspiration and everlasting pillars of strength.

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I, once again express our gratitude to Allah for His Mercy, including the blessing of successfully completing this masterpiece, the verses of intellect, a thesis. Alhamdulillah.

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CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

Malaysia has changed its status to be an ageing nation, as the population of 65 years and above has already reached approximately 7.3% in the last quarter of 2022 (Azuar, 2022). According to the United Nations (2013), the country will be officially declared an ageing nation when the older adult population surpasses 7% of the total population. In addition, the declaration of this status attainment in Malaysia is earlier than what has been expected, as the nation is forecasted to reach this status in 2030. Moreover, the older adult population is projected to expand further over time, increasing to seven million (17.6%) out of Malaysia's estimated total population of 40 million people in 2040 (Tey et al., 2016). The significant growth of the older adult population is mainly because of the increase in average life expectancy and the decrease in the mortality rate (Griffith et al., 2019).

Due to this, the anticipated expenditure by the government will increase to cover the healthcare sector, with most older adults having numerous advanced diseases and complex healthcare requirements (Griffith et al., 2019). Also, this older adult population likely demonstrates a greater dependence and demand for healthcare services than the general population (Rowe, 2015). Moreover, cognitive and functional deterioration are frequent in this population (Thompson et al., 2016), with physiological and anatomical alterations in older adults influencing the pharmacokinetic and pharmacodynamic of the medications (Klotz, 2009; Reeve et al., 2015).

Approximately 60% of older adult patients in Malaysia are non-adherence to medication (Chang et al., 2021). Medication non-adherence is the critical reason for treatment failure, where the treatment and clinical outcomes are not achieved (Baryakova et al., 2023). Other than that, non-adherence among the older adult population was reported to result in higher hospital readmissions, increased duration of

stay, reduced quality of life, poor clinical outcomes, and several unfavourable effects (Teo et al., 2015; Toh et al., 2014; Tsai et al., 2012). When older adult patients suffer from this condition, they are prone to receive overtreatment and even more medications prescribed (Baretella et al., 2023).

Besides, the overall cost of returned and unused medication in the outpatient pharmacy department in a Malaysian hospital was high, at approximately RM100 per patient (Jamalud-Din et al., 2022). The estimated cost of non-adherence will exceed a few million ringgits per year. Hence, the non-adherence issue will cause a substantial financial burden in the long run, especially among the older adult population.

Myriad factors contribute to medication non-adherence, such as patient-related, medication-related, physician-related, system-based and other factors (Yap et al., 2016). Specifically, medication-related factors include polypharmacy, medication regimen complexity, and modification in the regimen. While patient-related factors, demographics, treatment satisfaction, and patient behaviours could influence medication adherence. Wiffen et al. (2012) also proposed a similar concept, explaining that treatment satisfaction and medication regimen complexity are a few examples factors for non-adherence. Thus, our research's intended determinants for non-adherence are the medication regimen complexity (MRC) and treatment satisfaction.

The term "medication regimen complexity " has been defined in several ways. Previously, medication regimen complexity was known as a simple count of medications administered per patient (Ayele et al., 2019). However, the number of medications taken cannot quantify the complexity measure of the medication regimen, which also must describe the various routes of administration, dosage forms, dosing frequencies and additional medication instructions (Ayele et al., 2019). A study by George et al. (2004) quantified the medication regimen complexity and developed a scale for this purpose which is known as Medication Regimen Complexity Index (MRCI).

Treatment satisfaction is interpreted as a patient-reported outcome measure (PROM), which is the total of the patient’s satisfaction with the perception and expectation of the treatment given. The patient will most likely be satisfied when the

treatment can fulfill the perception and expectation (Aljumah et al., 2014). This PROM can be attributed to any types of treatment such as therapy, procedures, advice on dietary and lifestyle, and medications (van Zuuren et al., 2021). However, this research will focus on the patient's satisfaction with the medications. It has been demonstrated that treatment satisfaction is determined by the satisfaction of medication's effectiveness, the convenience of medication administration, and the presence of undesirable side effects and others (Aljumah et al., 2014). Collectively, treatment satisfaction could be one of the strong predictors that influence medication adherence. There is one notable study by Atkinson et al. (2004), where they developed a generic measurement tool able to evaluate the level of treatment satisfaction, known as the Treatment Satisfaction Questionnaire for Medication (TSQM). Later on, this generic measurement tool was improvised into TSQM version II by the same developer, in which some of the items were deleted, reworded and modified in order to produce a much more valid and reliable instrument (Atkinson et al., 2005).

However, there is a lack of evidence concerning the association between medication regimen complexity, treatment satisfaction, and medication adherence altogether among Malaysian older adult patients. Because there has been an exponential rise in the ageing population, distinct clinical characteristics, and a high prevalence of chronic diseases, favouring the emergence of the complexity of pharmacotherapies, it is essential to explore this association (Ferreira et al., 2015).

1.2 PROBLEM STATEMENT

Medication regimen complexity, treatment satisfaction and medication adherence are three key factors that affect achieving the desired clinical outcomes in older adult patients. To the best of our knowledge, no study evaluated treatment satisfaction among older adults in Malaysia. Additionally, no validated tool in the Malay language can be used to assess patient's treatment satisfaction. Studies on medication regimen complexity among Malaysian older adults focused only on patients with acute infections (Akhtar et al., 2021a; Akhtar et al., 2021b). No study has addressed this issue in older adults with stable chronic conditions. Furthermore, medication regimen complexity and treatment satisfaction are crucial determinants of medication adherence. Nevertheless,

there is no study that assessed the impact of these factors on medication adherence among Malaysian older adults.

1.3 RESEARCH OBJECTIVES

This study embarks on the following objectives:

1.3.1 General Objective

To explore the association between medication regimen complexity, treatment satisfaction, and medication adherence among Malaysian older adult outpatients in Sultan Ahmad Shah Medical Centre (SASMEC@IIUM)

1.3.2 Specific Objective

1.3.2.1 To translate and validate the Malay version of the Treatment Satisfaction Questionnaire for Medication Version II (TSQM v.II).

1.3.2.2 To assess the treatment satisfaction among Malaysian older adult outpatients using a translated and validated Malay version of TSQM v.II.

1.3.2.3 To evaluate the medication regimen complexity among Malaysian older adult outpatients using the Medication Regimen Complexity Index (MRCI).

1.3.2.4 To determine non-adherence prevalence among Malaysian older adult outpatients using the Malaysia Medication Adherence Assessment Tool (MyMAAT).

1.3.2.5 To assess the association of medication regimen complexity and other variables on medication adherence and treatment satisfaction using multivariate regression analysis.

1.3.2.6 To determine the association between treatment satisfaction and other variables on medication adherence using multivariate regression analysis.

1.3.2.7 To explore the direct and indirect effect of medication regimen complexity on medication adherence with treatment satisfaction as a mediator variable using mediation analysis.

1.4 RESEARCH QUESTIONS

1.4.1 Can the TSQM tool be translated and validated into the Malay version and to be used among the Malay-speaking population?

1.4.2 What is the level of treatment satisfaction among Malaysian older adult outpatients?

1.4.3 How much is the weightage of the medication regimen complexity for Malaysian older adult outpatients?

1.4.4 What is the prevalence of non-adherence among Malaysian older adult outpatients?

1.4.5 Does medication regimen complexity predict the patient's medication adherence and treatment satisfaction while adjusted for other variables?

1.4.6 Does treatment satisfaction significantly predict the patient's medication adherence while adjusted for other variables?

1.4.7 How does the mediating role of treatment satisfaction affect the association between medication regimen complexity and medication adherence?

1.5 RESEARCH HYPOTHESES

1.5.1 The translated Treatment Satisfaction Questionnaire for Medication (TSQM) in Malay is a valid and reliable measure for the Malaysian population.

1.5.2 The level of treatment satisfaction among Malaysian older adult outpatients is below half of the total scores.

1.5.3 High weightage of medication regimen complexity index can be seen among Malaysian older adult outpatients.

1.5.4 More than half of Malaysian older adult outpatients are non-adherent to their medications.

1.5.5 Medication regimen complexity is a significant predictor for medication adherence and treatment satisfaction while adjusted for other variables.

1.5.6 Treatment satisfaction is a significant predictor for medication adherence while adjusted for other variables.

1.5.7 Medication regimen complexity has a significant direct effect and indirect effect on medication adherence, with treatment satisfaction as a mediator variable.

1.6 SIGNIFICANCE OF STUDY

Generally, this research could contribute to the early step of strengthening the geriatric healthcare system in Malaysia. By obtaining medication regimen complexity data in this study, it is believed that an association between medication regimen complexity, medication adherence, and treatment satisfaction could be explored. From this primary result, healthcare professionals and policymakers could develop strategies to simplify the complex regimen by focusing on the prescribing and dispensing pattern that might improve the patient's reported outcomes, specifically those older adult patients diagnosed with multiple comorbidities and prescribed numerous chronic medications. This approach is in line with the fourth policy of Malaysian National Medicines Policy 3rd Edition (DUNas), which states that best pharmaceutical care practices shall be implemented at all levels of healthcare to ensure the quality use of medicine (Pharmaceutical Services Division, 2017). Also, following this policy, this research observes and monitors the drug utilisation activities by identifying the prescribing practices. With the implementation of good pharmaceutical care in this policy, the strategy to optimise and simplify the complex regimen therapy by adhering to relevant current guidelines could improve the quality use of medicine, thus potentially increasing patient's reported outcomes such as medication adherence and treatment satisfaction. Tailoring the medication regimen according to the patient's needs is a valuable approach to reduce the burden. Improved medication adherence and treatment satisfaction will eventually lead to better clinical outcomes, reduce hospitalisation and increase the quality of life.

CHAPTER TWO

LITERATURE REVIEW

2.1 CHARACTERISTICS OF THE OLDER ADULT POPULATION

2.1.1 Older Adult Data in Worldwide and Malaysia

According to the United Nations Department of Economic and Social Affairs (2022), it was reported that the proportion of individuals aged 65 years and older exceeded the proportion of children aged 5 years and younger for the first time in 2018. This notable finding signifies that the majority of the nations in the world experienced high rates of longevity and low rates of fertility (United Nations Department of Economic and Social Affairs, 2022). With a large proportion of the older adult population having a prolonged life expectancy and a lower rate of children entering the population, a rising number of older adults is expected to represent the total population (as shown in Figure 2.1). Additionally, the overall number and percentage of older adults were approximately 771 million in 2022 (9.7% of the total population), which was triple times more than the number of those in 1980 (258 million) (United Nations Department of Economic and Social Affairs, 2022). With an exponential rise, the projection continues to achieve approximately 1.6 billion (16.4% of the total population) in 2050 for the number and proportion of older people (United Nations Department of Economic and Social Affairs, 2022). Due to this, the proportion of older people is nearly twice the number of children aged 5 years and younger in 2050 (United Nations Department of Economic and Social Affairs, 2022).

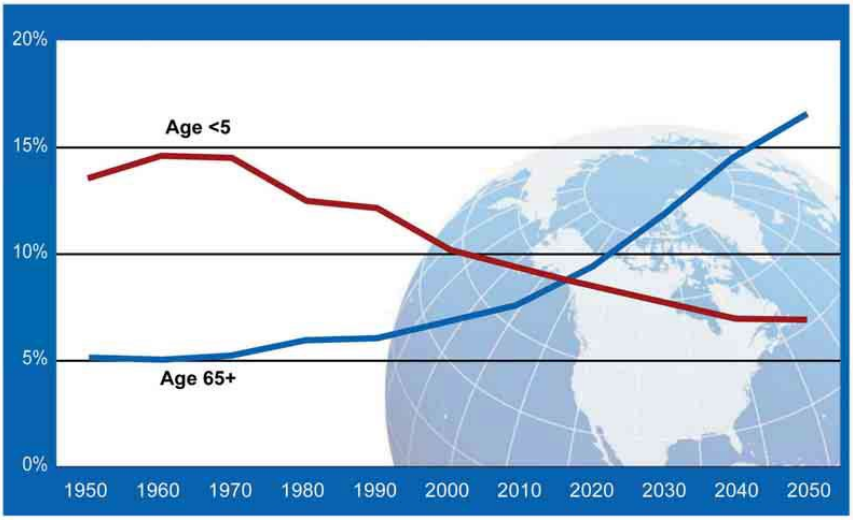


Figure 2.1: Percentage of children and older adult population from 1950-2050 (National Institute of Aging, 2011)

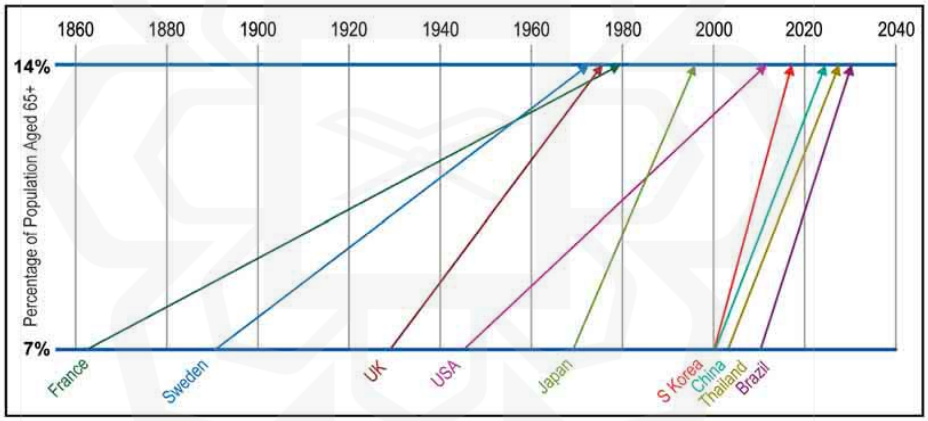


Figure 2.2: Time required for the nation to double the value of the 7% of the older adult population (National Institute of Aging, 2011)

Meanwhile, in Malaysia, the nation was officially declared as an ageing nation during the last quarter of 2022, with 7.3% of the older adult population aged ≥65 years making up the national population, which is rising faster than initially forecasted in 2030. According to the United Nations (2013), the declaration of the attainment of an ageing nation status is achieved when the nation reaches the proportion of 7% of the older adult population. As compared to the other 25 ageing countries, Japan (28.7%) is

the leading nation with the highest percentage of the older adult population, accompanied by Italy (23%), Finland (21.9) and other countries (Azuar, 2022). Based on Figure 2.2, France took the longest time to reach the double value of 7% of the older adult population (138 years), followed by Sweden (85 years) and the United States of America (69 years) (National Institutes of Health, 2018). However, those nations that attained the ageing status in the early 21st century such as South Korea, China, Brazil and Thailand reported only took approximately 25 years to achieve this doubling, with the projected duration for Malaysia being 23 years (National Institutes of Health, 2018).

Due to this, the majority of the ageing nations have made a well-planned preparation to adapt their systems to fit the growing number of the older adult population in terms of social support, economic, and specifically the healthcare aspects by enhancing the sustainability of long-term care management and universal healthcare-delivery system. According to the National Institutes of Health (2018), the survey mentioned that the ageing process is associated with multiple distinct clinical characteristics and healthcare-related outcomes as compared to younger population. It is associated with alteration in cognitive function, body systems, body composition changes, and other clinical aspects.

2.1.2 Alteration of Physiological and Anatomical Aspects in Older Adult

2.1.2.1 Central nervous system

It is reported that neurological disorder is one of the ageing process biological manifestations due to the inability and disruption of the neuronal cells in the brain to transmit the signals (Amarya et al., 2018). A few examples of chronic neurodegenerative diseases such as dementia, Parkinsonism, stroke and many other neurological disorders are highly associated with the ageing process of the older adult population (Amarya et al., 2018). Alzheimer's disease is the most common type of dementia, frequently presenting with cognitive impairment such as forgetfulness, time disoriented, loss of memory, slow thinking process, and lack of judgment (Amarya et al., 2018). The pathologic mechanism of Alzheimer's disease is elaborated based on the deposition of senile plaques and neurofibrillary tangles. From this mechanism, inflammatory cascades are triggered near the plaques and promote the damage of neuronal cells (Jahn, 2013). Thus, the clinical manifestations of dementia heavily impacted physical, psychological, and social support for the older adult population, with family members and caregivers also affected.

In Malaysia, the chronic neurodegenerative disease of dementia is the second primary determinant of disability burden among ≥ 80-year-old females and third leading cause of disability among males (National Institutes of Health, 2018). According to the National Institutes of Health (2018), the general prevalence of dementia among Malaysian older adults was 8.5%, with higher prevalence reported in rural areas, participants with low education levels and low monthly income. The finding was consistent with the World Health Organisation (WHO), which predicted the prevalence of dementia was between 5% and 8% of the older adult population (World Health Organisation, 2018). Hence, in the present study should consider excluding neurodegenerative disease patients in the sample size, as they cannot provide a comprehensive and accurate answer for our quantitative measures.

2.1.2.2 Sensory systems

Vision impairment is characterised as a decreased degree of visual acuity that leads to the inability to see, which requires treatment (World Health Organization, 2023).

Impairment of vision also influences a nation's economic landscape and productivity level (Marques et al., 2021). The primary causes of age-related blindness and vision disability among the older adult population are cataracts with a proportion of 51%, followed by glaucoma (8%), macular degeneration (5%), and diabetic retinopathy (1%), which most of the ophthalmic diseases mentioned are preventable and avoidable (National Institutes of Health, 2018). In Malaysia, the overall prevalence of Malaysian older adults with visual impairment is 4.5%, with age-related macular degeneration and cataracts among the most common risk factors reported. Older adults in rural areas, lower-income groups and those with low education levels are associated with a high prevalence of visual disability due to poor accessibility to treatment (National Institutes of Health, 2018). Thus, despite the visual disability experienced by a few Malaysian older adult populations, the present study is able to include older adult patients with visual impairment with the aid of family members/caregivers and a suitable data collection approach (e.g., physical interview).

Hearing impairment is either partial or complete hearing loss of sensorineural (e.g., inner ear, cochlear), conductive (e.g., impaction of cerumen, fluid) or mixed hearing loss of sensorineural and conductive types (Tanna et al., 2023). It is stated that hearing disability heavily affects the ability to communicate, listen and the quality of life of the older adult population (Löhler et al., 2019). One of the most common causes of hearing disability worldwide among older adults is presbycusis, age-related hearing impairment. It is a progressive symmetrical sensorineural loss affecting spiral ganglion and cochlea hair cells (Lee, 2013). In Malaysia, the overall prevalence of hearing impairment among the older adult population is 6.4%, with most reported cases among those with poor socioeconomic status, a similar association with visual impairment patients (National Institutes of Health, 2018). Therefore, our research must consider whether to include or exclude this type of patient, as the patient's hearing ability varies. Those mild to moderately impaired (able to communicate appropriately) can be considered to participate in the study, while severely impaired hearing loss should be excluded.

2.1.2.3 Other systems

The progressive ageing process among the older adult population is also described as diminished muscle mass, loss of bone mineral density, and elevated fat deposition

(Colón et al., 2018). Regarding fat composition, most older adult populations presented with decreased appendicular subcutaneous fat and increased visceral fat. As a result of the redistribution of body fat, there is a noticeable increase in adiposity markers among older adult populations (Ponti et al., 2019). Next, the reduction of muscle strength associated with the ageing process affects the activities of daily living and mobilisation of the older adult population (Keller & Engelhardt, 2013). Muscle wasting occurs when the amount of muscle fibres declines, along with chemical build-up and waste products that decrease the integrity of the muscle (Keller & Engelhardt, 2013). In addition, reduced 20-40% of the muscle fibres, known as sarcopenia, are commonly noticed among the ≥70-year-old population (Keller & Engelhardt, 2013). Other than that, reduced bone density is due to an advanced turnover rate and increased bone resorption with age, leading to an increased risk of fracture. Furthermore, older adult women experienced approximately 20% deterioration of bone density due to reduced oestrogen levels after the menopause period (Cheng et al., 2022). Wasting cartilage can also be seen in age-related musculoskeletal disorders, in which connective tissue becomes stiff and fibrosis and leads to restriction of the extent of the motion and movement immobilisation (Cheng et al., 2022).

Hence, age-related musculoskeletal disorders with reduced muscle strength and locomotion mechanisms are linked to decreased functional status (Minetto et al., 2020). In Malaysia, the prevalence of dependency on others to perform activities of daily living (ADL) and instrumental activities of daily living (IADL) are 17.0% and 21.3%, respectively. As a result, the incapability of the older adult population to perform daily life tasks will need help from caregivers/family members (National Institutes of Health, 2018). This alarming finding should be addressed accordingly to reduce the level of dependency by promoting suitable physical activities and avoiding excessive sedentary lifestyles.

2.1.2.4 Pharmacokinetics in Older Adult Population

2.1.2.4.1 Absorption

The common change in drug absorption among the older adult population is reduced gastric acidity, which will cause the increased absorption of weakly acidic drugs and decreased absorption of weakly basic drugs. Increased pH levels are associated with the

ageing process due to hypochlorhydria (gastric mucosal atrophy) and prolonged use of histamine-2 receptor antagonists (H2RA) and proton pump inhibitors (PPI) agents. For instance, the phosphate binder agent of calcium carbonate is a weakly basic drug that requires an acidic environment, resulting in reduced calcium absorption and the risk of constipation. Other pharmacokinetic changes among the older adult population are decreased gastrointestinal motility and delayed gastric emptying, which decreases the peak concentration and affects the drug absorption (Klotz, 2009; Reeve et al., 2015).

2.1.2.4.2 Distribution

As shown in Figure 2.3, age-related body composition is associated with increased body fat, with a decrease in total body water, extracellular body fluid and plasma volume. Hydrophilic drugs (e.g., digoxin) have a reduced volume of distribution and lipophilic drugs (e.g., diazepam) have a rising volume of distribution. Other than that, the older adult population also presented with decreased levels of serum albumin and increased levels of α1-acid glycoprotein. Toxicity could happen if the highly protein-bound drugs (e.g., warfarin) stay in the free form and lead to an increase in the serum concentrations of unbound drugs (Klotz, 2009; Reeve et al., 2015).

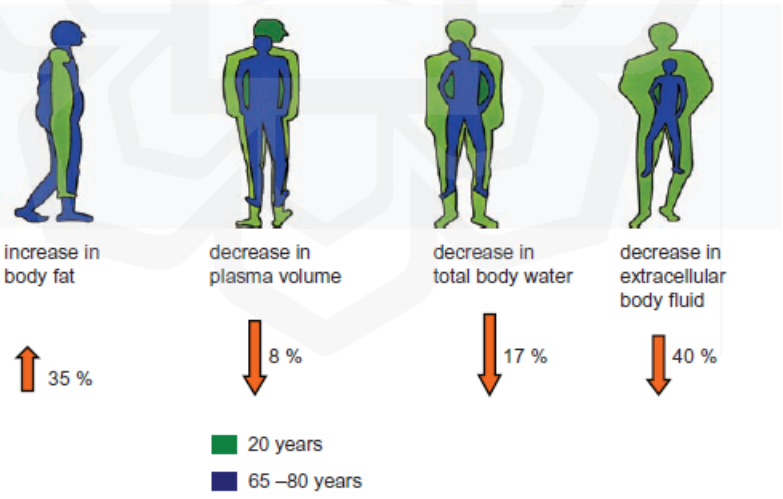


Figure 2.3: Alteration in body composition among the older adult and young adult population (Klotz, 2009)

2.1.2.4.3 Metabolism

Active drugs turn to inactive forms under the metabolism process, primarily through the cytochrome P-450 enzyme. In the ageing population, decreases in liver volume, hepatic blood flow and metabolic capacity are the main factors that influence the changes in hepatic clearance.

Phase I metabolism consists of oxidation, reduction and hydrolysis reactions that will decrease by 30 – 50% due to decreased hepatic blood flow. It is reported that older adults ≥65 years old have a reduction in hepatic blood flow within 20 – 50%. Some of the capacity-limited CYP-metabolised drugs such as benzodiazepines, naproxen, valproic acid, warfarin, indomethacin and theophylline were found to have a significantly reduced hepatic clearance, as a result of diminished enzyme metabolic capacity in the older adult population (Butler & Begg, 2008).

Dose adjustment of the maintenance dose should be reduced or individualised since the hepatic metabolism function could be reduced in this population. Phase II of hepatic metabolism, comprised of the conjugation process, appears insignificant alteration among the older adult population (Klotz, 2009; Reeve et al., 2015).

2.1.2.4.4 Elimination

The main altered pharmacokinetic process associated with advancing age is the elimination phase, which is responsible for drug removal via renal. Diminished renal functions are commonly observed after age 40, with an average of 8 ml/min reduction of glomerular filtration rate (GFR) per decade (van der Burgh et al., 2021). Due to this, the drugs eliminated via the renal pathway will have a decrease in the elimination process and stay longer in the body because of the rise in half-life duration. Examples of hydrophilic drugs such as digoxin, dabigatran, rivaroxaban, gentamicin and lithium are among the common drugs that were affected in terms of renal clearance due to the reduced GFR level (Drenth-van Maanen et al., 2020).

Other than that, the size of the kidney is reduced by 20 – 30% in the older adult population, with the presence of tubular atrophy and an increase of fibrosis using microscopic analysis. Dose adjustment of the renally cleared drugs should be reduced and individualised since renal function is diminished among the ageing population (Klotz, 2009; Reeve et al., 2015).

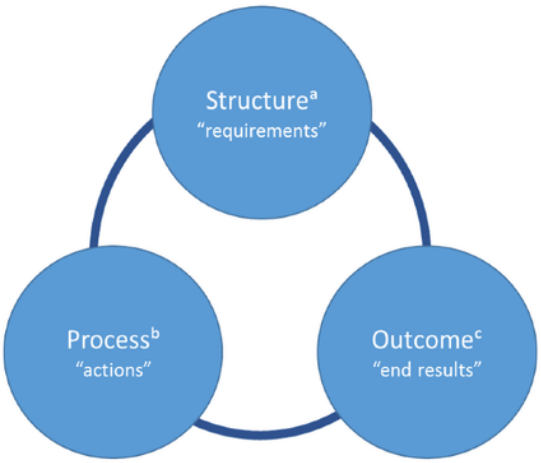
2.1.3 Summary of Characteristics of Older Adult Populations

Conclusively, the issues pertaining to the older adult population require appropriate action from many stakeholders. With the exponential growth of the ageing adult population, national policy should focus on the system's adaptability to fit this population. Along with progressively chronic diseases from age-related alteration in terms of their physiological and anatomical aspects, older adult populations possess unique and distinct characteristics compared to other groups and populations. With multiple unique attributes in the older adult population, the inclusion and exclusion criteria of the sample in this research should be sufficiently emphasised. Lastly, the changes in the pharmacokinetics of the ageing population should be a concern and require an extensive understanding since the dosing requirement must be individualised based on the patient's condition to minimise the risk of negative outcomes such as the presence of adverse drug reaction, the drug toxicity, potential drug-drug interactions and other clinical outcomes. Since the older adult population possess the uniqueness and distinct clinical characteristics as compared to the general adult population, it is a must to assess their healthcare-related outcomes in a routine basis throughout their treatment plan to ensure fulfilment of the goal of the treatment.

2.2 EVALUATION OF HEALTHCARE-RELATED MEASURES

In order to comprehend the basic principles and cause-and-effect mechanism in healthcare settings, evaluation of the healthcare must be fulfilled by a comprehensive assessment of the healthcare-related values using a scientific data collection approach and analysis (Rees et al., 2014). According to The Donabedian Theory, the evaluation of healthcare-related measures has three main components (as shown in Figure 2.4): (1) Structure (e.g., equipment, infrastructure, facilities), (2) Process (e.g., activities of prescribing, screening, dispensing) and (3) Outcomes (e.g., final outcome such as clinical outcome, intermediate outcome such as patient's satisfaction, adherence) (Rees et al., 2014). Typically, the evaluation of healthcare-related measures mainly concentrates on the structure and process components, with lesser attention to the outcome element (Rees et al., 2014). In recent years, numerous studies have focused on evaluating healthcare-related outcomes that are not routinely assessed in clinical practice (Rees et al., 2014).

An example that illustrates the actual healthcare settings with these three components starts with physicians in the medical outpatient department issuing prescriptions in electronic health records (structure). Activities of screening, filling and dispensing the medication by the pharmacists (process) and finally, the patient could benefit from the administered medication (outcome), intermediate outcome such as treatment satisfaction, adherence to the medication and clinical outcome such as the decreased mortality rate, reduce diseases progression and improve functional outcomes. Therefore, our research will focus intensely on two types of intermediate outcomes, which are medication adherence and treatment satisfaction. Intermediate outcomes mainly evaluate patients' socio-behavioural aspects based on the medication administered by observing the utilisation of medication use in a regimen based on prescribing and dispensing activities.



a. What an organization needs to have to provide health care
b. The actions in giving and receiving health care
c. End results as a consequence of providing care

Figure 2.4: Quality of healthcare by Donabedian Model (Tossaint et al., 2021)

2.2.1 Medication Use Evaluation

Medication Use Evaluation (MUE) is the utilisation study that mainly evaluates the medication use in the patient's regimenf as a result of the prescribing and dispensing activities. It comes with a lot of distinct terminologies that are interchangeably used, such as drug utilisation review (DUR), drug utilisation evaluation (DUE) and drug utilisation research (DUR). But all of these definitions aim for a similar thing, which means the wide-ranging healthcare discipline incorporating descriptive and inferential analysis approaches to evaluate, comprehend and quantify the appropriateness of medication use and assess the possible interventions to improve the quality of the prescribing and dispensing activities (Strom et al., 2023). For that reason, the MUE offers quality assurance, supplementary assessments and feedback to the prescribers and pharmacists about any issues of medication use. Thus, most of the time, MUE is a pharmacist-led approach that can mitigate the risk of adverse drug events, improve clinical outcomes, decrease unnecessary healthcare expenditure and enhance patient-related outcomes (Strom et al., 2023).

Utilisation of medication is very common among older adults due to various factors (De Oliveira & Dos Santos, 2016). One of the factors is the high incidence of multimorbidity (co-existence of chronic diseases) reported in Malaysia, which is 40.6%

(Ghazali et al., 2021). As a result, many medications were prescribed and administered to older adult patients for their respective diseases. Consequently, myriad difficulties are experienced by the older adult population when administering their medication such as polypharmacy, adverse effects, and complexity of the medication regimen, which requires frequent medication use evaluation and reviews (Christopher et al., 2023).

Numerous studies have postulated that polypharmacy is the use of five medications or more being prescribed and administered to the patient (Masnoon et al., 2017). According to Chang et al. (2021), their meta-analysis study indicated that the prevalence of polypharmacy among the Malaysian older adult population ranged from 20.3% to 100%. They demonstrated that the pooled prevalence of polypharmacy from multiple studies was 49.5%, nearly half of the Malaysian older adult population (as shown in Figure 2.5). The wide range of the reported prevalence among this population is probably because of the different settings (e.g., primary/secondary/tertiary care), various research designs and variations of polypharmacy definition by each study (Chang et al., 2021). However, polypharmacy could only quantify the medication use on the simple numerical count of the prescribed medications. Instead, quantifying the medication use should extensively describe the characteristics of the medication in terms of its route of administration, dosage form, dosing frequency and additional instructions, in which the measurement of medication regimen complexity takes into place.

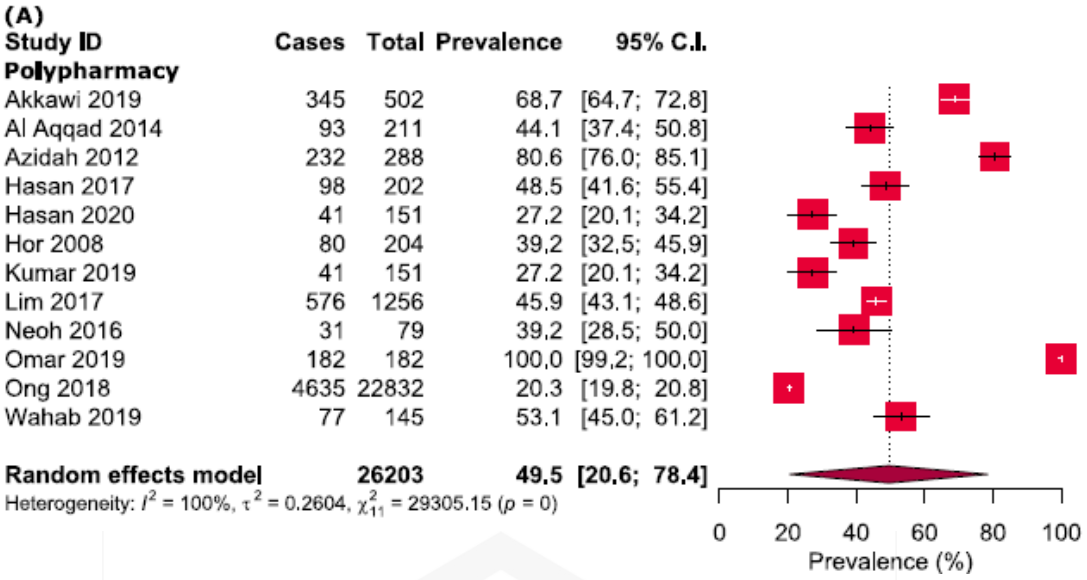


Figure 2.5: Pooled prevalence of polypharmacy from multiple studies among Malaysian older adult population (Chang et al., 2021)

2.2.1.1 Development and Quantification of Measurement Tool for Evaluating Medication Regimen Complexity

A medication regimen comprises rich information regarding the list of prescribed medications, dosage form, dose of medication, dosing frequency, specific counselling instructions, and many more. For instance, a patient is prescribed with a few medications but must take an inhaler, insulin injection and other devices, as well as multiple additional instructions on administering them with high dosing frequency. Compared to a patient with polypharmacy, all the medications are administered orally with minimal additional instruction and the least dosing frequency. Thus, each of these components in the medication regimen should have its specific weightage, which could explain its complexity in the patient's medication regimen. One of the studies by George et al. (2004) developed a measurement tool called the Medication Regimen Complexity Index (MRCI) for quantifying medication regimen complexity. The concept of medication regimen complexity comprises the dosage form, route of administration, frequency of drug administration, and the types of additional instructions required to enact a complexity of the medication regimen of the patients received. Other than that, MRCI tool must be filled healthcare providers/researchers as they have the access to the patient's medication profile in electronic health records.

George et al. (2004) indicate in their study that this measurement applies to the prescribed medication, excluding any over-the-counter (OTC) medication, traditional medication, health supplements, and any other unprescribed medication available. This index has three components: (1) Component A is dosage forms, (2) Component B is dosing frequency and (3) Component C is additional directions/instructions for each prescribed medication. To calculate the score, sum up all three components of the medication regimen complexity to describe the overall MRCI score.

However, several issues have been reported when measuring the medication regimen complexity. For instance, the misinterpretations of section C frequently occurred because of insufficient information regarding the additional instructions/counselling points in the electronic health record (Dierich, 2010; Saez de la Fuente et al., 2016). Also, some miscalculations could cause mathematical errors during the data entries (Dierich, 2010; Saez de la Fuente et al., 2016). Until one of the studies by Yeh et al. (2017) appeared with a much easier method to obtain and calculate MRCI values to prevent mathematical errors during the data entries, MRCI values were calculated by electronic data captured using Microsoft Access software. This MRCI form template was developed by Libby et al. (2013), in which, after completing data entries on each component, the software will automatically sum up all the scores for each component of the MRCI. Thus, the template developed by Libby et al. (2013) will ease and fasten the data collection process for assessing MRCI.

According to Alves-Conceição et al. (2018), the systematic review shows that the measurement tool of MRCI constructed by George et al. (2004) has been cross-culturally validated. In addition, both studies conducted by Paquin et al. (2013) and Morello et al. (2018) mentioned that the MRCI instrument underwent the most extensive testing and has been supported as a practical tool for measuring patients with varying MRC levels. Hence, the development of MRCI is reliable and valid to be a generic measurement for any disease and population. Thus, Malaysian older adult population in the present study was suitable population for assessing their complexity of the medication regimen using MRCI.

2.2.2 Intermediate Outcomes

The intermediate outcomes ultimately relied on the credibility of the physician (to prescribe) and pharmacist (to screen and dispense) the medication and the patient's ability to take the medication appropriately (Rees et al., 2014). Therefore, intermediate outcomes will emphasise patients' socio-behavioural aspects based on the medication administered to the patient such as quality of life, medication adherence, patient's satisfaction, well-being and other outcomes (Rees et al., 2014). In this research, our primary interests in intermediate outcomes are medication adherence and treatment satisfaction.

2.2.2.1 Medication Adherence

According to Wiffen et al. (2012), one of the chapters in their textbook, "Oxford Handbook of Clinical Pharmacy," denotes the definition of compliance, concordance and adherence. These terminologies are interchangeably used in clinical settings, even though each term describes a different meaning.

The definition of "compliance" is a one-way type of communication in which a paternalistic relationship between a healthcare provider and the patient is applied. In this case, the patient has the restricted right to give an opinion, resulting in few to no opportunities to discuss or negotiate about the treatment plan.

For "concordance," the term refers to an absolute two-way type of communication in which partnership relationships between a healthcare provider and the patient are established in the clinical settings. Patients can be involved in the discussion and negotiation about the treatment plan, in which the discussion mainly takes the patient's concerns into the healthcare provider's consideration and a treatment-making decision is highly tailored based on the patient's preference. Nonetheless, this type of communication in real-life situations rarely happens due to a shortage of healthcare providers, a high volume of patients and busy working environments. Thus, healthcare professionals rarely mention and recognise the definition of concordance in a clinical setting.

Meanwhile, "adherence" is defined as mild paternalistic and partnership relationships between physicians and patients. It is somewhere between compliance and concordance conditions, where the physician acknowledges the patient's preference and

concern about the treatment plan. However, the patient has little influence on the selection of the medication and treatment-making decisions. So, after the prescribing process, the adherence interventions are primarily facilitated by pharmacists and nurses. Their responsibility to improve adherence support is higher as compared to the physician. In this study, our primary focus is to concentrate on evaluating self-reported medication adherence among patients.

As specified by Yap et al. (2016), medication non-adherence among older adult patients was associated with various factors, such as patient-related, medication-related, physician-related, healthcare-related and other miscellaneous factors (Yap et al., 2016). Specifically, the medication-related factors involve polypharmacy, medication regimen complexity and alteration in medication regimens. Other, patient-related factors include sociodemographic, dependency in management of medication and treatment satisfaction. Primarily, it has been proposed that treatment satisfaction and medication regimen complexity are the leading causes of medication non-adherence (Yap et al., 2016). Wiffen et al. (2012) also stated with similar findings that both of these factors were key determinants of non-adherence (Wiffen et al., 2012). Thus, our study will examine the association of medication regimen complexity, treatment satisfaction and medication adherence among older patients in Malaysia.

2.2.2.1.1 Assessment of Medication Adherence Measures

Generally, there are numerous methods to evaluate the patient's medication adherence have been developed, either determined by objective or subjective measures. Examples of well-known objective measures able to evaluate a patient's medication adherence are therapeutic drug monitoring (TDM), medication event monitoring systems (MEMSs), treatment response, pharmacy record and dose count. Meanwhile, subjective measures comprised a self-reporting scale using questionnaire, simple reports from caregivers/family members and others. From all the measurements, the self-reporting scale is the most preferred way to assess medication adherence because it is cost-effective, time-saving, highly flexible and practical, even though it comes with a few limitations (e.g., overestimation and fatigue bias) (Wiffen et al., 2012).

According to Nguyen et al. (2014), their systematic review indicates nearly 40 self-reported and validated measurement tools to assess medication adherence in many versions. The most common medication adherence instrument used in Malaysia is the Malaysian Medication Adherence Scale (MALMAS), developed based on the Morisky Medication Adherence Scale (MMAS). However, in 2015, the usage of the MALMAS measurement tool was restricted due to licensing purposes, resulting in a charge of US$1.5 per questionnaire (Marcus, 2017). Due to this, the MALMAS is no longer economical and cost-effective for healthcare professionals and researchers to be used as a medication adherence assessment for research, clinical, and education purposes in Malaysia healthcare services.

Then, Hatah et al. (2020) developed and validated a measurement tool known as the Malaysia Medication Adherence Assessment Tool (MyMAAT). This measurement tool is approved for research and education purposes (non-proprietary and non-commercial) as a screening tool for determining patient non-adherence to their medication. MyMAAT has also undergone logical validity (e.g., face and content validity), construct validity (e.g., exploratory factor analysis) and reliability study (e.g., Cronbach's α) of psychometric testing throughout the study. Our research will implement this tool as a part of the methodological procedure since MyMAAT is a validated self-reported scale for evaluating the level of medication adherence in the Malaysian context.

2.2.2.2 Treatment Satisfaction

Treatment satisfaction is broadly defined as a comprehensive patient's perception and viewpoints of the treatment experience, whether it fulfilled the expectations range from therapy, procedures, advice on dietary and lifestyle, healthcare delivery system and medications (van Zuuren et al., 2021). Specifically, treatment satisfaction toward medications could influence medication-taking behaviour, such as willingness to continue administering the medication and medication adherence, which also influence the clinical outcome and treatment response (Wiffen et al., 2012). Thus, healthcare providers should acknowledge the necessity of treatment satisfaction related to the medication evaluation since it would impact the patient's well-being, functional status, and quality of life (Feeny et al., 2013). One study conducted by Atkinson et al. (2004)

developed a psychometrically sound and generic instrument for assessing treatment satisfaction, known as the Treatment Satisfaction Questionnaire for Medication (TSQM).

To date, there are three readily available versions of TSQM: (1) TSQM Version 1.4, (2) TSQM Version II and (3) TSQM Version 9. In this 14-item-measurement tool of TSQM Version 1.4, the treatment satisfaction for medication described four primary domains: satisfaction toward medication effectiveness, side effects, convenience of medication administration and general/global satisfaction. However, based on feedback from TSQM Version 1.4, some items were modified and deleted, and then the model was tested for good model fit, resulting in 11 items of TSQM Version II. Other than that, the development of TSQM Version 9 produced a version with much fewer items due to the exclusion of the side effects domain in the measurement tool. Thus, our research will implement TSQM Version II since it comprehensively evaluates the patient's satisfaction with medication based on four primary domains. However, to the best of our knowledge, there is no available TSQM Version II in Malay, which means this tool is yet to be translated, cross-culturally adapted and validated in the Malaysian context.

2.3 TRANSLATION AND CROSS-CULTURAL ADAPTATION OF QUESTIONNAIRE

With the diversity of the human population worldwide from various multinational and multiracial backgrounds, the essentiality of adaptation of healthcare measures has also escalated rapidly. Most of the time, the measurement tools were constructed in English-speaking countries, with most of the population using English as their native language (Squires, 2018). Thus, there is a greater need for translation, adaptation and validation of the healthcare measures to be utilised in a local context, the whole process known as the cross-cultural adaptation process. This cross-cultural adaptation of healthcare outcome measures not only comprises a linguistic approach by simple translation step, but it consists of multiple rigorous methods to obtain similarity and cultural equivalence with the original version of the questionnaire (Mohamad Marzuki et al., 2018). In addition, the cross-culturally adapted questionnaire has a more significant impact on researchers and healthcare professionals in healthcare institutions (e.g., physicians, pharmacists, nurses, and others), with this measure being tailored to fit demographics based on linguistic, ethnic, and cultural characteristics of the patients, which able to assess the patient's reported outcomes accurately (Zun et al., 2019).

There are various existing guidelines and recommendations on cross-cultural adaptation and validation of questionnaires reported. Our most preferred guidelines for this present study are from Beaton et al. (2000) and Sousa & Rojjanasrirat (2011). Both guidelines presented a clear, rigorous standard steps for research on cross-cultural healthcare measures. Despite slight differences were reported, both studies share the similarity of the majority step. Figure 2.6 shows the steps involved in forward translation, synthesis, backward translation, comparison, pilot testing, and full psychometric testing of the final version. For our research, due to the unavailability of TSQM Version II in Malay, the whole process of cross-cultural adaptation should be applied in order to produce a measurement tool that is reliable and valid for the Malaysian context for assessing treatment satisfaction toward medication.

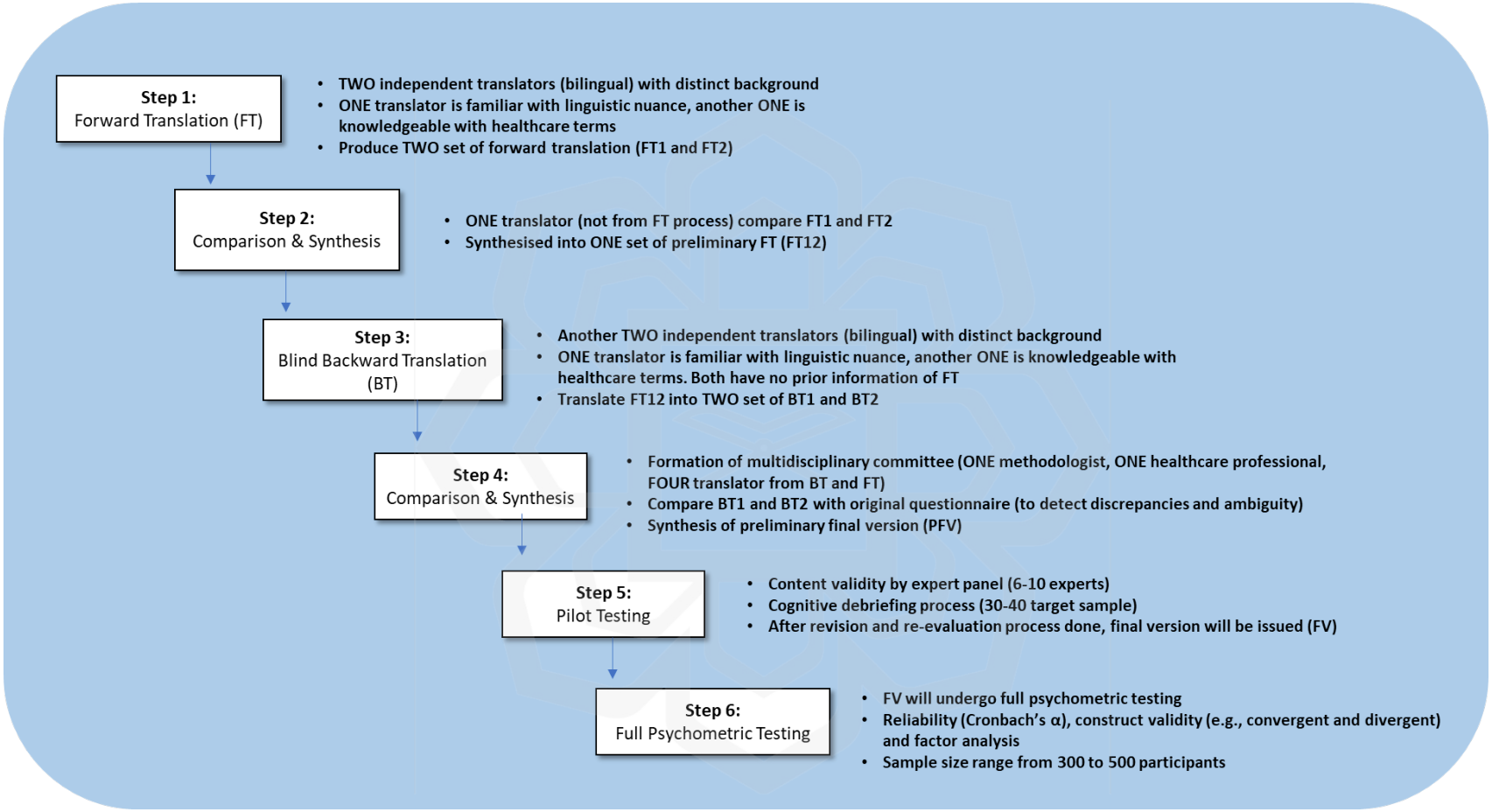


Figure 2.6: Graphical presentation of the cross-cultural adaptation process (Sousa & Rojjanasrirat, 2011)

2.4 REVIEW OF EMPIRICAL STUDIES

2.4.1 Evaluation of Medication Regimen Complexity Index (MRCI) among Older Adult Population

The evidence of assessment of MRCI on the older adult population is still lacking in Malaysia. Based on Table 2.1, the average MRCI score reported among the older adult population in various settings ranges between 9.0 and 27.0, while the average of prescribed medication per patient ranges between 3.0 and 11.0. Only a few studies reported the evaluation of MRCI among Malaysian older adults (Akhtar et al., 2021a; Akhtar et al., 2021b). However, both of these studies only assessed the older adult population diagnosed with acute infection, which only included participants diagnosed with urinary tract infection (UTI) and respiratory tract infection (RTI) episodes regardless of their comorbidities and prescribed medication as their inclusion criteria. Thus, both studies reported a lower average number of medications prescribed per patient and MRCI score than other studies.

Furthermore, two studies reported a very high average number of medications prescribed per patient and MRCI, conducted by Parker et al. (2019) and Tesfaye et al. (2019) in Australia and Norway, respectively. The basis behind the high score of MRCI is that both studies have similar populations: older adults with chronic kidney disease (CKD). CKD patients will most likely be prescribed with various medications such as lipid-lowering agents, antihypertensive, antidiabetic, anti-anaemic and phosphate binders to treat the multiple complications of CKD, along with some medications acquired with complex additional instructions. Therefore, both studies were conducted among older adult patients with CKD with the highest MRCI scores and high medication counts per patient compared to similar studies.

These studies also have similar and consistent findings with a study by Félix & Henriques (2021) in Lisbon, Portugal, evaluating MRCI scores among the multimorbidity older adult population. The study also showed that older adult patients with comorbidities have a high MRCI score and the number of medications prescribed per patient. Again, about one-third of patients with multimorbidity in this study were prescribed with numerous cardiovascular medications, including beta-blocker agents, calcium channel blockers, renin-angiotensin system agents, lipid modifying agents, etc.

Hence, the older adult patient with multimorbidity most likely will have a more complex regimen due to the numerous medications prescribed.

Our research will include older adult patients without focusing on any specific disease or comorbidities. Conclusively, Table 2.1 shows all recent studies evaluating MRCI among older adult populations.

Table 2.1: Comparison of empirical studies on the evaluation of medication regimen complexity index (MRCI) among the older adult population

Studies	MRCI score	Prescribed drugs/patient	Population	Nation
Wimmer et al. (2016)	9.0	3.0	Older adults	Sweden
Bazargan et al. (2017)	15.1	5.7	Community-dwelling, African American older adults	USA
Abada et al. (2017)	19.6	9.4	Community-dwelling older adults	USA
Tesfaye et al. (2019)	27.0	10.0	Older adults with CKD	Australia
Parker et al. (2019)	22.8	11.0	Older adults with CKD	Norway
Santos et al. (2019)	17.0	6.0	Hospitalised older adults	Brazil
Adinkrah et al. (2020)	12.1	5.9	African American elderly	USA
Félix & Henriques (2021)	20.4	7.9	Comorbid older adult population	Portugal
Akhtar et al. (2021b)	14.0	5.0	UTI among geriatric patients	Malaysia
Akhtar et al. (2021a)	11.8	4.0	RTI among geriatric patients	Malaysia

Note : CKD = chronic kidney disease, RTI = respiratory tract infection, UTI = urinary tract infection

2.4.2 Prevalence of Non-Adherence Among Older Adult Patients

The prevalence of non-adherence rates among older adult patients has been conducted in various settings in different countries. As shown in Table 2.2, eight recent studies from 2017 to 2023 reported a prevalence of poor adherence to medications ranging from 45.0% to 83.2%, with six different measurement tools used. All the reported rates of medication non-adherence studies in Malaysia widely range from one to another, with three studies were conducted in Malaysia, including prevalence assessment from the states of Sabah (65.8%), Selangor (83.2%), and Penang (46.5%) (Christopher et al., 2023; Selvakumar et al., 2023; Shim et al., 2018), with most of the reported rates were above 50 percent. Other than that, both studies reported in Portugal by Gomes et al. (2019) and Félix & Henriques (2021) indicate that the prevalence of non-adherence among the older adult population is quite similar to one another, with approximately half of the population. Lastly, our neighbouring nation, Singapore also reported a high prevalence of medication non-adherence among the older adult population (60.0%), consistent with some of the studies in Malaysia.

The wide range of prevalence of non-adherence among the older adult population shown in Table 2.2 can be explained by the different research designs, various measurement tools, the type of older adult population, the settings, and other factors. Most studies reported that more than half of the older adult patients were non-adherent. To the best of our knowledge, there is a lack of study for assessing the prevalence of medication non-adherence among Malaysian older adults in the state of Pahang, Malaysia.

Table 2.2: Comparison of empirical studies on the prevalence of medication non-adherence among older adult population

Studies	Non-adherence prevalence (%)	Type of measurement	Population	Country
Abada et al. (2017)	54.8	MMAS	Community-dwelling older adults	USA
Shim et al. (2018)	65.8	MALMAS	Elderly outpatients	Sabah, Malaysia
Parker et al. (2019)	45.0	MMAS	Elderly patients with chronic kidney disease	Norway
Gomes et al. (2019)	47.7	MTA	Polymedicated elderly	Portugal
Félix & Henriques (2021)	56.3	MTA	Older people with multimorbidity	Portugal
Chew et al. (2021)	60.0	MARS	Community-dwelling older adult with chronic disease	Singapore
Christopher et al. (2023)	46.5	MedUseQ	Older adults in primary healthcare	Penang, Malaysia
Selvakumar et al. (2023)	83.2	MyMAAT	Older adults with multiple chronic conditions	Selangor, Malaysia

Note: MMAS = Morisky Medication Adherence Scale, MALMAS = Malaysian Medication Adherence Scale, MTA = Measurement Treatment Adherence, MARS = Medication Adherence Report Scale, MedUseQ = Medication Use Questionnaire, MyMAAT = Malaysia Medication Adherence Assessment Tool

2.4.3 Evaluation of Treatment Satisfaction among Older Adult Population

As shown in Table 2.3, the evaluation of treatment satisfaction for medication using the TSQM tool among older adults is still lacking in Malaysia. Several studies have been reported outside Malaysia, such as Italy, Lebanon, and South Korea, with most studies assessing treatment satisfaction among elderly patients using various TSQM versions.

A study by Lapolla et al. (2020) in Italy showed that the satisfaction of side effects was not measured since the side effect domain is not available in TSQM Version 9, while the rest of the studies measured all four domains (e.g., Effectiveness, Side Effects, Convenience, and General Satisfaction) using TSQM Version 1.4. The average overall treatment satisfaction ranged from 59.28 to 77.36, with the highest satisfaction score reported by Sakr et al. (2018) and the lowest by Byun et al. (2019). Therefore, since limited studies have been reported, our study aimed to evaluate treatment satisfaction using the TSQM tool among Malaysian older adult patients.

2.4.4 Psychometric Testing of Treatment Satisfaction Questionnaire for Medication (TSQM)

In order to produce a valid and reliable questionnaire, psychometric testing should be done in the newly developed, translated or adapted measurement tool. Similarly, TSQM was developed in English and is used in most English-speaking countries. However, the questionnaire should be valid, reliable and psychometrically sound to assess treatment satisfaction in the intended cultural context. Many studies applied reliability and validity testing of TSQM in different cultural settings, but most of the studies did not perform full psychometric testing. Full psychometric testing should be done extensively to explain the whole validity and reliability of the measurement tool. As shown in Table 2.4, there are several studies demonstrating the full psychometric testing of TSQM were conducted, including in the USA, Brazil, and India (Alam et al., 2018; Atkinson et al., 2005; Sauer Liberato et al., 2016).

A study by Atkinson et al. (2005) reported the development of TSQM Version II, which was the refinement of the previous versions (Version 1.4). Even though it was not part of the cross-cultural adaptation process, the psychometric testing done in this study was comprehensive and psychometrically sound to produce a valid and reliable questionnaire. On the other hand, the studies conducted by Alam et al. (2018) and Sauer

Liberato et al. (2016) were cross-culturally adapted to their culture, which was the Portuguese-speaking population in Brazil and the Hindi-speaking population in India, respectively, with proper psychometric testing done in both studies.

As shown in Table 2.4, for the reliability test, all studies performed the internal consistency test using Cronbach's α, and all reported studies showed that Cronbach's α values were in the acceptable range (≥0.7) (Alam et al., 2018; Atkinson et al., 2005; Sauer Liberato et al., 2016). Nonetheless, only studies conducted by Alam et al. (2018) and Sauer Liberato et al. (2016) reported additional reliability testing of the composite reliability (CR) and average variance extracted (AVE), which both tests achieved the acceptable values in both studies (CR ≥ 0.6 and AVE ≥ 0.5). Therefore, the analysis of the reliability test should include Cronbach's α, CR and AVE to explain the comprehensive reliability of the study.

For validation testing, all the above-mentioned studies applied confirmatory factor analysis (CFA), with a slight difference in a study by Alam et al. (2018), in which they performed the first-order confirmatory factor analysis. Meanwhile, the studies reported by Atkinson et al. (2005) and Sauer Liberato et al. (2016) conducted the second-order confirmatory factor analysis, with the 'General Satisfaction' domain as a higher/second-order construct. Due to that, both path coefficient diagrams reported by Atkinson et al. (2005) and Sauer Liberato et al. (2016) have similar patterns of low factor loading with the 'General Satisfaction' domain to the 'Side Effects' domain (below 0.6), which affect the unidimensionality and cause the disturbance of the model because only a small proportion of the sample experienced side effects. However, both studies practiced a flexible judgment by still maintaining and not removing the 'Side Effect' domain because of the theoretical justification, in which they prioritise the meaningfulness of the theoretical construct rather than strictly following statistical criteria. In addition to that, the goodness-of-fit (e.g., CFI, RMSEA, Chi-square/df, etc.) indexes also showed that the measurement model for both studies were satisfactory, even though the 'Side Effect' domain was retained. On the other hand, first-order CFA constructed by Alam et al. (2018) shows that the goodness-of-fit was good, with the achievement of unidimensionality (all item's factor loading ≥0.60) and discriminant validity (correlation between latent constructs ≤0.85). Thus, implementing either first-order or second-order CFA is still suitable for cross-cultural adaptation of TSQM.

In conclusion, to the best of our knowledge, there are no valid generic tools that can be used to evaluate patient satisfaction in the Malay language. More specifically, there is no cross-cultural adapted and validated Malay version of TSQM Version II for the Malaysian context. Hence, our research will adhere to all steps of cross-cultural adaptation, such as the translation process, pilot testing study, and full psychometric testing, in order to produce a valid and reliable Malay TSQM measurement tool.

Table 2.3: Evaluation of treatment satisfaction using Treatment Satisfaction Questionnaire for Medication (TSQM) tool among older adult population.

Studies	(Sakr et al., 2018)	(Byun et al., 2019)	(Lapolla et al., 2020)
TSQM Version	TSQM 1.4	TSQM 1.4	TSQM 9
Population	Elderly patients	Postmenopausal osteoporosis (PMO) elderly patients	Elderly patient with type 2 diabetes mellitus
Nation	Lebanon	South Korea	Italy
TS Effectiveness	71.26	56.10	75.76
TS Side Effects	91.95	64.20	NA
TS Convenience	77.69	63.00	78.23
TS General Satisfaction	68.52	53.80	72.23
Average Treatment Satisfaction (From 4 domains)	77.36	59.28	75.41

Table 2.4: Psychometric testing process of TSQM

Studies	Atkinson et al. (2005)	Sauer Liberato et al. (2016)	Alam et al. (2018)
TSQM Version	English TSQM Version II	Portuguese TSQM 1.4	English and Hindi TSQM Version 1.4
Population and settings	342 outpatient pharmacy consumers in the USA	300 Portuguese-speaking Brazilian patients	380 Indian patients visiting private clinic centre in Delhi
Reliability	• Cronbach's α ranged from 0.88 to 0.94 for all domains. • Ceiling effect: effectiveness (8.2%), side effects (76.7%), convenience (30.6%), general satisfaction (14.3%)	• Cronbach's α ranged from 0.78 to 0.88 for all domains. • Construct reliability ranged from 0.80 to 0.98 for all domains. • Average Variance Extracted range from 0.51 to 0.91	• Cronbach's α is 0.86 for overall items. • Construct reliability ranged from 0.82 to 0.981 for all domains. • Average Variance Extracted range from 0.53 to 0.77

Validity	• Factorial validity using second-order HCFA suggests a good model fit. • Path coefficient diagram shows the factor loading of global satisfaction towards various domains : (1) 0.96 for effectiveness, (2) 0.34 for side effects, (3) 0.36 for convenience	• Hierarchical second-order confirmatory factor analysis (HCFA) suggests a good fit of the model to the data. • Path coefficient diagram shows the factor loading of global satisfaction towards various domains and items: (1) 0.81 for effectiveness, (2) 0.18 for side effects, (3) 0.80 for convenience, (4) item 12-14 (0.68, 0.61 and 0.82)	• First-order confirmatory factor analysis (CFA) suggests model fit estimation was satisfactory. • Correlation of exogenous constructs was below than 0.85, and ranges from 0.25 to 0.44, which indicates discriminant validity is achieved. • Factor loading for all items in each domain were above 0.6, ranges from 0.70 to 0.95, which refers to good unidimensionality

2.4.5 Association between Medication Regimen Complexity (MRC), Medication Adherence (MA) and Treatment Satisfaction (TS) among Older Adult Populations

2.4.5.1 MRC on MA

For the association between medication regimen complexity and medication adherence, several studies have been conducted among the older adult population across various conditions and settings. A study conducted by Abada et al. (2017) among older community-dwelling adults in the USA indicates that medication regimen complexity is a significant determinant of medication adherence, which is consistent with findings from other studies as well (Bazargan et al., 2017; Kuo et al., 2017). However, several lines of evidence indicate that the medication regimen complexity is not statistically significant to medication adherence among older patients (Federman et al., 2021; Félix & Henriques, 2021; González-Bueno et al., 2021; Parker et al., 2019). Even though similar research has been done, this discrepancy between studies could be attributed to different research designs, types of instruments used, target populations and other factors. However, there is a lack of conclusive findings regarding this association, especially in the context of the Malaysian older adult population.

2.4.5.2 TS on MA

Regarding the association between treatment satisfaction and medication adherence, much literature explores this association by implementing various research designs and different measurement tools among older adult populations. Most studies demonstrated a significant association between treatment satisfaction and medication adherence (Abu Bakar et al., 2016; Al-Ruthia et al., 2017; Loganathan et al., 2017; Yang et al., 2023). In contrast, only one study has contradicting findings where the association was insignificant (Ponnusankar et al., 2022). On the other hand, one study indicates a partially significant association with only one of the domains in treatment satisfaction is significant to medication adherence, while the rest is insignificant (Byun et al., 2019).

In Malaysia, studies by Abu Bakar et al. (2016) and Loganathan et al. (2017) are examples of research that explore such association among the Malaysian general adult population, specifically the diabetic-specific group. However, both studies

involved a relatively small number of patients and focused only on diabetic patients regardless of their age. Hence, there is still a lack of conclusive evidence concerning the association between treatment satisfaction and medication adherence, specifically among older Malaysian adults.

2.4.5.3 MRC with TS and others (MRC, TS and MA altogether)

Some studies determine the significant association between medication regimen complexity and satisfaction toward treatment (De Las Aguas Robustillo Cortés et al., 2017; Sendekie et al., 2023). To the best of our knowledge, there is a lack of studies that assess the association between MRC and TS among the Malaysian older adult population, in addition to research exploring MRC, TS and MA variables altogether among older Malaysian adults. Our research focused on exploring the association between these outcomes, which could be illustrated by the proposed conceptual framework (as shown in Figure 2.7). MRC as an independent variable (IV), treatment satisfaction as a mediator variable (MV) and medication adherence as a dependent variable (DV).

2.5 Conceptual Framework

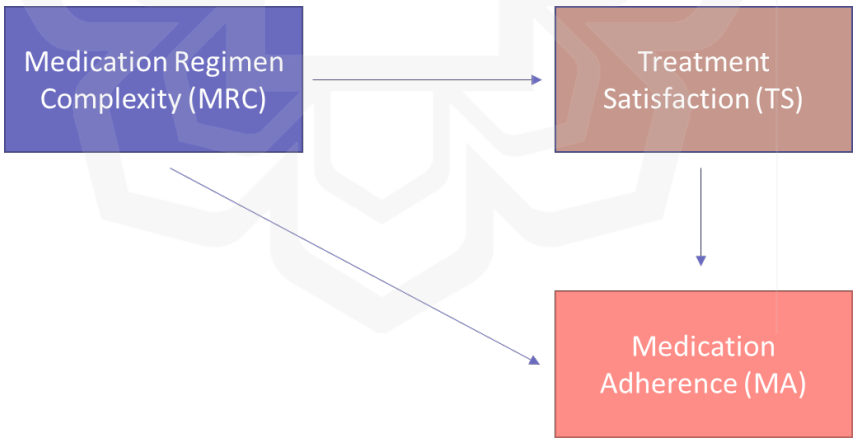


Figure 2.7: Conceptual framework shows the possible association between all variables

CHAPTER THREE

VALIDATION AND CROSS-CULTURAL ADAPTATION OF TRANSLATED MALAY VERSION FOR TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION VERSION II (M-TSQM V.II) AMONG GERIATRIC PATIENTS IN MALAYSIA: A FULL PSYCHOMETRIC TESTING STUDY

3.1 INTRODUCTION

3.1.1 Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs)

Patient-reported outcomes (PROs) are an interpretation of the health, clinical, functional status and quality of life outcomes reported by the patients. Various distinct purposes have been established for PRO, which can measure outcomes in absolute terms. Firstly, this evaluation of PRO helps to assess the patient's standpoint on the estimated level of the acceptability of the treatment/care received. Next, the PRO also able to assess the negative behaviour (e.g., low satisfaction, misconception) on certain treatment and therapeutic plans indicated for the patient. Then, PRO can also determine the patient's experiences of treatment received within the healthcare settings. Lastly, it is also associated with the patient's rating on the level of the severity of the clinical manifestation (e.g., pain) (Weldring & Smith, 2013).

PRO plays a massive role in clinical decision-making because it could provide a comprehensive and holistic view, as this information should be established, coordinated and accessible to others. For instance, in the process of the pharmacoepidemiological surveillance (Phase IV) of post-marketing studies, all the newly marketed medications are lacking in terms of reported severe adverse effects, drug-drug interactions and contraindications, particularly on a certain group of patients, even though the medication is clinically beneficial to most of the patient at the early stage (Black, 2013). Other than that, older patients may experience the incidence of geriatric syndromes as a result of certain prescribed medications such as delirium, falls,

depression and cognitive impairment, which increases the need for good reporting of these special side effects among this population (Akkawi et al., 2020).

In patient-centred care, the approach for comprehensive assessment by the patient plays an integral part in empowering the decision-making process and engagement between patients and healthcare providers. In older adult population, the preliminary findings of the older patients and healthcare providers engagement in clinical settings were limited and lack of specific evaluations on the older patient's healthcare measures (Elliott et al., 2016). Thus, this active collaboration will promote an extensive and personalised treatment plan and enhance patient-provider relationships (Barry & Edgman-Levitan, 2012). The assessment of the outcomes must be carried out systematically and organised so that our healthcare setting can make an informed decision by acknowledging the patient's perspective of the treatment. Patient-reported outcome measures (PROMs) are the measurement tool to evaluate any PROs, such as health-related quality of life and treatment satisfaction. Depending on their purpose, these instruments could be generic or specific. It is in the form of a questionnaire and is commonly delivered as a self-administered questionnaire (Weldring & Smith, 2013).

In recent years, the development of measurement tools in medical research has extensively emerged as a prospect for transforming and innovating the healthcare system, where the patient places at the centre of the whole healthcare system. For example, it has been compulsory in the United Kingdom (UK) to implement PROMs to report outcomes for particular elective surgical patients for the purpose of gathering PROs information regarding the efficacy of patient care within the National Health Service (NHS). The UK government has urged this mandatory adoption of PROMs to facilitate the assessment of health services, highlight benefits and drawbacks in the delivery of healthcare, encourage quality improvement, and promote preference for the patients (Peters et al., 2014).

Therefore, developing a reliable, valid, and concise PROMs measurement tool aims to increase the response rates and reduce fatigue bias among the selected criteria participants, especially those underserved groups of patients (e.g., rural patients, poor socioeconomic status, and geriatric patients). In addition, it can exhibit the precision and accuracy of the outcomes being measured, such as treatment satisfaction and many other PROMs (Black, 2013). Other than that, the PROMs are also regularly used in

different cultures, where it is compulsory to translate and cross-culturally adapt the PROMs into the local context. Implementing the translated measurement tool's validation and reliability process (e.g., content validity, construct validity, statistical validity, and others) is crucial to producing a valid and reliable tool (Sousa & Rojjanasrirat, 2011).

3.1.2 Development of Treatment Satisfaction Questionnaire for Medication (TSQM)

Given this, treatment satisfaction measures should be utilised in setting up healthcare delivery systems. Their satisfaction with medication attributes likely influences patients' medication adherence and treatment perseverance over time. Such characteristics involve the extent to which treatment is regarded as effective and reducing any risk to one's present or future health, the ability of the medication to reduce the disease symptoms, the tolerability of the side effects, and the difficulty associated with the convenience of the medication (Atkinson et al., 2005).

Atkinson et al. (2004) developed the TSQM (version 1.4) as a generic measurement of patient treatment satisfaction with various medications among patients with chronic diseases, such as respiratory, endocrinology, cardiovascular, infectious diseases, and many others. This TSQM measurement tool consists of 14 items within four types of domains: effectiveness, side effects, convenience, and general satisfaction. Implementing generic measurements of patient satisfaction with drug treatment enables comparisons of this construct across various clinical conditions and medication categories. On the other hand, this measurement also could be incorporated into cost-effectiveness analysis and clinical decision-making in healthcare settings (Atkinson et al., 2004).

Then, the developer of this instrument came out with another study on the improvised version of TSQM (version II). Some items were retained, worded, and dropped in the content modifications and item reduction process based on the patient's feedback obtained during the data collection on previous TSQM v1.4. The refinement of the TSQM v.II by the developers by applying a robust construct validation of

hierarchical structural equation modelling (SEM), which is not utilised in the earlier version of TSQM (Atkinson et al., 2005). Hence, the refinement of the TSQM reduced it to 11 items in v.II.

Furthermore, in the global context, this measurement tool of TSQM was cross-culturally adapted and validated into various other language versions, specifically in non-English speaking countries. Examples of cross-cultural adaptations of TSQM published are the Japanese version (Watanabe-Fujinuma et al., 2019), the Brazilian version (Liberato et al., 2020; Sauer Liberato et al., 2016), the Kurdish version (Al-Mufti et al., 2022), the Arabic version (Shilbayeh et al., 2018), the Persian version (Shahrbabaki et al., 2022), the Greek version (Dardiotis et al., 2022). Despite many studies applying reliability and validity testing of TSQM in different cultural settings, most of the studies did not perform full psychometric testing. Performing a full psychometric testing may describe the comprehensiveness of validity and reliability of the instruments (Mohajan, 2017). There are several studies demonstrating the full psychometric testing of TSQM, including in the USA (TSQM developer), Brazil, and India (Alam et al., 2018; Atkinson et al., 2005; Sauer Liberato et al., 2016). To the best of our knowledge, there is no available Malay version of TSQM v.II validated and tested on the Malay-speaking community. Hence, this instrument should be adapted to Malaysian healthcare settings to assess patient treatment satisfaction in Malay-speaking communities.

3.1.3 Study Objectives

There are three main objectives for this study:

i. To translate TSQM v.II into the Malay version
ii. To assess the full psychometric testing of the translated TSQM v.II in the Malay version in order for this measurement to be available in Malay-speaking populations by using confirmatory factor analysis (CFA).
iii. To evaluate the treatment satisfaction for medication in terms of its effectiveness, side effects, convenience, and general satisfaction among Malaysian older adult patients in Sultan Ahmad Shah Medical Centre@IIUM (SASMEC@IIUM)

3.2 METHODS

3.2.1 Study Population and Settings

A unicentric, observational, and cross-sectional study was conducted on 429 participants of Malaysian older adult patients who completed the M-TSQM v.II tool by convenience sampling on the day of their routine appointment and consultation with their respective specialist clinics, where the patients participated in the study. The data were collected from February to September 2023. The sampling technique implemented in this study was non-probability sampling, specifically convenience sampling. Other than that, secondary data sources such as clinical data, prescribed medications and comorbidities were obtained from electronic health records/physical medical records. Primary data sources such as sociodemographics and treatment satisfaction were obtained via the physical interview method. The information was collected in a confidential setting by the researcher. The purpose of the first contact with the participants was to explain the research aims and obtain their consent.

The inclusive criteria includes :

1. Malaysian citizens.
2. Older adult outpatients aged 65 years old and above;
3. Patients who had been using at least three prescribed chronic medications for the past three months;
4. Consented to take part in the study;
5. Able to speak and understand the Malay language

However, the participants were excluded from the study if the participants met one or more of the following criteria :

1. Unable to give proper informed consent (e.g., patients with cognitive impairment such as dementia and Alzheimer diseases);
2. Severe language barriers (e.g., cannot speak and understand Malay language, unable to communicate appropriately);
3. Missing value and information from the electronic health record;
4. Enrolled in another clinical research (e.g., clinical trial)

As for sample size calculation, this study applied the rule of thumb of 10 participants for each item ratio for factor analysis (Wolf et al., 2013). Thus, the recommended sample size for this study is a minimum of 110 participants.

3.2.2 Measurement Tool

3.2.2.1 Sociodemographic and medication profiles

Each participant's sociodemographic assessment includes age, gender, ethnicity, diagnosis, marital status, education level, participant's monthly income, employment status, geographic location, employment status, and medication management. The medication management subcategories comprise three options: self-management, partially self-managed, and full management by family members/caregivers.

3.2.2.2 Malay version of the Treatment Satisfaction Questionnaire for Medication v.II (M-TSQM v.II)

Each patient's treatment satisfaction was assessed using M-TSQM v.II. This generic measurement tool assesses patient satisfaction with the treatment regimen during the last two to three weeks or following the patient's last dose. The administration of this instrument is in a self-reported measurement. There are 11 items divided into four subscales: Effectiveness, Side Effects, Convenience, and General Satisfaction.

Domains of Effectiveness, Convenience, and General Satisfaction have 7-point Likert-type scales ranging from 1("Extremely Dissatisfied") to 7("Extremely Satisfied). For the Side Effects domain, it had one dichotomous scale (presence of side effects) of "Yes" and "No" and another three items with 5-point Likert-type scales ranging from 1("Extremely Dissatisfied") to 5("Not at all Dissatisfied). Those participants who answered "No" in the presence of side effects were automatically rated on a scale of 5("Not at all Dissatisfied) because of the absence of side effects.

Each TSQM domain score ranges from 0 to 100, with higher values indicating more patient satisfaction. For the calculation of each domain, the total scores of each domain minus the number of questions in that domain, then divided by the maximum

score subtract the minimum score of that domain multiplied by 100 (Liberato et al., 2020). The formula was as mentioned below:

$$TSQM\ Domain\ Score = \frac{[(Total\ score\ of\ per\ domain) - (no.of\ items)]}{(Maximum - Minimum\ domain\ score)} \times 100$$

3.2.3 Study Stages

3.2.3.1 Stage 1: Translation Process

Since this questionnaire is unavailable in Malay, our study has translated and validated the TSQM into Malay. Step 1 for translation is forward translation (FT), where the original language (English) has been translated into the target language (Malay) by two independent translators. Both translators were native Malay speakers.

The translators were from the Malaysian Institute of Translation & Books (ITBM) and Centre for Language and Pre-University Academic Development (CELPAD), International Islamic University Malaysia (IIUM). Prior to the translation process, one of the translators was exposed to the research background and details of the study. In contrast, the other translator directly translated the questionnaire without knowing the details of the study. After the forward translation process, two translated forms (FT1 and FT2) of the translated version were produced by each translator.

Step 2 compares and synthesises the two FT versions of the questionnaires. These forms (FT1 and FT2), alongside the original questionnaire, were sent to one of the pharmacy practice field's experts to detect discrepancies and ambiguity of each item regarding wording, meanings and actual concepts. The expert synthesised the preliminary translated TSQM measurement tool (FT12) version.

Then, Step 3 was a backward translation, working from the synthesised one (FT12) was retranslated into the original language (English). One independent translator was appointed to translate utterly blind to the original version of TSQM (never seen the original version of TSQM). The translator was already aware of healthcare terminologies and had no contribution during TSQM forward translation. In addition, the backward translation process is only the validity-checking process where the translated version was reflected in the original language of the TSQM instrument.

After the backward translation, Step 4 was the formation of the multidisciplinary expert committee to compare the structure, phrasing, and grammatical features of the sentence, consistency in meaning, and appropriateness of the instructions, questions, and response categories between backward translations 1 (BTL1) to the original instrument of TSQM in the original language. Our committee consists of one healthcare practitioner who is knowledgeable about the construct of the TSQM instrument, and all three bilingual translators participating in Step 1 (forward translation of the TSQM measurement tool into the target language) and Step 3 (back translation of the TSQM measurement tool from the target language into the original language). Finally, the synthesis of the preliminary final version (PFV) for pilot testing was produced (Beaton et al., 2000; Sousa & Rojjanasrirat, 2011).

3.2.3.2 Stage 2: Pilot Testing of The Pre-Final Version (PFV)

3.2.3.2.1 Content Validity by Expert Panels

Expert panels have been assigned to assess the instructions, response structure, and instrument items for conceptual equivalence. A total of seven members of the expert panel have already been appointed, who are experts in the related area of interest (from clinical backgrounds such as physician and pharmacist), and Malay is the mother language, to further determine the conceptual, item, semantic and operational equivalent of the translated TSQM items (Junkes et al., 2015).

The expert panels have already assessed the relevance and clarity of each question on the instrument to determine the content validity index (CVI) for each item. Evaluation of CVI was based on items-level CVI (I-CVI) and scale-level CVI (S-CVI). Another validation was the Kappa statistic(κ), the consensus of the inter-rater agreement index among all the panellists were also evaluated in this study (Faria et al., 2013).

3.2.3.2.2 Cognitive Debriefing

Thirty-eight older adult participants completed the cognitive debriefing process to assess the clarity of each item in the pre-final version. Participants selected in this

process were asked to answer all the items and rate whether all the items were clear or unclear using a dichotomous scale. From this response, the calculation of inter-rater agreement within the samples selected was calculated using Kappa (κ). Before performing a full psychometric testing, this process was another strong support for determining the conceptual, experiential, semantic and operational equivalent of the translated TSQM items, easing the understanding of the participants (Sousa & Rojjanasrirat, 2011).

3.2.3.2.3 Re-evaluation process by the multidisciplinary expert committee

In the re-evaluation process by the multidisciplinary expert committee, all committee members were notified of some items that needed improvement and amendment based on CVI and Kappa (κ) values from previous processes (e.g., content validation by panellists and cognitive debriefing by participants). After the re-evaluation process was done, all the items were validated and ready for full psychometric testing of the final version (M-TSQM v.II). Table 3.1 depicts the list of bilingual items in Malay version of Treatment Satisfaction Questionnaire for Medication (M-TSQM v.II).

3.2.3.3 Stage 3: Full Psychometric Testing of Final Version and Statistical Analysis

3.2.3.3.1 Descriptive Data

All descriptive data were sorted and analysed using Statistical Package for the Social Sciences version (SPSS) 27.0. The normality of the data was evaluated by using skewness and kurtosis. For categorical variables, the data were displayed as frequency and percentage of proportion.

3.2.3.3.2 Reliability

For reliability assessment, the first psychometric testing used in this stage is to measure internal consistency using Cronbach's α. Then, the measurement of reliability and internal consistency of the measured latent construct, known as composite reliability (CR), were also measured to provide a comprehensive reliability assessment.

3.2.3.3.3 Validity

Another viable test implemented in this study is the construct validity using confirmatory factor analysis (CFA). Second-order CFA was used to analyse the hierarchical factor structure of M-TSQM v.II using AMOS version 26. The measurement model was constructed with two levels of latent construct. The first-order construct level comprised underlying dimensions of Effectiveness, Side Effects and Convenience; meanwhile, the second-order latent construct contains the General Satisfaction. This hierarchical confirmatory factor analysis was defined from the previous model of TSQM v.II (Atkinson et al., 2005; Sauer Liberato et al., 2016) in their population. Lastly, the goodness-of-fit of the model was assessed with favourable fitness indices such as χ^2/df, Goodness of Fit Index (GFI), Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), and Normed Fit Index (NFI).

3.2.4 Ethical Considerations

Ethical approval for this study was obtained from the IIUM Research Ethics Committee (IREC 2021-144) and the Department of Education and Research in SASMEC@IIUM (IISR21-06-201). The information was collected in a confidential setting by the researcher. The purpose of the first contact with the participants was to explain the aims of the research to obtain their consent to participate in the research. To get the participant's consent, an informed consent form was handed out to acquire the participants' signatures. A copy of the informed consent form was kept by each participant and researcher.

3.3 RESULT

3.3.1 Sociodemographic and clinical characteristics profile

Table 3.2 shows that the study involved 429 Malaysian older adult outpatients at SASMEC@IIUM, the participants had a mean age of 71.98 (SD = 5.48) years. The male patients accounted for 57.6% (n = 247), slightly outnumbering the females. The majority of the participants were Malay, making up 82.5% (n = 354), followed by Chinese (8.9%, n = 38) and Indian (8.2%, n = 35). Additionally, 78.8% of the sample were married (n = 338), while 22.2% (n = 91) had various marital statuses such as widowed, divorced, or single. Next, the proportion revealed that 57.3% (n=246) reside in urban areas, while 42.7% (n=183) come from rural settings. Urban defines the geographical location that population resides were >80,000, while town within the 10,000 to 80,000, and lastly rural areas consist of <10,000 populations (Taylor et al., 2021).

The study exhibits the varied approaches for medication management, with 50.6% (n = 217) of participants being self-managed, 39.2% (n = 168) being partially self-managed and 10.3% (n=44) relied on full management by caregivers. In terms of treatment satisfaction, participants reported satisfied with treatment based on domains: Effectiveness scores of 70.69 (SD=19.38), Side Effects of 87.37 (SD=21.78), Convenience of 65.59 (SD=21.18), and General Satisfaction of 71.99 (SD=18.85). Hence, the average score for overall treatment satisfaction, assessed across four domains in M-TSQM v.II among Malaysian older adult outpatients was 73.91 (SD=15.23).

3.3.2 Content validity and cognitive debriefing of PFV

As shown in Table 3.3, for the content validity process by seven experts, this study indicated with excellent level of content validity especially under the dimension of "Relevance" of the instrument. Both the mean I-CVI and S-CVI/UA attaining a perfect score of 1.00, signifies the high relevance concept of each item when assessed for treatment satisfaction. An important parameter of Kappa statistic(κ) showed perfect inter-rater agreement between experts in evaluating the instrument's relevance (>0.74).

Meanwhile, for the "Clarity" dimension, the assessment yielded a positive outcome, with the mean I-CVI of 0.88 and the S-CVI/UA of 0.45. The CVI for the

"Clarity" dimension was reported with a slightly lower value than "Relevance", due to three items demonstrated with I-CVI below than 0.80. In addition, the Kappa statistic(κ) also indicated these three items with a good agreement (0.60 – 0.74), while the rest of the items had a perfect inter-rater agreement between experts.

In the cognitive debriefing process (n=38), for the "Clarity" dimension, the evaluation of inter-rater agreement among the participants using Kappa (κ) aligns with the content validity process by experts, which same items reported with moderate agreement. Therefore, these items (e.g., SE4, C8 and C9) underwent revisions and corrections to enhance their clarity, as shown in Table 3.3.

3.3.3 Reliability

For internal consistency using Cronbach's α, all the domains in the M-TSQM v.II yielded a value above 0.7 of the acceptable range. Each domain demonstrated a good level of internal consistency among the items measuring participants' satisfaction with treatment effectiveness, side effects, convenience and general satisfaction. Because Cronbach's α coefficients have the potential to overestimate the scale for reliability, the coefficients of composite reliability (CR) were calculated. In terms of the CR of latent construct in the structural equation model, all domains exhibit a CR value above 0.6, which also indicates good reliability, as shown in Table 3.5.

3.3.4 Construct validity

Figure 3.1 illustrates the path diagram of the second order of the confirmatory factor analysis (CFA), with 11 items in four domains demonstrated with acceptable factor loading (≥0.6). However, the factor loading from the domain of "General Satisfaction" to the "Side Effects" was reported with a very low value (0.27). In comparison, "General Satisfaction" to "Convenience" and "Effectiveness" showed acceptable values of factor loading, which are 0.79 and 0.88 respectively. Therefore, the unidimensionality of our measurement model is not achieved.

Table 3.7 depicts the unidimensionality was not achieved, but hierarchical confirmatory factor analysis (CFA) stated otherwise. CFA successfully exhibits the construct validity of M-TSQM v.II based on the fitness indexes, in terms of its absolute

(GFI and RMSEA), incremental (CFI, TLI and NFI) and parsimonious fit (χ^2/df). The model was good fit with the values: GFI = 0.969, RMSEA = 0.051, CFI = 0.988, TLI = 0.984, NFI = 0.978 and χ^2/df = 2.122. Overall, the proposed measurement model of the instrument indicates the model fit to the data.

In Table 3.5, for convergent validity, the reported values of AVE of each construct in this model ranged between 0.696 to 0.822. Thus, AVE values signify that the convergent validity in this study is achieved when the value is ≥0.5. Moreover, for each of the four individual constructs, the CR is notably higher than the corresponding AVE. Hence, all respective constructs meet the statistical criteria for convergent validity.

Table 3.1: List of bilingual items in Malay version of Treatment Satisfaction Questionnaire for Medication (M-TSQM v.II)

#	Items
	Effectiveness/*Keberkesanan*
E1	How satisfied or dissatisfied are you with the ability of the medication to prevent or treat the condition? *Sejauh manakah anda berpuas hati dengan keupayaan ubat anda untuk mencegah atau merawat sesuatu penyakit?*
E2	How satisfied or dissatisfied are you with the way the medication relieves symptoms? *Sejauh manakah anda berpuas hati dengan cara ubat anda melegakan gejala(simptom) penyakit?*
	Side Effects/*Kesan Sampingan*
SE3	As a result of taking this medication, do you experience any side effects at all? *Selepas mengambil ubat, adakah anda mengalami apa-apa kesan sampingan?*
SE4	How dissatisfied are you by side effects that interfere with your physical health and ability to function (e.g., strength, energy levels)? *Sejauh manakah anda tidak berpuas hati dengan kesan sampingan ubat yang mengganggu kesihatan fizikal dan keupayaan anda untuk berfungsi (contohnya, kekuatan, tahap tenaga)?*
SE5	How dissatisfied are you by side effects that interfere with your mental function (e.g., ability to think clearly, stay awake)? *Sejauh manakah anda tidak berpuas hati dengan kesan sampingan ubat yang mengganggu fungsi mental anda (contohnya, keupayaan untuk berfikir dengan baik, sentiasa berjaga)?*
SE6	How dissatisfied are you by side effects that interfere with your mood or emotions (e.g., anxiety/fear, sadness, irritation/anger)? *Sejauh manakah anda tidak berpuas hati dengan kesan sampingan ubat yang mengganggu perasaan atau emosi anda (contohnya, kebimbangan/ketakutan, kesedihan, kejengkelan/kemarahan)?*
	Convenience/*Kemudahan*

C7 How satisfied or dissatisfied are you with how easy the medication is to use?
Sejauh manakah anda berpuas hati dengan betapa mudahnya cara penggunaan/pengambilan ubat anda?

C8 How satisfied or dissatisfied are you with how easy it is to plan when you will use the medication each time?
Sejauh manakah anda berpuas hati dengan betapa mudahnya untuk merancang masa bagi setiap penggunaan/pengambilan ubat anda?

C9 How satisfied or dissatisfied are you by how often you are expected to use/take the medication?
Sejauh manakah anda berpuas hati dengan kekerapan penggunaan/pengambilan ubat anda?

General Satisfaction/ *Kepuasan Secara Menyeluruh*

GS10 How satisfied are you that the good things about this medication outweigh the bad things?
Sejauh manakah anda berpuas hati bahawa kebaikan tentang ubat anda mengatasi keburukannya?

GS11 Taking all things into account, how satisfied or dissatisfied are you with this medication?
Dengan mengambil kira semua perkara, sejauh manakah anda berpuas hati terhadap ubat anda?

Table 3.2: Sociodemographic profile for cross-cultural adaptation of M-TSQM v.II

Variable	Number of patients (%) (n=429)
Age (mean ± SD)	71.98 ± 5.48
Gender	
Male	247 (57.6)
Female	182 (42.4)
Ethnicity	
Malay	354 (82.5)
Chinese	38 (8.9)
Indian	35 (8.2)
Others	2 (0.4)
Marital Status	
Married	338 (77.5)
Widowed	87 (20.0)
Divorced	2 (0.5)
Single	2 (0.5)
Geographical Location	

Urban	246 (57.3)
Rural	183 (42.7)
Education Level	
College/University	181 (42.2)
Secondary school	152 (35.4)
Primary school	93 (21.7)
No formal education	3 (0.7)
Employment Status	
Retired/Pensioner	219 (51.0)
Housewife	92 (21.4)
Unemployed	91 (21.2)
Self-employed	23 (5.4)
Employed	4 (0.9)
Income per month	
< RM 1000	148 (34.5)
RM 1000 - RM 2500	93 (21.7)
RM 2501 - RM 4000	66 (15.4)
RM 4001 - RM 4999	54(12.6)
≥ RM 5000	68(15.9)
Management of Medication	**Number of patients (%)**

Self-managed	217 (50.6)
Partially self-managed	168 (39.2)
Fully managed by family members/caregivers	44 (10.3)
Treatment Satisfaction (mean ± SD)	
Effectiveness	70.69 ± 19.38
Side Effects	87.37 ± 21.78
Convenience	65.59 ± 21.18
General Satisfaction	71.99 ± 18.85
Overall Mean Treatment Satisfaction	73.91 ± 15.23
Presence of Side Effects	
Yes	122 (28.4)
No	307 (71.6)

Table 3.3: Assessment of content validation of each Treatment Satisfaction Questionnaire for Medication (M-TSQM v.II) items by panellists (n=7) and cognitive debriefing by the participants (n=38)

TSQM Domain	Relevance* (n=7)		Clarity† (n=7)		Clarity (n=38)	Results
	CVI	Kappa (κ)	CVI	Kappa (κ)	Kappa (κ)	
E1	1.00	1.00	1.000	1.000	0.895	VALIDATED
E2	1.00	1.00	1.000	1.000	0.974	VALIDATED
SE3	1.00	1.00	1.000	1.000	1.000	VALIDATED
SE4	1.00	1.00	0.714	0.658	0.681	Revised & corrected
SE5	1.00	1.00	0.857	0.849	0.868	VALIDATED
SE6	1.00	1.00	0.857	0.849	0.895	VALIDATED
C7	1.00	1.00	1.000	1.000	0.974	VALIDATED
C8	1.00	1.00	0.714	0.658	0.582	Revised & corrected
C9	1.00	1.00	0.714	0.658	0.426	Revised & corrected
GS10	1.00	1.00	0.857	0.849	0.842	VALIDATED
GS11	1.00	1.00	1.000	1.000	0.921	VALIDATED

*Mean I-CVI = 1.00; S-CVI/UA = 1.00; †Mean I-CVI = 0.88; S-CVI/UA = 0.45

Table 3.4: Descriptive statistics for each Treatment Satisfaction Questionnaire for Medication (TSQM-M) item and domain

TSQM Domain	Items	Mean	SD	Skewness	Kurtosis
Effectiveness*	E1	5.15	1.24	-0.60	0.21
	E2	5.33	1.27		
Side Effects†	SE4	4.35	1.14	-1.51	1.09
	SE5	4.52	0.90		
	SE6	4.62	0.74		
Convenience*	C7	4.74	1.51	-0.38	-0.45
	C8	4.95	1.36		
	C9	5.12	1.40		
General Satisfaction*	GS10	5.43	1.18	-0.32	-0.66
	GS11	5.21	1.22		

* Domain has 7 points Likert-scale; † Domain has 5 points Likert-scale; SE3 is excluded because of dichotomous outcome (presence of side effects)

Table 3.5: Reliability of each Treatment Satisfaction Questionnaire for Medication (TSQM-M) domain

TSQM Domain	Cronbach's α	Composite Reliability (CR)	Average Variance Extracted (AVE)
Effectiveness	0.837	0.851	0.740
Side Effects	0.916	0.933	0.822
Convenience	0.873	0.873	0.696
General Satisfaction	0.876	0.873	0.775

Table 3.6: Inter-Item Correlation Matrix of Treatment Satisfaction Questionnaire for Medication (TSQM) in Malay version

Items	E1	E2	S4	S5	S6	C7	C8	C9	GS10	GS11
	Effectiveness									
E1	1.000	0.719	0.180	0.181	0.212	0.495	0.481	0.493	0.682	0.672
E2	0.719	1.000	0.189	0.182	0.202	0.401	0.383	0.372	0.635	0.620
			Side Effects							
S4	0.180	0.189	1.000	0.827	0.814	0.078	0.156	0.054	0.223	0.212
S5	0.181	0.182	0.827	1.000	0.817	0.105	0.202	0.042	0.218	0.227
S6	0.212	0.202	0.814	0.817	1.000	0.095	0.184	0.087	0.241	0.243
						Convenience				
C7	0.495	0.401	0.078	0.105	0.095	1.000	0.688	0.752	0.603	0.634
C8	0.481	0.383	0.156	0.202	0.184	0.688	1.000	0.650	0.582	0.581
C9	0.493	0.372	0.054	0.042	0.087	0.752	0.650	1.000	0.607	0.591
									General Satisfaction	
GS10	0.682	0.635	0.223	0.218	0.241	0.603	0.582	0.607	1.000	0.781
GS11	0.672	0.620	0.212	0.227	0.243	0.634	0.581	0.591	0.781	1.000

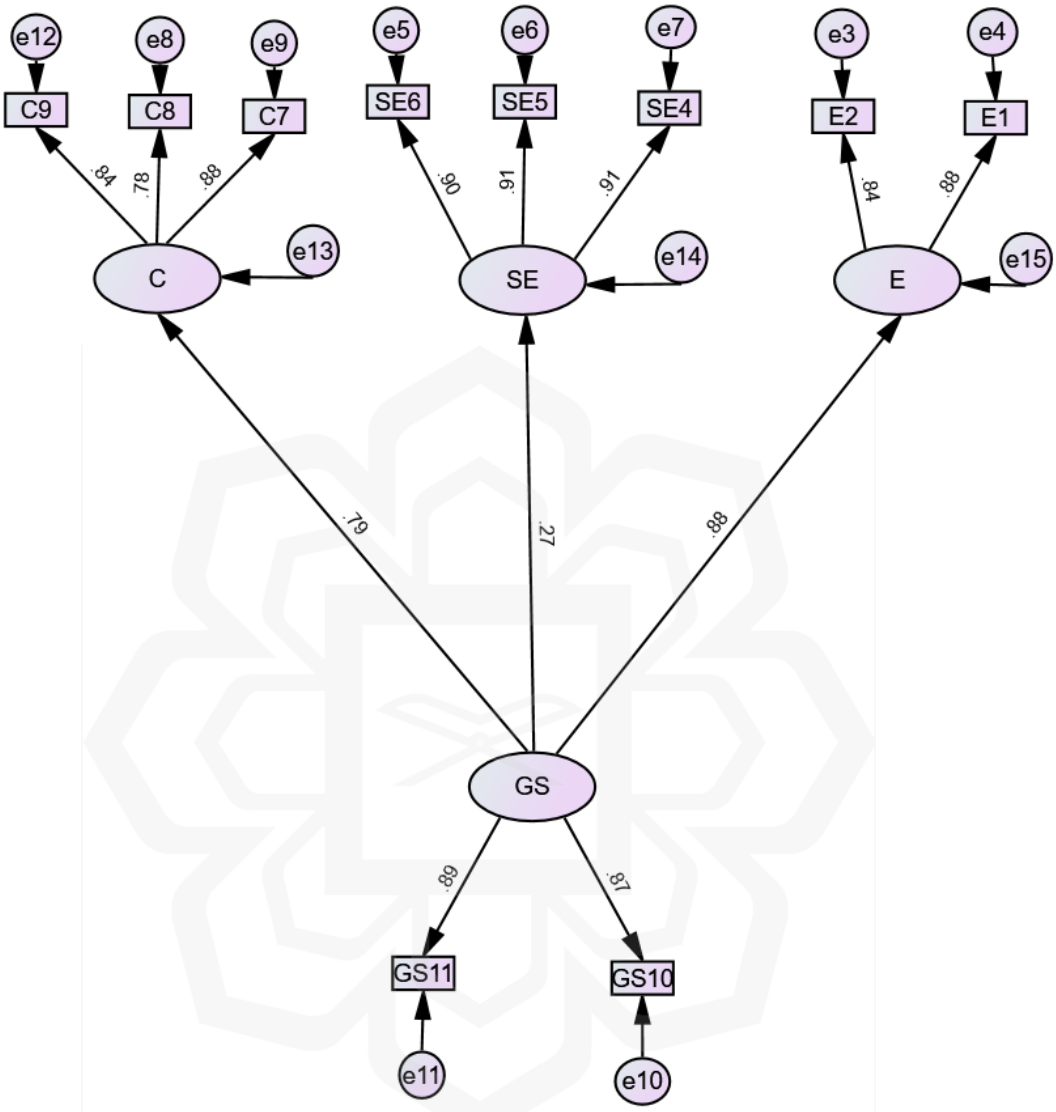


Figure 3.1: Path Diagram for CFA of M-TSQM v.II (n=429)

Table 3.7: Confirmatory Factor Analysis Model Fit for Treatment Satisfaction Questionnaire for Medication (TSQM) in Malay version (n=429)

Category	Index	Level of acceptance	Value
Parsimonious fit	χ^2 / df	<5.0	2.122
Absolute fit	GFI	>0.90	0.969
	RMSEA	<0.08	0.051
Incremental fit	CFI	>0.90	0.988
	TLI	>0.90	0.984
	NFI	>0.90	0.978

χ^2/df = Chi-Square/Degrees of Freedom, GFI = Goodness of Fit Index, RMSEA = (95% CI) Root Mean Square Error of Approximation, CFI = Comparative Fit Index, TLI = Tucker-Lewis Index, NFI = Normed Fit Index

3.4 DISCUSSION

The purpose of the present study is to assess the full psychometric properties of translated Malay version of TSQM v.II among Malay-speaking older adult population. Since the original TSQM is a validated and reliable measurement tool being used in most English-speaking countries, our study cross-culturally adapted this instrument to Malay for the Malaysian population. Hence, this valid, reliable and psychometrically sound generic instrument could measure key components of patient's satisfaction toward treatment based on its effectiveness, side effects, convenience and general satisfaction with various types and dosage forms of medications, especially among Malaysian older adult patients.

For validation testing, our study still retained four constructs in this instrument, even though the construct validity using CFA stated otherwise. Unidimensionality could not be achieved since the loading factor of the "General Satisfaction" to "Side Effects" construct was very low and not within the acceptable range. In comparison, similar studies applied CFA, a study by Alam et al. (2018), in which they performed the first-order confirmatory factor analysis (Alam et al., 2018). Meanwhile, the studies reported by Atkinson et al. (2005) and Sauer Liberato et al. (2016) conducted the second-order confirmatory factor analysis, with the 'General Satisfaction' domain as a higher/second-order construct (Atkinson et al., 2005; Sauer Liberato et al., 2016), which were similar to the present study.

Then, both path coefficient diagrams reported by Atkinson et al. (2005) and Sauer Liberato et al. (2016) had similar patterns of low factor loading with the 'General Satisfaction' domain to the 'Side Effects' domain (below 0.6), which affect the unidimensionality and cause the disturbance of the model because only a small proportion of the sample experienced side effects and highly satisfied range. However, both studies practiced a flexible judgment by still maintaining and not removing the 'Side Effect' domain because of the theoretical justification, in which they prioritise the meaningfulness of the theoretical construct rather than strictly following statistical criteria.

In addition to that, the goodness-of-fit (e.g., CFI, RMSEA, Chisq/df, etc.) indexes also showed that the measurement model for both studies was a good fit, even though the 'Side Effect' domain was retained, which is similar to the present study. On

the other hand, the first-order CFA constructed by Alam et al. (2018) shows that the goodness-of-fit was good, with the achievement of unidimensionality (all item's factor loading ≥0.60) and discriminant validity (correlation between latent constructs ≤0.85). By any means, implementing either first-order or second-order CFA is still suitable for cross-cultural adaptation of TSQM. Thus, the present study suggests that the model fits the data using second-order CFA, despite the unidimensionality not being achieved.

For reliability, M-TSQM v.II demonstrated a good internal consistency based on Cronbach's α value and composite reliability (CR). The implementation of CR in this study strengthens the measurement of internal consistency, which incorporates structural equations modelling (SEM) using confirmatory factor analysis. Utilisation of Cronbach's α value only tends to have overestimation risks. Other than that, the CR values depend on the factors loading and error variances in SEM, while Cronbach's α values are based on average inter-item correlation. Therefore, both measurements provide comprehensive estimates of reliability in this study, which are similar implementation of other cross-cultural adaptation studies of TSQM (Alam et al., 2018; Sauer Liberato et al., 2016).

Regarding the level of treatment satisfaction, the scores were based on the nature of the diseases in the population (Sauer Liberato et al., 2016). As shown in Table 3.8, our study reported a mean of 73.91 (SD = 15.23) for overall treatment satisfaction, which is comparable to several similar studies evaluating treatment satisfaction using TSQM outside Malaysia, such as in Italy, Lebanon, and South Korea among older adult population (Byun et al., 2019; Lapolla et al., 2020; Sakr et al., 2018). In South Korea, the overall satisfaction scores were among the lowest due to the inclusion of postmenopausal osteoporosis (PMO) in their study population (Byun et al., 2019). Low levels of satisfaction might be varied according to the unique administration of the medication (e.g., bisphosphonate) in their study. In comparison, the general older adult population regardless of the medical condition scored higher levels of treatment satisfaction, which is supported by the findings in the recent study and the study conducted in Lebanon (Sakr et al., 2018). Consistent with the developer of TSQM, their research also stated that the overall satisfaction highly differed based on the diagnosis, clinical characteristics, and type of medication prescribed (Atkinson et al., 2005).

There were several limitations concerning this study. Firstly, the recent study was only conducted among Malaysian older adult patients in a unicentric setting in Pahang, Malaysia. This aspect limits the generalisability of the findings to other states. Secondly, there were only about one-fourth of the participants reported side effects of any medications in this study. Statistically, this might have minimised the variation in the "Side Effects" domain. The interference with the naturalistic studies might happen such as the assessment of side/adverse effects in a way that is not common routine in clinical settings. Sometimes, even the patients could also not aware of the incidence of side effects. Thus, it will cause disturbance to the CFA model.

Future work should emphasise increasing the generalisability of the study among other Malaysian populations in multiple institutions of other states in Malaysia. Next, the implementation of the TSQM Version 9 could be considered, since the "Side Effects" domain was excluded from the measurement to avoid psychometric statistical disturbance.

Table 3.8: Comparison of TSQM scores for each domain on certain diseases and nations among older adults

TSQM Domain Score	Malaysian older adult patients (Present study)	Lebanese elderly patients (Sakr et al., 2018)	Postmenopausal osteoporosis (PMO) elderly patients in South Korea (Byun et al., 2019)	Elderly patient with type 2 diabetes mellitus in Italy (Lapolla et al., 2020)
TSQM Version	TSQM II	TSQM 1.4	TSQM 1.4	TSQM 9
Effectiveness	70.69	71.26	56.10	75.76
Side Effects	87.37	91.95	64.20	NA
Convenience	65.59	77.69	63.00	78.23
General Satisfaction	71.99	68.52	53.80	72.23
Overall TSQM	73.91	77.36	59.28	75.41

3.5 CONCLUSION

The cross-cultural adaptation of M-TSQM v.II demonstrated favourable validity findings in terms of its content validity and construct validity. It also showed good reliability of the construct in the measurement tool. Retainment of four constructs in M-TSQM v.II exhibits a robust model fit with favourable fitness indexes using second-order CFA, even though the unidimensionality is not achieved. To conclude, the M-TSQM v.II is a valid, reliable and psychometrically sound instrument to assess treatment satisfaction among Malay-speaking populations.

For the significance to clinical practice, this translated Malay version of TSQM could be utilised crucially to capture the trueness level of treatment satisfaction in Malaysian healthcare settings, since it has been validated to consider the cultural and language nuances of the Malaysian context. Other than that, this measurement tool could aid the thorough understanding of the patient's satisfaction with the treatment. It will act as a guide for healthcare professionals to individualise the treatment based on the patient's need, which potentially leads to better medication adherence in future especially among underserved populations.

CHAPTER FOUR

INVESTIGATING THE ASSOCIATION BETWEEN MEDICATION REGIMEN COMPLEXITY (MRC), MEDICATION ADHERENCE (MA) AND TREATMENT SATISFACTION (TS) AMONG MALAYSIAN GERIATRIC PATIENTS VISITING OUTPATIENT CLINICS IN SASMEC@IIUM

4.1 INTRODUCTION

Older adults usually have multiple comorbidities that require the use of multiple medications to control these conditions. However, medication adherence among this population is still suboptimal (Emadi et al., 2022). Poor medication adherence is believed to be the critical reason for treatment failure, where the treatment and clinical outcomes are not achieved (Baryakova et al., 2023). Poor medication adherence is a major challenge experienced by the older adult population, and it is highly associated with unfavourable clinical outcomes of their medical conditions (Smaje et al., 2018).

Treatment satisfaction is interpreted as a patient-reported outcome measure (PROM), which is the total of the patient's satisfaction with the perception and expectation of the treatment given (Aljumah et al., 2014). It has been demonstrated that treatment satisfaction is determined by the satisfaction of medication's effectiveness, the convenience of medication administration, and the presence of undesirable side effects (Aljumah et al., 2014). The development of a generic measurement tool enabled researchers to evaluate the level of treatment satisfaction in different patients. A commonly used tool is the Treatment Satisfaction Questionnaire for Medication (TSQM) (Atkinson et al., 2004).

Previously, it was known that MRC could be explained as a simple count of medications administered per patient. However, the number of medications taken cannot quantify the complexity measure of the medication regimen, which also must describe the various routes of administration, dosage forms, dosing frequencies and additional medication instructions (Ayele et al., 2019). A study by George et al. (2004) quantified the medication regimen complexity, known as the Medication Regimen Complexity Index (MRCI) (George et al., 2004).

To the best of our knowledge, there is a scarcity of conclusive findings regarding the studies investigating the association between medication regimen complexity, treatment satisfaction, and medication adherence altogether, especially among Malaysian older adults' outpatients. The selection for the outpatient settings for this study was the patient's well-being much stable and felt less distressed as compared to inpatient settings, which the patient may express their preferences precisely (Schneeberger et al., 2023). Thus, the objectives of this research were (1) to study the impact of medication regimen complexity and other variables on medication adherence and treatment satisfaction, (2) to determine the association between treatment satisfaction and other variables with medication adherence, and (3) to identify the mediator variable in the proposed framework using mediator analysis.

4.2 METHODOLOGY

4.2.1 Study Design and Settings

A unicentric hospital-based cross-sectional study was conducted among older adult patients in a teaching hospital in Pahang, Malaysia, known as Sultan Ahmad Shah Medical Centre (SASMEC)@IIUM between March 2023 and September 2023. This study was conducted in various medical outpatient department settings, specifically at the Department of Orthopaedic, Traumatology & Rehabilitation and Department of Internal Medicine (Cardiology and Cardiothoracic Clinic, Respirology Clinic, Haematology Clinic, Nephrology Clinic, Endocrinology Clinic, Neuromedical Clinic, Gastroenterology Clinic and General Medical Clinic 1).

The sampling technique implemented in this study was non-probability sampling, specifically convenience sampling. Other than that, secondary data sources such as clinical data, prescribed medications and comorbidities were obtained from electronic health records/physical medical records. While for primary data sources such as sociodemographic, treatment satisfaction, and medication adherence were obtained via the physical interview, in which the data collector/researcher facilitates the participant's understanding of each item. The aim and outcome of this study were explained to the participants before obtaining their consent during their follow-up at the respective clinics.

4.2.2 Sample Size

The sample size was calculated using the Raosoft sample size calculator. For this research, the margin of error was set to 5 %, the confidence level was 95%, the population size was 20,000, and the prevalence of nonadherence was 60% (Chang et al., 2021). After the calculation, the recommended sample size for this study is approximately 363 patients. An additional 20% were included in the sample size, accounting for the contingency of possible attrition and non-response of participants in the study to achieve enough statistical power.

4.2.3 Study Population

Participants were recruited on the day of their routine appointment and consultation with their respective clinics, where the patient was invited to participate in the study. The general aim of the study and ethical considerations were explained briefly. The selection criteria for the participants in this study were as follows :

1. Malaysian citizens.
2. Older adult outpatients aged 65 years old and above;
3. Patients who had been using at least three prescribed chronic medications for the past three months;
4. Consented to take part in the study;
5. Able to speak and understand the Malay language

However, the participants were excluded from the study if the participants met one or more of the following criteria :

1. Unable to give proper informed consent (e.g., patients with cognitive impairment such as dementia and Alzheimer diseases);
2. Severe language barriers (e.g., cannot speak and understand Malay language, unable to communicate appropriately);
3. Missing value and information from the electronic health record;
4. Enrolled in another clinical research (e.g., clinical trial)

4.2.4 Operational Definitions and Measurement Tools

Polypharmacy and hyperpolypharmacy were defined as concurrent use of ≥ 5 and ≥ 10 medications, respectively (Masnoon et al., 2017). Medication management was assessed by asking the patients whether they managed their medications by themselves or by some assistance from caregivers or totally by caregivers. Based on that, medication management was categeorised as self-managed by the patient, partially self-managed, or fully managed by family members/caregivers. The Charlson Comorbidity Index (CCI) was used to evaluate the clinimetric properties of the patient's morbidity (Charlson et al., 2022). A CCI score of 1–2 represents mild comorbidities, whereas 3–4 and ≥5 represent moderate and severe comorbidities, respectively (Huang et al., 2014). Diseases were classified using the International Classification of Diseases 11th (ICD-11), which is a global standard for reporting the classification of health and diagnosis information (Harrison et al., 2021). The medications were classified based on the Anatomical Therapeutic Chemical (ATC) classification, which considers the active ingredient of the drug in proportion to body systems (*WHOCC - ATC/DDD Index*, 2023).

4.2.4.1 Medication Regimen Complexity (MRC)

The Medication Regimen Complexity Index (MRCI) is a validated 65-item instrument that measures and quantifies the complexity of the patient's overall medication regimen by yielding weights based on dosage formulations, route of administration, dosing frequencies, and additional administration instructions (George et al., 2004). There are three components in this measurement tool: component A (dosage form), component B (dosing frequency) and component C (additional instructions). One study has categorised and set the cut-off point for the MRCI score, in which low complexity is below 15, moderate complexity range within 15.5 to 20 and high complexity score is above 20.5 (Belachew et al., 2022). MRCI-related information was extracted from electronic health records/physical medical charts. To ease the calculation process, this research implemented automated calculation of MRCI by using Microsoft Access v1.0, developed by Libby et al. (2013). A higher MRCI indicates a more complex medication regimen and this measurement tool has no maximum score.

4.2.4.2 Medication Adherence

Malaysia Medication Assessment Adherence Tool (MyMAAT) was used as an evaluation tool to assess the patient's adherence to the medication. It is readily available in Malay and English languages. MyMAAT comprises three parts: perception of the

patient's adherence to medication, category of patient's adherence toward medication, and summary of patient's adherence toward medication. This 12-item questionnaire has a 5-point Likert-type scale ranging from 1 (“Strongly Agree”) to 5 (“Strongly Disagree). The minimum total score is 12 points, and the maximum is 60 points. Therefore, a total score of 54 and above indicates good adherence, whereas a total score below 54 indicates moderate and poor adherence (Hatah et al., 2020).

4.2.5 Statistical Analysis

4.2.5.1 Descriptive Analysis

All the statistical analyses were done using Statistical Package for the Social Sciences version (SPSS) 27.0. For descriptive data, continuous variables were analysed as mean and standard deviation, while categorical variables were analysed as frequency and percentage. All the data were sorted and screened for any extreme cases/outliers and normality of the data. The normality test evaluated data using skewness and kurtosis (Byrne, 2016; Hair et al., 2010). Mahalanobis distance is the analysis used to detect extreme cases/outliers (Li et al., 2019).

4.2.5.2 Test of Relationship

Factors that might be associated with either treatment satisfaction or medication adherence were tested using univariate and multivariate analyses. Chi-square test, *t*-test and simple linear regression were used for univariate analyses. Binomial logistic regression was applied to test the predictors of medication nonadherence, while multiple linear regression was used to check factors associated with treatment satisfaction and MRC by the Enter entrance method. Logistic regression was computed because medication nonadherence is a binary variable, while linear regression was computed because treatment satisfaction and MRC are continuous variables. Hosmer–Lemeshow’s test and area under the receiver operating curve (ROC) were used to determine the goodness of fit of the regression models. We also used the mediation analysis proposed by Hayes to explore the direct and indirect effect of medication regimen complexity on medication adherence with treatment satisfaction as a mediator variable (Hayes, 2013).

4.3 RESULT

A total of 498 participants were recruited for this study, with some excluding procedures for those who did not fulfil the criteria requirement. For the whole data collection process, a total of 69 participants were excluded due to some of the following reasons. 13 participants were cognitive impairment (e.g., dementia, Alzheimer's disease), 15 participants were prescribed with non-chronic medication and discontinued the medication, 7 participants had a severe language barrier, 10 participants were <65 years old and 5 participants withdrew from the study. During the data screening procedure, our research must exclude another 12 participants with missing data and 7 participants with extreme values/outliers, due to inaccurate measures during data collection. Lastly, 429 participants have fulfilled the criteria and the related data of all these participants are ready to be analysed.

4.3.1 Sociodemographic and clinical characteristics of the sample

As shown in Table 4.3, from the sample of 429 Malaysian older adult outpatient individuals in SASMEC@IIUM, the mean age of the participants was 71.98 (SD = 5.48) years old and 72% of the participants were within the 65 – 74 years old category. The proportion of male patients (57.6%, n = 247) was slightly higher as compared to females, with Malay participants being the significant proportion of the total population (82.5%, n = 354), followed by Chinese (8.9%, n = 38) and Indian (8.2%, n = 35). Other than that, married participants in the sample comprise 78.8% (n = 338); different marital statuses such as widowed, divorced and single were 22.2% (n = 91).

Meanwhile, in Table 4.4, for clinical characteristic data, the mean of 5.35 (SD = 2.08) score for the Charlson Comorbidity Index (CCI) was recorded, along with approximately more than half of the sample being categorised as severe CCI (60.1%, n = 258). Based on the ICD-11 classification, the most common diagnosis among Malaysian older adults is circulatory system diseases (e.g., hypertension, dyslipidaemia, ischaemic heart disease, etc.) with a percentage of 44.8%, followed by 15.5% from endocrine, nutritional and metabolic diseases (e.g., diabetes mellitus, hyperthyroidism, etc.) and 9.9% from genitourinary system diseases (e.g., chronic kidney disease, benign prostatic hyperplasia, etc.).

For medication-related characteristics, an average of 7.69 (SD = 2.59) prescribed medication per participant, with 90.2% (n = 387) of the participants having polypharmacy with at least 5 medications. Based on ATC classification for a therapeutic group, various common types of groups prescribed chronic medication to the patient were the cardiovascular system (37.0%, n = 1227), alimentary tract & metabolism (27.1%, n = 898), blood & blood-forming organs (11.5%, n = 380) and respiratory system (6.7%, n = 222) See in Table 4.4. Besides, half of the participants were able to manage their medications by themselves (50.6%, n = 217), while the rest of the participants were partially and fully managed by family members/caregivers, which are 39.2% (n = 168) and 10.3%(n = 44) respectively.

In regard to measurement outcomes, it was found that the prevalence of moderate/poor adherence among Malaysian older adults in this study was 51.0% (n = 219). Meanwhile, the mean of treatment satisfaction scores for each domain: 70.69 (SD = 19.38) for effectiveness, 87.37 (SD = 21.78) for side effects, 65.59 (SD = 21.18) for convenience and 71.99 (SD=18.85) for general satisfaction were measured. Overall treatment satisfaction from four domains was 73.91 (SD=15.23). Lastly, the calculated score for the mean of medication regimen complexity was 17.37 (SD=7.07), with moderate to high complexity consisting of 53.3% (n = 230) of the total participants involved in this research.

4.3.2 Factors associated with MRC, medication nonadherence and treatment satisfaction

As shown in Table 4.1, the multivariate linear regression model includes several demographics and characteristics variables that were potentially to have significant association with MRC. The significant level for the independent variables was set to $p < 0.05$ in all regression models. Then, the model exhibited that Charlson Comorbidity Index (CCI) score (β = 0.500, 95% CI: 0.239 – 0.760, $p < 0.001$), the presence of polypharmacy (β = 5.772, 95% CI: 4.073 – 7.471, $p < 0.001$) and hyperpolypharmacy (β = 14.929, 95% CI: 12.971 – 16.888 , $p < 0.001$) were the significant determinants for a high MRCI score.

Table 4.1: Factors associated with high medication regimen complexity (MRC) score using multivariate linear regression

Independent variables	β	95% Confidence Interval	*p* value
Charlson Comorbidity Index	**0.500**	**0.239 – 0.760**	**<0.001**
Age	-0.032	-0.135 – 0.072	0.549
Gender			
Male	0.661	-0.341 – 1.662	0.195
Female	1	(Ref)	(Ref)
Polypharmacy			
No polypharmacy (3 – 4 medications)	1	(Ref)	(Ref)
Polypharmacy (5 – 9 medications)	**5.772**	**4.073 – 7.471**	**<0.001**
Hyperpolypharmacy (≥10 medications)	**14.929**	**12.971 – 16.888**	**<0.001**
Marital status			
Married	-0.747	-2.105 – 0.610	0.262
Other (widowed, divorced & single)	1	(Ref)	(Ref)

Note: R^2 = 0.492, Adjusted R^2 = 0.482, Ref is a reference group for the categorical variable

Table 4.3 depicts the results of the chi-square test and *t*-test of medication adherence as the dependent variable with the involvement of several independent variables. Various factors were significantly associated with medication nonadherence. After controlling for covariables using multivariate logistic regression analysis, four factors significantly predicted nonadherence to the medications: (1) MRC (AOR = 1.179, 95% CI: 1.064 – 1.306, p = 0.002), (2) overall treatment satisfaction (AOR = 0.847, 95% CI: 0.811 – 0.884, $p < 0.001$), (3) partially self-managed medication (AOR

= 2.675, 95% CI: 1.259 – 5.685, p = 0.011) and (4) fully managed by family members/caregivers (AOR = 8.436, 95% CI: 2.003 – 35.524, p = 0.004). All assumptions needed to apply the multiple logistic regression were met before running the model. The multiple logistic regression model statistically and significantly predicted patient nonadherence. Additionally, the area under the ROC curve of 96.0% and p-value of 0.489 for the Hosmer and Lemeshow test indicates that this logistic regression model is a good fit for the data as depicted in Figure 4.1 and Table 4.5. Box plot illustration for factors associated with nonadherence were shown in Figure 4.2 and Figure 4.3

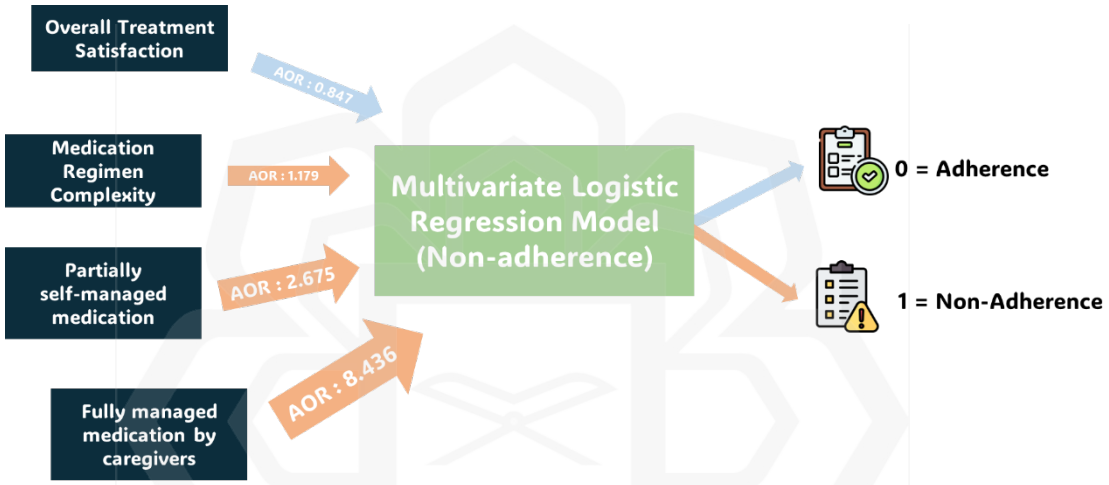


Figure 4.1: The significant determinants for nonadherence using multivariate logistic regression. The larger the arrow is the greater the impact is. AOR: adjusted odd ratio.

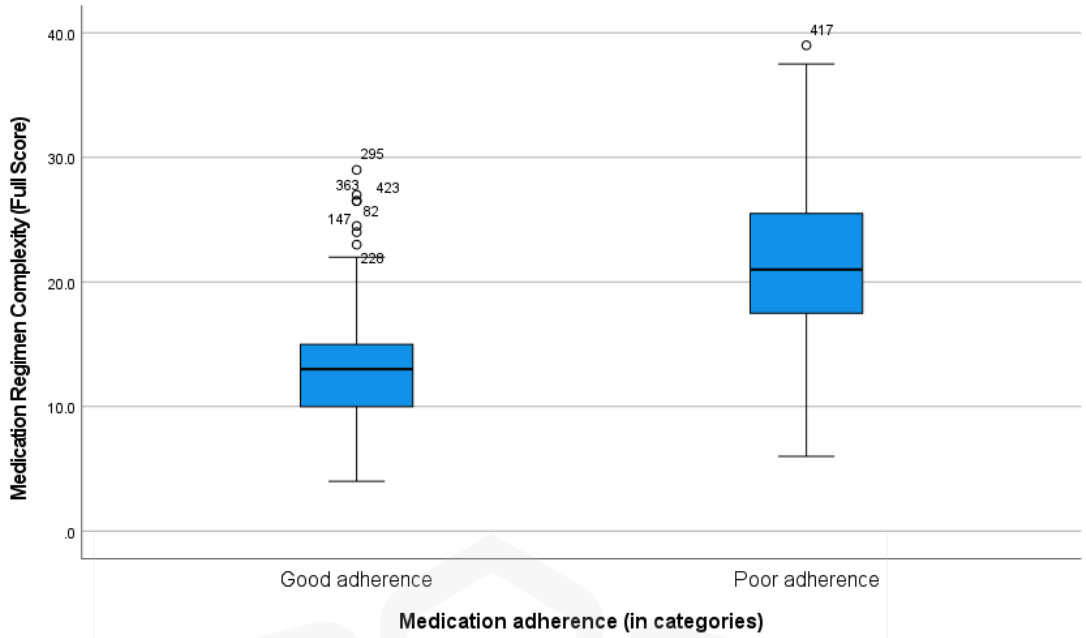


Figure 4.2: Test of Differences for Boxplot of Chi-Square mean values of MRC among adherence/nonadherence groups

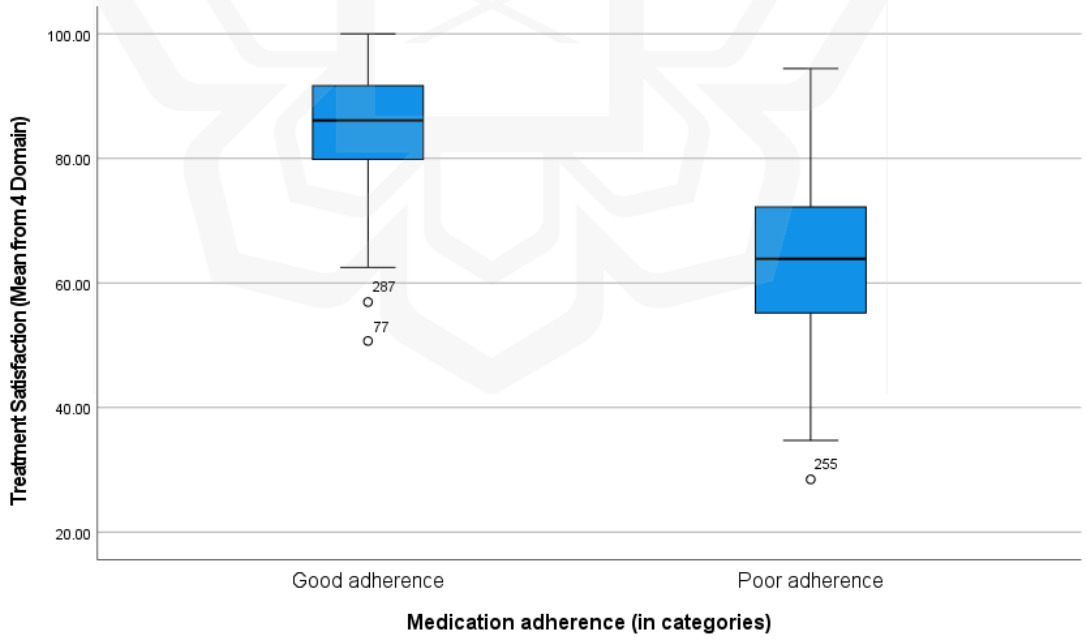


Figure 4.3: Test of Differences for Boxplot of Chi-Square mean values of overall treatment satisfaction among adherence/nonadherence groups

Table 4.6 shows univariate and multivariate analyses that were conducted to determine the significant predictors of overall treatment satisfaction. After adjusting for

other covariates, only three predictors were significantly associated with overall treatment satisfaction, namely, (1) MRC (β = -1.395, 95% CI: -1.635 – -1.155, p < 0.001), (2) CCI (β = -0.746, 95% CI: -1.303 – -0.189, p = 0.009) and (3) self-managed medication (β = 5.554, 95% CI: 1.634 – 9.474, p = 0.006). Conclusively, the value of R^2 in this multivariate linear regression model is 50.3%, and the combination of the medication regimen complexity, self-managed medication and CCI variables could explain the variance in overall treatment satisfaction in this model. Figure 4.4 illustrates the scatterplot with a regression line of MRC to the overall treatment satisfaction.

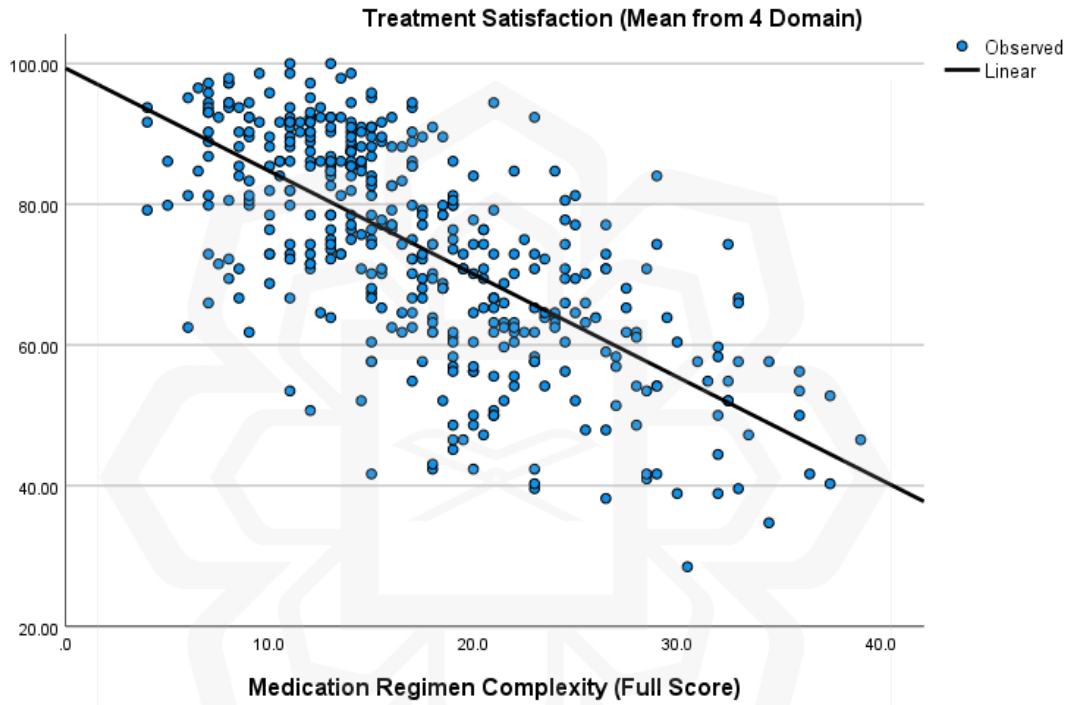


Figure 4.4: Scatterplot with a regression line of relationship between MRC and overall treatment satisfaction

4.3.3 The impact of MRC on medication adherence through treatment satisfaction

The mediation analysis indicates a significant effect of the indirect pathway of medication regimen complexity on nonadherence through treatment satisfaction (β = 0.230, 95% CI = 0.175 – 0.316). The direct pathway demonstrates a significant effect of medication regimen complexity on nonadherence (β = 0.211, 95% CI = 0.140 – 0.282). Since both pathways showed significant effects, treatment satisfaction partially mediated the effect of medication regimen complexity on nonadherence. Table 4.2

Table 4.2: Evaluation of direct effect and indirect effect of MRC on medication non-adherence through treatment satisfaction using mediator analysis

Association	Direct Effect	95% CI Direct Effect	Indirect Effect	95% CI Indirect Effect	*z*-score	Remarks
MRC -> treatment satisfaction -> medication non-adherence	0.211 ($p <$ 0.001)	0.140 – 0.282	0.230	0.175 – 0.316	5.828	Partial mediation

Table 4.3: Demographic and medical characteristics of the patients with comparison of adherence/nonadherence groups (n=429)

Variable	Overall patients (%)	Adherence (n=210)	Non-Adherence (n=219)	*p*-value
Age (mean ± SD)	71.98 ± 5.48	71.50 ± 5.07	72.44 ± 5.83	0.073
65 – 69 years old	157 (36.6)	79 (18.4)	78 (18.2)	
70 – 74 years old	152 (35.4)	83 (19.3)	69 (16.1)	0.052
≥75 years old	120 (28.0)	48 (11.2)	72 (16.8)	
Gender				
Male	247 (57.6)	113 (26.3%)	134 (31.2%)	0.122
Female	182 (42.4)	97 (22.6%)	85 (19.8%)	
Ethnicity				
Malay	354 (82.5)	168 (39.2)	186 (43.3)	0.179
Non - Malay	75 (17.5)	42 (9.8)	33 (7.7)	
Marital Status				
Married	338 (78.8)	173 (40.3)	165 (38.5)	
Others (widowed, divorced or single)	91 (21.2)	37 (8.6)	54 (12.6)	0.075
Residency				

Urban	246 (57.3)	118 (27.5)	128 (29.8)	0.637
Rural	183 (42.7)	92 (21.4)	91 (21.2)	
Education Level				
College/University	181 (42.2)	90 (21.0)	91 (21.2)	0.234
Secondary school	152 (35.4)	80 (18.6)	72 (16.8)	
Primary school or no formal education	96 (22.4)	40 (9.3)	56 (13.1)	
Employment Status				
Pensioner	219 (51.0)	110 (25.6)	109 (25.4)	0.246
Unemployed	91 (21.2)	38 (8.9)	53 (12.4)	
Housewife	92 (21.4)	45 (10.5)	47 (11.0)	
Self-employed & employed	27 (6.3)	17 (4.0)	10 (2.3)	
Income per month				
< RM 1000	148 (34.5)	66 (15.4)	82 (19.1)	0.484
RM 1000 - RM 2500	93 (21.7)	52 (12.1)	41 (9.6)	
RM 2501 - RM 4000	66 (15.4)	30 (7.0)	36 (8.4)	
RM 4001 - RM 4999	54(12.6)	28 (6.5)	26 (6.1)	
≥ RM 5000	68(15.9)	34 (7.9)	34 (7.9)	
Management of Medications				
Self-managed	217 (50.6)	162 (37.8)	55 (12.8)	<0.001[a]

Partially self-managed	168 (39.2)	42 (9.8)	126 (29.4)	
Fully managed by family members/caregivers	44 (10.3)	6 (1.4)	38 (8.9)	
Charlson Comorbidity Index				
CCI (mean ± SD)	5.35 ± 2.08	4.78 ± 1.89	5.90 ± 2.10	<0.001[b]
Mild CCI (≤ 2)	21 (4.9)	17 (4.0)	4 (0.9)	
Moderate CCI (3 – 4)	150 (35.0)	91 (21.2)	59 (13.8)	<0.001[a]
Severe CCI (≥ 5)	258 (60.1)	102 (23.8)	156 (36.4)	
Treatment Satisfaction (mean ± SD)				
Effectiveness	70.69 ± 19.38	82.14 ± 13.04	59.70 ± 18.08	<0.001[b]
Side Effects	87.37 ± 21.78	93.06 ± 15.57	81.93 ± 25.23	<0.001[b]
Convenience	65.59 ± 21.18	79.23 ± 14.60	52.51 ± 18.02	<0.001[b]
General Satisfaction	71.99 ± 18.85	86.03 ± 11.03	58.52 ± 14.44	<0.001[b]
Overall Mean Treatment Satisfaction	73.91 ± 15.23	85.12 ± 8.67	63.17 ± 12.10	<0.001[b]
Medication Regimen Complexity				
Total MRCI (mean ± SD)	17.38 ± 7.07	12.76 ± 4.27	21.81 ± 6.35	<0.001[b]
Component A (Dosage Form) (mean ± SD)	3.62 ± 2.77	2.20 ± 1.77	4.99 ± 2.88	<0.001[b]

Component B (Dosing Frequency) (mean ± SD)	10.09 ± 4.31	7.80 ± 2.69	12.29 ± 4.43	<0.001[b]
Component C (Additional Instruction) (mean ± SD)	3.67 ± 1.88	2.77 ± 1.50	4.53 ± 1.81	<0.001[b]
Low complexity (≤ 15)	199 (46.4)	169 (39.4)	30 (7.0)	
Medium complexity (15.5 – 20)	100 (23.3)	32 (7.5)	68 (15.9)	<0.001[a]
High complexity (≥ 20.5)	130 (30.3)	9 (2.1)	121 (28.2)	
Prescribed Medications				
Per Patient (mean ± SD)	7.69 ± 2.59	6.37 ± 1.96	8.95 ± 2.49	<0.001[b]
No polypharmacy (3 – 4 medications)	42 (9.8)	35 (8.2)	7 (1.6)	
Polypharmacy (5 – 9 medications)	288 (67.1)	166 (38.7)	122 (28.4)	<0.001[a]
Hyperpolypharmacy (≥10 medications)	99 (23.1)	9 (2.1)	90 (21.0)	

Note: [a] Statistically significant *p* values from continuous variables using *t*- test; [b] Statistically significant *p* values from categorical variables using Chi-square test**;** Based on normality test, the normally distributed data was reported as mean and standard deviation values (mean ± SD), while the non-normally distributed data was expressed as median values.

Table 4.4: Descriptive statistics of prescribed medication in outpatient clinic settings

Variable	(n=429)
Medication Regimen Complexity	**Number of patients (%)**
Total MRCI (mean ± SD)	17.38 ± 7.07
Component A (Dosage Form) (mean ± SD)	3.62 ± 2.77
Component B (Dosing Frequency) (mean ± SD)	10.09 ± 4.31
Component C (Additional Instruction) (mean ± SD)	3.67 ± 1.88
Low complexity (≤ 15)	199 (46.4%)
Medium complexity (15.5 – 20)	100 (23.3%)
High complexity (≥ 20.5)	130 (30.3%)
Medication count	
Prescribed Drugs/Patient (mean ± SD)	7.69 ± 2.59
No polypharmacy (3 – 4 medications)	42 (9.8%)
Polypharmacy (5 – 9 medications)	288 (67.1%)
Hyper polypharmacy (≥10 medications)	99 (23.1%)
Therapeutic groups according to ATC classification	**Number of medication (%) (N=3315)**
Cardiovascular system	1227 (37.0%)
Alimentary tract & metabolism	898 (27.1%)
Blood & blood-forming organs	380 (11.5%)
Respiratory system	222 (6.7%)
Musculoskeletal system	147 (4.4%)
Nervous system	146 (4.4%)
Genitourinary system	101 (3.1%)
Sensory organs	63 (1.9%)
Dermatological	51 (1.5%)
Systemic hormones	32 (1.0%)
Antineoplastics	30 (0.9%)
Anti-infective and various	18 (0.5%)

Table 4.5: Variables included in the nonadherence logistic regression model

Independent variables	Adjusted Odds Ratio (AOR)	95% Confidence Interval (CI)	*p* value
Medication Regimen Complexity	**1.179**	**1.064 – 1.306**	**0.002***
Treatment Satisfaction (Overall)	**0.847**	**0.811 – 0.884**	**<0.001***
Charlson Comorbidity Index	0.945	0.773 – 1.115	0.580
Medication management			
Self-managed	1	(Ref)	(Ref)
Partially self-managed	**2.675**	**1.259 – 5.685**	**0.011***
Fully managed by family members/caregivers	**8.436**	**2.003 – 35.524**	**0.004***
Number of medications per patient/polypharmacy	1.120	0.882 – 1.421	0.354
Other variables			
Age	1.026	0.946 – 1.113	0.531
Gender			
Male	1	(Ref)	(Ref)
Female	0.992	0.450 – 2.189	0.985
Marital status			
Married	1	(Ref)	(Ref)
Other (widowed, divorced & single)	1.046	0.390 - 2.808	0.929
Geographical location			
Urban	1	(Ref)	(Ref)
Rural	0.889	0.407 – 1.943	0.768
Education level			
College/university	1	(Ref)	(Ref)

Secondary school	1.085	0.326 – 3.612	0.894
Primary school & other (no formal education)	2.794	0.610 – 12.282	0.186
Income status			
< RM 1000	1.242	0.699 – 2.209	0.394
RM 1000 - RM 2500	0.357	0.421 – 1.476	0.195
RM 2501 - RM 4000	1.444	0.431 – 4.387	0.551
RM 4001 - RM 4999	0.602	0.164 – 2.208	0.444
≥ RM 5000	1	(Ref)	(Ref)

Omnibus Test of Model Coefficient (Chi-square = 372.85, $p < 0.001$)

Hosmer and Lemeshow Test [$\chi^2(8) = 7.453$, $p = 0.489$]

Area under Receiver Operating Characteristic (ROC) curve = 0.960 (95% CI: 0.944,0.976)

Note: Ref is a reference group for the categorical variable

Table 4.6: Univariate and multivariate linear regression to identify predictors of treatment satisfaction

Independent variable	Univariate analysis			Multivariate analysis		
	β	95% CI	*p* value	β	95% CI	*p* value
Medication Regimen Complexity	**-1.462**	**-1.612 , -1.311**	**<0.001**	**-1.395**	**-1.635 , -1.155**	**<0.001***
Number of medications per patient/polypharmacy	-2.979	-3.462 , -2.497	<0.001	0.577	-0.075 , 1.230	0.083
Charlson Comorbidity Index	**-2.534**	**-3.189 , -1.879**	**<0.001**	**-0.746**	**-1.303 , -0.189**	**0.009***
Medication management						
Self-managed	**17.383**	**13.019 , 21.747**	**<0.001**	**5.554**	**1.634 , 9.474**	**0.006**
Partially self-managed	3.905	-0.565 , 8.375	0.087	1.323	-2.351 , 4.997	0.479
Fully managed by family members/caregivers	(Ref)			(Ref)		
Marital status						
Married	3.983	0.464 , 7.502	0.027	2.283	-0.299 , 4.864	0.083
Other (widowed, divorced & single)	(Ref)			(Ref)		
Geographical location						

Urban	0.146	-2.870 , 3.071	0.922	1.334	-0.780 , 3.447	0.216
Rural	(Ref)			(Ref)		

$R^2 = 0.503$, Adjusted $R^2 = 0.494$

95% CI = 95% Confidence Interval for β

Note: Ref is a reference group for the categorical variable

4.4 DISCUSSION

This study showed that 51.0% of the older adult patients visiting outpatient clinics were nonadherent to their chronic medications. Similar findings reported from Portugal, Singapore and the USA revealed that the prevalence of nonadherence among older adults was 56.3%, 60.0% and 54.8%, respectively (Abada et al., 2017; Chew et al., 2021; Félix & Henriques, 2021). Additionally, a systematic review and meta-analysis demonstrated that the pooled prevalence of nonadherence among older adult patients in Malaysia was 60.6% (Chang et al., 2021). Hence, all studies reported a comparable prevalence to ours, with more than half of the older adult patients being nonadherent.

One meta-analysis study indicated that the prevalence of polypharmacy among the Malaysian older adult population ranged from 20.3% to 100% (Chang et al., 2021). Myriad definitions of polypharmacy terminology have been implemented in various studies, which signify the wide range of polypharmacy prevalence reported in this meta-analysis study. Their study also demonstrated that the pooled prevalence of polypharmacy from multiple studies was 49.5%, which means that nearly half of Malaysian older adult patients were polypharmacy (Chang et al., 2021). Nevertheless, the prevalence of polypharmacy in the current study was found to be 90.2%, which means that the majority of patients visiting our study site were exposed to polypharmacy. This difference could be attributed to the fact that the SASMEC@IIUM is a teaching hospital and tertiary care setting in which most of the participants in this population are referred to various outpatient specialist clinics. The pooled prevalence (49.5%) reported in the above-mentioned meta-analysis was derived from heterogeneous studies conducted in primary, secondary and tertiary healthcare settings, which may affect the number of prescribed medications per patients. Moreover, the reported CCI score in our study was much higher than that reported in the other studies. High number of comorbidities is the basis for the increase in polypharmacy prevalence with most of the patients diagnosed with severe comorbidities (high CCI score). A study conducted among older patients with chronic pain in Germany found a significant association between CCI score and polypharmacy (Schneider et al., 2021).

Next, our study showed an average CCI score of 5.4, indicating a high and severe comorbidity burden within our study population. Another study conducted in a

tertiary care hospital in Thailand among the geriatric population reported a score of 4.7, which implies that our study has a slightly higher comorbidity burden (Limpawattana et al., 2013). It is common for older adult patients to be diagnosed with multiple morbidities and subsequently have a high CCI (Akkawi & Mohamed, 2018).

The reported mean MRC score in this study was 17.38 (SD = 7.07), which can be categorised into medium complexity (15.5 – 20) (Belachew et al., 2022). In comparison, two studies that evaluated MRC among Malaysian older adults diagnosed with acute infections (i.e., UTI and RTI) reported low complexity (≤ 15.0), which were 14.0 and 11.8, respectively (Akhtar et al., 2021a; Akhtar et al., 2021b). Other studies also evaluated MRC among chronic kidney disease (CKD) older patients in Australia and Norway, with reported higher MRC scores of 27.0 and 22.8, respectively, which are classified as high complexity (≥20.5) (Parker et al., 2019; Tesfaye et al., 2019). A wide range of medication regimen complexity scores reported in distinct studies explained the variation in medication regimens across various patient populations and healthcare settings. Our study was also able to identify the significant determinants of high MRC scores, which are the CCI and the presence of polypharmacy in their regimen using a regression model. A possible explanation for this might be that most comorbid older adult patients in this present study were severely morbid and diagnosed with various diseases, leading to more prescribed concurrent medications according to their management plan. Hence, the complexity of medication regimens arises as a result of this phenomenon. This finding is broadly supported and consistent with other literature, in which they also reported that increasing CCI scores and polypharmacy were associated with higher MRCI scores (Albayrak & Demirbaş, 2023; Parker et al., 2019).

Furthermore, our study reported a mean of 73.91 (SD = 15.23) for overall treatment satisfaction, which is comparable to several similar studies evaluating treatment satisfaction using TSQM outside Malaysia, such as Italy, Lebanon, and South Korea (Byun et al., 2019; Lapolla et al., 2020; Sakr et al., 2018). The average overall treatment satisfaction ranged from 59.28 to 77.36, with the highest satisfaction score reported by Sakr et al. (2018), who conducted the study among Lebanese general elderly population (Sakr et al., 2018). Meanwhile, a study by Byun et al. (2019) among postmenopausal osteoporosis in South Korea reported the lowest satisfaction score (Byun et al., 2019). The varied satisfaction score might be due to the type of population

selected in the sample size (i.e., general population in Lebanon *vs.* diseases-specific population in South Korea). Thus, our treatment satisfaction score falls within the range of similar studies, indicating that our study population is reasonably satisfied with the treatment, which can be considered a positive benchmark of the treatment effectiveness provided to the patients.

Our research proved that increasing MRC is a significant predictor of nonadherence. In comparison, several reports have examined the negative association between MRC and medication adherence among older patients across groups of diseases and localities, in which the most of the studies indicated that MRC was negatively associated with medication adherence (Abada et al., 2017; Bazargan et al., 2017; Belachew et al., 2022; Ghimire et al., 2016; Kuo et al., 2017; Wakai et al., 2021). Meanwhile, a few studies found no negative association between these variables (Federman et al., 2021; Félix & Henriques, 2021; Parker et al., 2019). This finding further describes that complex medication regimens could increase the cognitive load among older adult patients, with some of them having difficulty comprehending the whole medication instructions due to cognitive deterioration. Therefore, it also leads to regimen confusion between the medications taken and results in nonadherence among the older adult population.

The current study demonstrates that treatment satisfaction is a significant predictor of medication adherence after adjusting for other covariates. This finding is consistent with several studies that show a positive association between these variables among older adult patients (Abu Bakar et al., 2016; Al-Ruthia et al., 2017; Loganathan et al., 2017; Yang et al., 2023). Hence, this may explain why patients who are satisfied with their medication have enhanced motivation due to their expectations being fulfilled. Therefore, good treatment satisfaction suffices as a positive reinforcement for patient adherence.

Additionally, this study indicates that MRC is a significant predictor of treatment satisfaction even after controlling for other variables. In fact, a limited number of studies assess this association. A possible explanation for this might be that MRC could relate to the inconvenience of taking medication. Older adult patients often experience such difficulty while taking their medication, especially with complex instructions for certain medications. Therefore, the patient may suffer from frustration

and demotivation, which could lead to low treatment satisfaction. Our result corroborates with other findings, in which these studies explained that pharmacotherapeutic complexity among their population was associated with lower level of treatment satisfaction (De Las Aguas Robustillo Cortés et al., 2017; Sendekie et al., 2023). Additionally, this also aligns with one systematic review, which signifies the frequent evaluation of patient-reported outcomes measures (PROM) such as quality of life and patient satisfaction have a positive impact on the patient's experience if the simplification of medication regimen complexity interventions studies could be done (Alves-Conceição et al., 2018).

The mediation analysis revealed that treatment satisfaction partially mediated the association between MRC and nonadherence. Treatment satisfaction acts as a partial mediator, which means the presence of this factor only accounts for the partial influence of MRC on non-adherence. To justify, there is only part of the association between MRC and non-adherence that can be explained by the patient's satisfaction with their treatment via indirect effect in mediation analysis. In other words, a more complex medication regimen leads to lower treatment satisfaction and, subsequently, poorer medication adherence. Moreover, the direct effect of MRC to non-adherence in mediation analysis is also significant, which means the association may not involve the mediation of treatment satisfaction. This means that in addition to its direct effect on medication adherence, MRC also indirectly affects medication adherence through patient's satisfaction on the treatment. This finding is consistent with the studies by other researchers, which suggest that nonadherence is affected by MRC and treatment satisfaction (Wiffen et al., 2012; Yap et al., 2016). However, neither study could explain the mediating role of treatment satisfaction in this association due to the scarcity of studies assessing this association between these three variables altogether. Thus, this finding supports our hypothesis in the proposed framework, in which our study expected the role of treatment satisfaction as a mediating variable in this association. Future research should focus on determining treatment satisfaction as the mediator role of MRC in medication adherence. Emphasising the evaluation of treatment satisfaction could promote the integration of the patient in the clinical settings routine. Therefore, the patient's preferences will be prioritised, and medication regimen can be personalised to make positive impact on medication adherence among older adult patients.

Both regression models indicate that medication management is significantly associated with medication adherence and treatment satisfaction. Participants who were either partially or fully dependent on other people – in terms of management medications – had a significantly higher possibility of being nonadherent to their medications compared with independent patients. There are similarities between our findings and those described by other researchers (Gomes et al., 2019). A possible explanation for this result is that older patients who managed medications by themselves have a higher level of engagement and control over their medication. However, those who rely on the caregiver cannot fully engage with their treatment plan and lose control over their medication, which leads to nonadherence. Additionally, communication barriers between patients and caregivers might contribute to misunderstanding and a lack of clarity regarding the treatment, which could also influence adherence (Kwame & Petrucka, 2021). It is worth noting here that the assessment of patients' dependence on medication management was based only on one question. Although the question was clear and straightforward, it may not reflect the actual daily behaviour of the patients. Therefore, further studies should implement a valid measurement tool for determining the type of medication management.

Another covariate potentially associated with nonadherence and treatment satisfaction among older adults is the number of medications per patient/polypharmacy (Ulley et al., 2019). Initially, our findings showed that polypharmacy is associated with nonadherence and treatment satisfaction using univariate analysis. However, using multivariate analysis, our study demonstrated that polypharmacy is not a significant predictor of nonadherence or treatment satisfaction after controlling for other variables. The basis behind the lack of association might be due to the high prevalence of polypharmacy (>90%) in the study population, making it an indiscriminating factor between adherent and nonadherent patients. Another reason could be the presence of other strong predictors in the models, which influence nonadherence and treatment satisfaction in this population.

In addition, our incidental findings showed that CCI is a significant predictor of treatment satisfaction, which might be because severely morbid patients have poor prognosis for specific types of diseases (e.g., cancer, T2DM complications), leading to low treatment satisfaction. A study conducted in China supported our finding, in which

they reported that the severity of the disease contributes to lower medication satisfaction among COPD patients (Wu et al., 2023). Their finding demonstrated that those with more severe conditions tend to have lower satisfaction due to the high occurrence of symptoms (Wu et al., 2023). Consistent with our finding, a study conducted among diabetic patients in Ethiopia also signifies that diabetic patients with complications and multimorbidity were the key determinants of lower degree of treatment satisfaction (Sendekie et al., 2023). Thus, further studies should focus on assessing this association to identify the actual basis between these variables among older adult patients.

This present research can identify several limitations throughout the whole study process. First, the information on the additional instructions about the medication prescribed was not extensively updated in the electronic health record system; thus, MRCI could be underestimated. In addition, our study only considered the subjective measure of medication adherence using the self-reported measurement tool, in which patients tend to overestimate the level of adherence. Next, our research was conducted in a unicentric setting in Kuantan, Pahang, limiting the generalisation of the findings to the Malaysian older adult population. In addition, even though convenience sampling is quick, cost-effective and ease of access way for sampling method, the main limitation is the potential for sampling bias. Thus, based on setting and convenience sampling, the generaliasability of study is limited. A future multicentre longitudinal study implementing objective assessment for nonadherence is recommended.

4.5 CONCLUSION

The study explored the association between medication regimen complexity, treatment satisfaction and medication adherence among older adult patients in Pahang, Malaysia. Approximately half of the population was not adherent to their medications and had medium complexity regimens. The notable findings in this study showed that MRC, overall treatment satisfaction, and partial and full dependence on others to manage medications are significant predictors of medication nonadherence. Furthermore, the significant determinants influencing overall treatment satisfaction were MRC, CCI and self-managed medication. Last, treatment satisfaction partially mediated the association between MRC and non-adherence.

This study suggests that simplifying the medication regimen and involving patients in the treatment plan could be part of the strategy to solve the nonadherence issue in older adults. Future interventional studies are warranted to prove the above assumption. Other than that, recognising patient-reported outcomes such as treatment satisfaction could emphasise the importance of tailoring the medication regimen according to the patient's experiences. Therefore, ensuring the patient is satisfied with their treatment may address the issue of non-adherence among the older adult population.

CHAPTER FIVE

CONCLUSION

5.1 OVERALL CONCLUSION

Firstly, the cross-cultural adaptation of M-TSQM v.II yielded a positive outcome based on its content validity and construct validity, along with the reliability of each construct in this measurement tool. Although the non-attainment of unidimensionality, the retainment of the four constructs in M-TSQM v.II exhibits a strong model fit, corroborated by several favourable fitness indexes using second-order confirmatory factor analysis. In summary, the translated Malay version of TSQM v.II proves to be a valid, reliable and psychometrically sound measurement tool for assessing treatment satisfaction among Malay-speaking populations.

Next, the present study also investigated the association between medication regimen complexity, treatment satisfaction and medication adherence among older patients in Kuantan, Pahang. About half of the population in the study were non-adherence to the medication and had moderately complex medication regimens. Key findings emphasise the significant factors contributing to medication non-adherence among Malaysian older adults were medication regimen complexity, overall treatment satisfaction and reliance on caregivers for medication management. In addition, the noteworthy predictors such as medication regimen complexity, Charlson Comorbidity Index (CCI) and self-managed medication were affecting the degree of treatment satisfaction. Finally, based on mediator analysis, treatment satisfaction acts as a mediating variable with partial influence on the association between medication regimen complexity toward medication non-adherence.

5.2 FUTURE DIRECTION

The present study primarily focuses on the crucial matter concerning the well-being of health-related issues among geriatric/older adult patients. Improvement of the geriatric

healthcare system in Malaysia could be attained by addressing the issues of medication non-adherence and the factors associated with it. Emphasising the leading causes of non-adherence such as medication regimen complexity and treatment satisfaction could improve the health-related outcomes within this population, as well as reduce the incidence of re-hospitalisation, risk of further major complications, and the financial burden as a result of medication wastage.

Also, this key finding can inform multiple stakeholders such as policymakers, prescribers, pharmacists, nurses and other healthcare professionals for optimising the medication regimens to enhance the rate of adherence among Malaysian older adult patients. This finding could help the development of medication regimen simplification guidelines, which are tailored based on the patient's needs. Future simplification strategies are warranted to verify our significant findings in this study. Not to forget, patient-caregiver relationship issues should be addressed properly since they significantly influence non-adherence in the present study. With the empowerment of the caregiver in medication management, the role of the caregiver such as providing emotional support, facilitating the medication organisation and assisting the effective patient-provider communication should promote better medication adherence among this ageing population.

Lastly, recognising the treatment satisfaction outcomes as a mediating variable among this population facilitates the understanding of patient's preferences and experiences. This patient-centred approach can guide healthcare professionals to provide treatment regimens according to patient-specific care. The involvement of the patient in the centre of this healthcare system contributes to a better overall well-being among this population.

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Zun, A. B., Ibrahim, M. I., Mokhtar, A. M., Halim, A. S., & Wan Mansor, W. N. A. (2019). Translation, cross-cultural adaptation, and validation of the hospital consumer assessment of healthcare providers and systems (HCAHPS) into the Malay language. *International Journal of Environmental Research and Public Health*, *16*(11). https://doi.org/10.3390/ijerph16112054

APPENDIX I-A: PROOF OF THE PUBLISHED ABSTRACT PROCEEDING IN MALAYSIAN JOURNAL OF MEDICINE AND HEALTH SCIENCES (SCOPUS AND MYCITE INDEXED JOURNAL)

Malaysian Journal of Medicine and Health Sciences Vol.19 Supp 13, November 2023 (eISSN 2636-9346)

OP132

Evaluation of Medication Regimen Complexity and its Association with Medication Adherence Among Malaysian Older Adult Outpatients in a Teaching Hospital: A Cross-Sectional Study in Pahang, Malaysia

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ABSTRACT

Introduction: Approximately 60% of Malaysian older adults have poor medication adherence. Nonetheless, the determinants of non-adherence among the Malaysian older adult population are still lacking. This research evaluates medication regimen complexity (MRC) and its association with medication adherence among Malaysian older adults. **Methods:** A cross-sectional study was conducted in outpatient settings of a teaching hospital in Pahang, Malaysia via in-person interview. Medication Regimen Complexity Index (MRCI) and Malaysia Medication Adherence Assessment Tool (MyMAAT) were used to collect patients' medical information and medication adherence status. Univariate (χ^2 and t-test) and multivariate (logistic regression) analyses using SPSS software were applied. **Results:** A total of 429 participants were recruited, with the mean of total MRC is 17.38 ± 7.07 and the prevalence of non-adherence is 51.0% (n = 219). While adjusted for co-variables, multivariate logistic regression indicates three significant determinants of non-adherence: (1) Total MRC (adjusted odds ratio/aOR= 1.375, $p < 0.001$), (2) partially self-managed medication (aOR = 3.625, $p < 0.001$) and (3) fully managed medication by the family members/caregivers (aOR = 8.138, $p < 0.001$). The logistic regression model fit is good based on the Hosmer & Lemeshow test ($p = 0.162$) and the area under receiver operating characteristic/ROC curve is 0.917. **Conclusion:** Non-adherence might occur due to high MRC and patient's inability to manage their medications by themselves. Further studies should increase the generalisability of the Malaysian older adult population from other states in Malaysia, since the study is conducted only in a unicentric based in Pahang, Malaysia.

Keywords: Medication regimen complexity, Medication adherence, Malaysian older adult, regression analysis, Cross-sectional study

APPENDIX I-B: PROOF OF PUBLISHED PUBLICATION IN Q1 JOURNAL OF BMC GERIATRICS

Al Haqimy Mohammad Yunus *et al. BMC Geriatrics* (2024) 24:447
https://doi.org/10.1186/s12877-024-05016-y

BMC Geriatrics

RESEARCH Open Access

Investigating the association between medication regimen complexity, medication adherence and treatment satisfaction among Malaysian older adult patients: a cross-sectional study

Mohammad Adam Al Haqimy Mohammad Yunus[1], Muhammad Eid Akkawi[1,2*] and Abdul Rahman Fata Nahas[1,2]

Abstract

Background The prevalence of medication nonadherence among Malaysian older adults is approximately 60%. However, there is a lack of studies assessing the factors associated with medication nonadherence among this population. This research aims to explore the association between medication regimen complexity (MRC), treatment satisfaction and medication adherence among Malaysian older adults.

Method A cross-sectional study was conducted in outpatient clinics of a teaching hospital in Pahang, Malaysia, between April 2023 and September 2023. MRC Index (MRCI), Treatment Satisfaction for Medication version II (TSQM v.II), and the Malaysian Medication Adherence Assessment Tool (MyMAAT) were used. Multivariate linear and logistic regression models were performed to test the factors affecting treatment satisfaction and medication adherence. Mediator analysis was implemented to assess the mediating role of treatment satisfaction.

Result The study involved 429 Malaysian older adult patients, with a prevalence of nonadherence of 51.0% ($n=219$) and an MRCI mean score of 17.37 (SD = 7.07). The mean overall treatment satisfaction score was 73.91 (SD = 15.23). Multivariate logistic regression analysis expressed four significant predictors associated with nonadherence: MRC (AOR = 1.179, $p=0.002$), overall treatment satisfaction (AOR = 0.847, $p<0.001$), partially self-managed medication (AOR = 2.675, $p=0.011$) and fully managed medication by family members/caregivers (AOR = 8.436, $p=0.004$). Multivariate linear regression shows three predictors of treatment satisfaction: MRC ($\beta = -1.395$, $p<0.001$), Charlson Comorbidity Index (CCI) ($\beta = -0.746$, $p=0.009$) and self-managed medication ($\beta = 5.554$, $p=0.006$). Mediator analysis indicated that treatment satisfaction partially mediated the association between MRC and nonadherence.

Conclusion Nonadherence was quite prevalent among Malaysian older outpatients and was associated with regimen complexity, treatment satisfaction and patient dependence on others to manage their medications. Future studies should focus on interventions to control the factors that negatively affect patients' medication adherence.

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APPENDIX I-C: ACCEPTANCE LETTER OF PRESENTING SCIENTIFIC ABSTRACT IN 4TH INTERNATIONAL CONFERENCE OF PHARMACY AND HEALTH SCIENCES (4ICPHS) 2023

Date: 26 **September 2023**

Subject: Acceptance of your scientific abstract in ICPHS 2023
Reference Number: OP132

Dear Mr. Mohammad Adam Al Haqimy Bin Mohammad Yunus,
Good day to you. We are happy to inform that your abstract entitled "**Evaluation of Medication Regimen Complexity and its Association with Medication Adherence Among Malaysian Older Adult Outpatients in a Teaching Hospital: A Cross-Sectional Study in Pahang, Malaysia"** has been accepted for **Oral Presentation** 4th International Conference of Pharmacy and Health Sciences 2023 (ICPHS 2023). We will keep in touch with you shortly regarding the guidelines to prepare the presentation.

Should you have any queries related to registration, please contact the ICPHS 2023 registration committee through email: icphs2023@unikl.edu.my. Please contact ICPHS 2023 registration via the same email if you require official acceptance letter for visa application purposes.
Looking forward to meet you in Kuala Lumpur.

Best Regards
Dr. Judy Loo Ching Yee
Head of Scientific Committee, ICPHS 2023

APPENDIX II-A: AWARDED WITH BEST ORAL PRESENTER FOR CLINICAL PHARMACY & PHARMACY CATEGORY IN 4TH INTERNATIONAL CONFERENCE OF PHARMACY AND HEALTH SCIENCES (4ICPHS) 2023

MARA CORPORATION · UniKL UNIVERSITI KUALA LUMPUR

CERTIFICATE OF PARTICIPATION

This certificate is presented to

MOHAMMAD ADAM AL HAQIMY BIN MOHAMMAD YUNUS

Best Oral Presenter
Category: Clinical Pharmacy & Pharmacy Practice

4th International Conference of Pharmacy and Health Sciences (4ICPHS) 2023
Towards Sustainable Healthcare: From R&D and Industry to Society

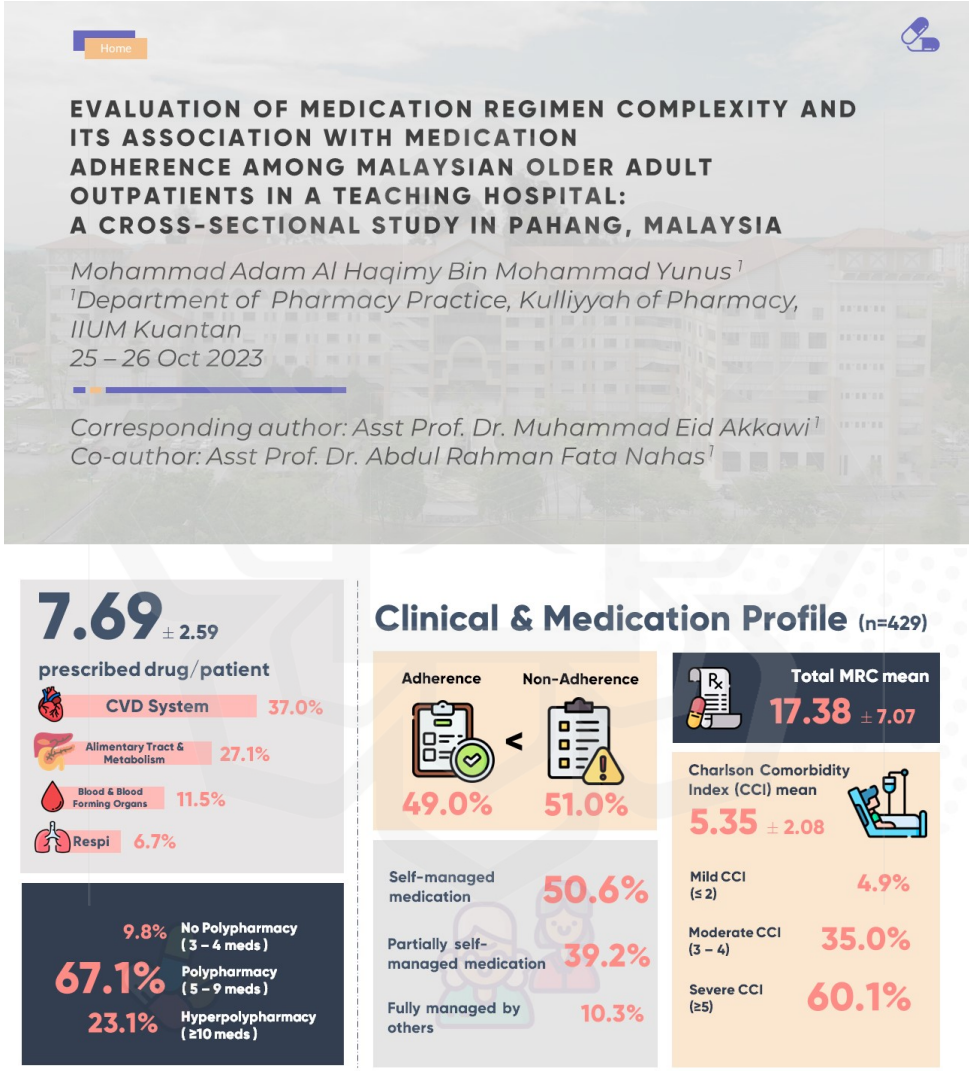
25th – 26th October 2023 | Seri Pacific Hotel, Kuala Lumpur

Dr. Nour Hanah Othman
Organising Chairperson

Prof. Dr. Ahmad Fuad Shamsuddin
Conference Advisor

Assoc. Prof. Ir. Dr. Azman Senin
Acting President/ Chief Executive Officer UniKL

APPENDIX II-B: SLIDE PRESENTATION FOR CLINICAL PHARMACY & PHARMACY CATEGORY IN 4TH INTERNATIONAL CONFERENCE OF PHARMACY AND HEALTH SCIENCES (4ICPHS) 2023



APPENDIX II-C: ORAL PRESENTER FOR CLINICAL PHARMACY & PHARMACY CATEGORY IN 4TH INTERNATIONAL CONFERENCE OF PHARMACY AND HEALTH SCIENCES (4ICPHS) 2023

APPENDIX III-A: APPROVAL TO CONDUCT RESEARCH IN SASMEC@IIUM

الجامعة الإسلامية العالمية ماليزيا
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
Garden of Knowledge and Virtue

SULTAN AHMAD SHAH MEDICAL CENTRE @IIUM

SULTAN AHMAD SHAH MEDICAL CENTRE @IIUM

Ref : IIUM/413/DEaR/14/11/2/IISR21-06-2021
Date : 14th July 2021

Asst. Prof. Dr. Muhammad Eid Akkawi
Department of Pharmacy Practice
Kulliyyah of Pharmacy
International Islamic University Malaysia

Assalamualaikum Wrt. Wbt

Dear Asst. Prof. Dr,

REPLY: APPROVAL TO CONDUCT RESEARCH IN SULTAN AHMAD SHAH (SASMEC) @ IIUM

May this letter reach you in the best of health and Iman by the grace of Allah Subhanahu Wata'ala

The above matter is kindly referred.

We would like to inform that your application to conduct research activities in Sultan Ahmad Shah Medical Centre (SASMEC) @ IIUM has been approved with the following condition:

1) The staff has undergone and passed the Re-Education of 'The New Norm' Program as he will physically present in SASMEC.

The details as below:

Name	:	Asst. Prof. Dr. Muhammad Eid Akkawi
Research Title	:	Investigating the association between medication regimen complexity and medication adherence among geriatric patients and the impact of an intervention on their medication adherence
Focus of research	:	1) Orthopaedic Clinic 2) Internal Medicine Clinic 3) Departmet of Pharmacy
Duration of research	:	01 Jun 2021- 01 Jun 2023

If you have any inquiry, please do not hesitate to contact:
1) Sr. Amira Farhana Mohd Maizam 09-591 2561/ amirafarhana@iium.edu.my
2) Sr. Norzaharah Mat Senor at norzaharah@iium.edu.my
3) Sr. Nazifah Zaidi at nazifah@iium.edu.my

Office Address: Sultan Ahmad Shah Medical Centre @IIUM
International Islamic University Malaysia, Jalan Sultan Hj Ahmad Shah, Bandar Indera Mahkota, 25200 Kuantan, Pahang Darul Makmur.
Tel: +6095912500 | Fax: +6095912699 | Website: http://www.iiummc.edu.my

APPENDIX III-B: APPROVAL TO CONDUCT RESEARCH IN SASMEC@IIUM

Your kind attention is highly appreciated.

Thank You.

Wassalam.

DR. NIK NUR FATNOON NIK AHMAD
Head
Department of Education and Research
Sultan Ahmad Shah Medical Centre @IIUM
International Islamic University Malaysia

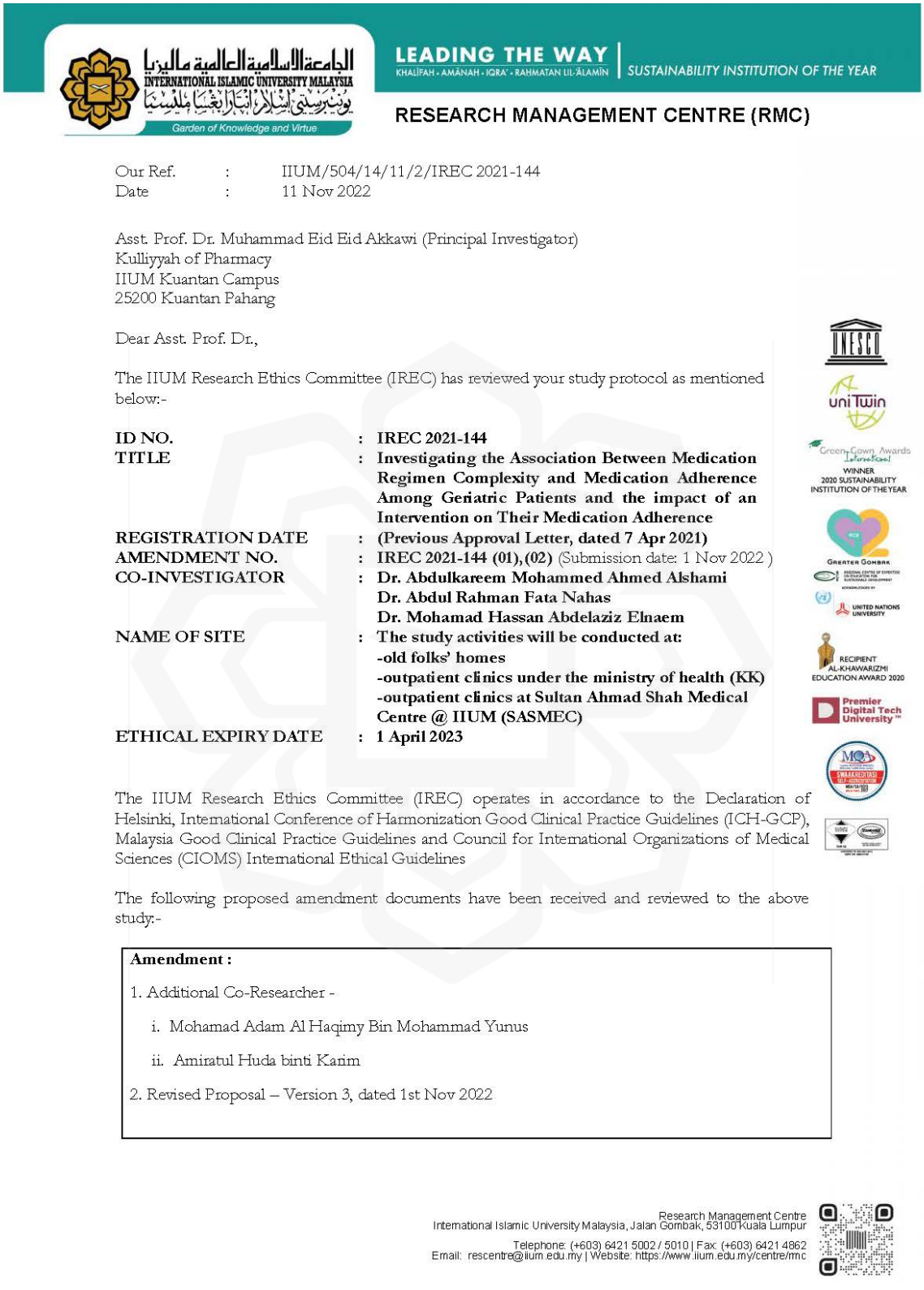
cc:
1. Prof. Dato' Dr. Mohamed Saufi bin Awang
Hospital Director, Sultan Ahmad Shah Medical Centre @IIUM

2. Prof Dr Zamzuri Zakaria
Director (Clinical), Sultan Ahmad Shah Medical Centre @IIUM

3. Madam Che Rokiah Binti Ismail
Head Department of Pharmacy, Sultan Ahmad Shah Medical Centre @IIUM

NNF/AFM/nnz

APPENDIX IV-A: IREC APPROVAL LETTER



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LEADING THE WAY
KHALIFAH · AMANAH · IQRA' · RAHMATAN LIL-'ALAMIN | SUSTAINABILITY INSTITUTION OF THE YEAR

RESEARCH MANAGEMENT CENTRE (RMC)

Our Ref. : IIUM/504/14/11/2/IREC 2021-144
Date : 11 Nov 2022

Asst. Prof. Dr. Muhammad Eid Eid Akkawi (Principal Investigator)
Kulliyyah of Pharmacy
IIUM Kuantan Campus
25200 Kuantan Pahang

Dear Asst. Prof. Dr.,

The IIUM Research Ethics Committee (IREC) has reviewed your study protocol as mentioned below:-

ID NO.	:	**IREC 2021-144**
TITLE	:	**Investigating the Association Between Medication Regimen Complexity and Medication Adherence Among Geriatric Patients and the impact of an Intervention on Their Medication Adherence**
REGISTRATION DATE	:	**(Previous Approval Letter, dated 7 Apr 2021)**
AMENDMENT NO.	:	**IREC 2021-144 (01),(02)** (Submission date: 1 Nov 2022)
CO-INVESTIGATOR	:	**Dr. Abdulkareem Mohammed Ahmed Alshami** **Dr. Abdul Rahman Fata Nahas** **Dr. Mohamad Hassan Abdelaziz Elnaem**
NAME OF SITE	:	**The study activities will be conducted at:** **-old folks' homes** **-outpatient clinics under the ministry of health (KK)** **-outpatient clinics at Sultan Ahmad Shah Medical Centre @ IIUM (SASMEC)**
ETHICAL EXPIRY DATE	:	**1 April 2023**

The IIUM Research Ethics Committee (IREC) operates in accordance to the Declaration of Helsinki, International Conference of Harmonization Good Clinical Practice Guidelines (ICH-GCP), Malaysia Good Clinical Practice Guidelines and Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines

The following proposed amendment documents have been received and reviewed to the above study:-

Amendment :

1. Additional Co-Researcher -
   i. Mohamad Adam Al Haqimy Bin Mohammad Yunus
   ii. Amiratul Huda binti Karim
2. Revised Proposal – Version 3, dated 1st Nov 2022

Research Management Centre
International Islamic University Malaysia, Jalan Gombak, 53100 Kuala Lumpur
Telephone: (+603) 6421 5002 / 5010 | Fax: (+603) 6421 4862
Email: rescentre@iium.edu.my | Website: https://www.iium.edu.my/centre/rmc

APPENDIX IV-B: IREC APPROVAL LETTER

Decision by IIUM Research Ethics Committee (IREC):

(√) Approved
( ) Disapproved **Date of Approval: 9 Nov 2022**

The investigator(s) are required to:

a) submit the 'Continuing Review Form' 30 days before **EXPIRY DATE** to renew Ethical Approval.
b) notify IREC of any change in protocol and obtaining further ethical approval as appropriate.
c) report any adverse incident during the course of a study to IREC even if the incident is not directly related to the study.
d) report to the IREC within 72 hours for all internal SAEs (occurring in IIUM PI site).
e) report in a prompt manner if the information impacts the continued ethical acceptability of the trial for external SAEs (occurring in participants at other sites).
f) provide information of minor protocol deviation in Progress Report or End Report whichever necessary.
g) report any major protocol deviation occurs within 5 working days.
h) submit Progress Report Form before the end of six (6) months given by IREC.
i) complete and submit the End of Project Report Form to the IREC Secretariat's Office.
j) All records and data subjects are **CONFIDENTIAL** and used only for the purposes of this study and all issues and procedures on data confidentiality must be observed.

Thank you.

Yours sincerely,

PROF. DR. NASSER MUHAMMAD AMJAD
Chairman,
IIUM Research Ethics Committee (IREC)

Copy : Protocol File – IREC 2021-144

DISCLAIMER: The approval letter only covers the ethical aspect of your study only. Any other permission/approval to use any facilities, data or human resource should fall under applicant's responsibility.

APPENDIX IV-C: IREC APPROVAL LETTER (EXTENSION)

Our Reference : IIUM/504/14/11/2/IREC 2021-144
Date : 3 April 2023

Asst. Prof. Dr. Muhammad Eid Eid Akkawi (Principal Investigator)
Kulliyyah of Pharmacy
IIUM Kuantan Campus
25200 Kuantan Pahang

Dear Asst. Prof. Dr.,

IREC ID	:	**IREC 2021-144**
Title	:	**Investigating the Association Between Medication Regimen Complexity and Medication Adherence Among Geriatric Patients and the impact of an Intervention on Their Medication Adherence**
Co-Investigator	:	**Dr. Abdulkareem Mohammed Ahmed Alshami** **Dr. Abdul Rahman Fata Nahas** **Dr. Mohamad Hassan Abdelaziz Elnaem** **Mohamad Adam Al Haqimy Bin Mohammad Yunus** **Amiratul Huda binti Karim**
Approval Date	:	**2 April 2023**
Ethical Expiry Date	:	**2 April 2024**

APPROVAL LETTER OF CONTINUING REVIEW APPLICATION

We would like to inform you that the **IIUM Research Ethics Committee (IREC)** received the Continuing Review Application Form on **29 March 2023.** Upon review of the Continuing Review Application Form, the IREC committee **APPROVED** your application to continue the aforementioned study for another one (1) year.

The investigator(s) are required to submit the:
a) End of Project Report Form to the IREC Secretariat's Office once the study was completed. You may download the form from website at www.iium.edu.my/centre/irec

Thank you for your continuing compliance with the requirements of the IREC.

Yours sincerely,

PROF. DR. NASSER MUHAMMAD AMJAD
Chairman
IIUM Research Ethics Committee (IREC)

APPENDIX V-A: STATEMENT OF WORK TO USE TSQM FROM IQVIA FOR DATA COLLECTION

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STATEMENT OF WORK
IQVIA Inc. ("IQVIA")
100 IMS Drive, Parsippany, NJ 07054

CLIENT INFO					ADDITIONAL INFO	
Company	International Islamic University Malaysia ("Client")				**Opportunity #**	3011244
Contact	Muhammad Eid Akkawi	**Phone**	0060186675232		**IQVIA Contact**	Lowo Kozamemik
Email	mhdeidak@iium.edu.my	**Fax**	NA		**Effective Date**	Last Date Signed Below
Address	Kulliyyah of Pharmacy, IIUM, Indera Mahkota, 25200, Kuantan, Pahang, Malaysia	**Invoicing Address**	N/A		**Issue any applicable Purchase Order to:** IQVIA Inc. 100 IMS Drive Parsippany, NJ 07054	

Services	Fee
TSQM and TSQM Scoring Algorithm License (collectively, "Licensed Materials") for 450 participants - in connection with protocol IREC-2021-144 titled "The association between medication regimen complexity, medication adherence and treatment satisfaction among Malaysian older adults"	
• Version II	
Total Fee	**Fee Waived**

	TERMS
General	This Statement of Work between Client and IQVIA is made pursuant to and incorporates by reference the terms and conditions of the IQVIA Licensing and Services Agreement General Terms and Conditions (April 2022) available at https://logc.iqvia.com/Contracts/LSA-0422 ("General Terms"). IQVIA shall provide the Services specified in this Statement of Work and Client agrees to pay for such Services in accordance with the General Terms and the terms of this Statement of Work (collectively the "Agreement Terms"). This Statement of Work shall constitute a binding agreement between the parties.
Schedule of Deliverables	Timelines for delivery of the items purchased are outlined in **Appendix A**.
Term	This Statement of Work shall commence on the Effective Date specified above and shall continue in effect during the Term of the Statement of Work (defined below) and payment by Client pursuant to the Agreement Terms.
Definitions	"TSQM" shall mean Treatment Satisfaction Questionnaire for Medication described at www.iqvia.com/TSQM "TSQM Scoring Algorithm" shall mean the algorithm developed by IQVIA to quantify the results of the TSQM. "Representatives" shall mean Client's employees, contractors, or agents. "Term" shall mean term of the Statement of Work starting on the Effective Date (stated above) through 31-Dec-2024.
Special Terms	The parties acknowledge and agree that the Licensed Materials provided under this Statement of Work are deemed to be "IQVIA Materials" as that term is defined in the General Terms. **Permitted Use** Notwithstanding anything to the contrary in the General Terms, IQVIA is providing Client with the Licensed Materials specified above. IQVIA is the owner of the Licensed Materials. These terms and conditions are applicable to Client's use of the Licensed Materials. Upon Client's acceptance of this Statement of Work, and subject to the terms of General Terms, IQVIA grants Client a limited, non sub-licensable, non-assignable, non-transferable, non-exclusive license to use the Licensed Materials (the "Limited License") in accordance with the permitted uses set forth herein. The Licensed Materials are the confidential information of IQVIA. Client will maintain the Licensed Materials in strict confidence and will only reveal the Licensed Materials to Client's Representatives set forth above in accordance with the terms of this Statement of Work and General Terms and then only to the extent required to administer the Project, and as described in the following paragraphs. Client will ensure that Client's

APPENDIX V-B: STATEMENT OF WORK TO USE TSQM FROM IQVIA FOR DATA COLLECTION

	Representatives treat the Licensed Materials as strictly confidential and will be responsible for their acts and omissions. If disclosure of the Licensed Materials is required by law, Client will notify IQVIA prior to such disclosure. Pursuant to the Limited License, Client or Client's Representatives, may download, print and use the Licensed Materials in the form provided by IQVIA only in connection with the Project under this Statement of Work. The TSQM portion of the Licensed Materials may only be administered by Client or Client's Representatives to patients participating in the Project. The TSQM Scoring Algorithms contained within the Licensed Materials may be provided only to Client's Representatives engaged in the Project for the sole purpose of scoring the TSQM portion of the Licensed Materials. Client may not modify or translate the Licensed Materials without the prior written consent of IQVIA. If any modifications to the Licensed Materials made by Client or its Representatives are incorporated into the Licensed Materials, Client hereby assigns to IQVIA all rights Client may have in any modifications. Client acknowledges the fact that modification to the TSQM may alter the psychometric properties of the questionnaire and assumes the responsibility for any risks that using an unvalidated instrument may have on the Project. Except as permitted herein, the Licensed Materials may not be copied, distributed or transmitted without the prior written consent of IQVIA. The Licensed Materials must always include the copyright notice as it appears on the Licensed Materials. Client will inform IQVIA upon the completion of the Project. Following completion of the Project, or upon termination of this Statement of Work, Client or Client's Representative agrees to provide to IQVIA all TSQM data only from the Project that could be used to build the psychometric properties of the Licensed Materials. Any data provided by Client will be kept confidential by IQVIA and used only to improve the psychometric properties of the Licensed Materials. **Appendix D** attached hereto describes the data to be provided to IQVIA and the format in which to send such data. **Publication Obligations** Client may publish its results obtained from authorized use of the Licensed Materials, provided that Client ensures that any such publication includes the following attribution: Atkinson MJ, Kumar R, Cappelleri JC, et al. Hierarchical construct validity of the treatment satisfaction questionnaire for medication (TSQM version II) among outpatient pharmacy consumers. Value Health 2005;8 Suppl 1:S9-S24. Those seeking information regarding or permission to use the TSQM are directed to IQVIA at www.iqvia.com/TSQM or TSQM@iqvia.com Prior to publication, Client agrees to send IQVIA (TSQM@iqvia.com) a copy of the proposed publication and IQVIA shall have up to thirty (30) days thereafter to provide Client written comments relating thereto. Client may not remove any copyright notices from the Licensed Materials when using such materials for the authorized use described herein. Any authorized use of the Licensed Materials, in whole or in part, must contain the following copyright notice: "Copyright © 2006 IQVIA. All rights reserved. Any use, distribution or reproduction, in whole or in part, is expressly prohibited without the prior express written permission of IQVIA."

	IQVIA INC.		INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
Signature	DocuSigned by: David Bard 0D322BFB9B08456...	Signature	
Name	David Bard	Name	Muhammad Eid Akkawi
Title	Head of PCS Instrument Services	Title	Assistant Professor
Date	24-Jul-2023	Date	21/07/2023
Please email signed documents to tsqm@iqvia.com			

APPENDIX VI-A: INFORMED CONSENT FORM (ENGLISH)

ID NO: Version 1.0 dated 7 February 2023

Informed Consent Form

This informed consent form is for older adult patients from Outpatient Clinics of Sultan Ahmad Shah Medical Centre@IIUM (SASMEC@IIUM), who were aged 65 years old and older and prescribed with at least 3 chronic medications, to participate in the research entitled "The Association Between Medication Regimen Complexity, Medication Adherence and Treatment Satisfaction Among Malaysian Older Adults".

Name of Principle Investigator: Asst. Prof. Dr. Muhammad Eid Akkawi
Co-investigators: Br. Mohammad Adam Al Haqimy Bin Mohammad Yunus, Asst Prof. Dr. Abdul Rahman Fata Nahas
Name of Organization: Department of Pharmacy Practice, Kulliyyah of Pharmacy, International Islamic University Malaysia.
Name of Sponsor: Nil.
Name of Project: The Association Between Medication Regimen Complexity, Medication Adherence and Treatment Satisfaction Among Malaysian Older Adults

This Informed Consent Form has two parts:

- Information Sheet (the details about the study)
- Certificate of Consent (for signatures if you choose to participate).

Part I: Information Sheet
Background of the study

Global demographic trends forecast exponential growth in the older adult population aged 60 and above across most nations. In Malaysia, the number of older adults over 60 has grown faster than that of younger people, as much as doubling from over 1 million to over 2.2 million people between 1991 – 2010. Moreover, it is projected that this gap will broaden further over time, with a forecast increase to 7 million (or 17.6%) of the estimated total population of 40 million people in Malaysia in the year 2040. A significant proportion of older adults have numerous advanced diseases and complex healthcare requirements. Besides that, this older adult population likely demonstrates a greater dependence and demand for healthcare services compared to the young people. Due to these issues will inevitably lead to the use of multiple medications prescribed to older adult patients. Therefore, it will cause unavoidable issues such as adverse drug reactions, drug-drug interactions and drug-disease interactions. As consequence of these issues, patients have poor adherence to the medications and low satisfaction with their treatment.

APPENDIX VI-B: INFORMED CONSENT FORM (ENGLISH)

ID NO: Version 1.0 dated 7 February 2023

Purpose of study

Generally, this research aims to explore the association between medication regimen complexity, medication adherence and treatment satisfaction among Malaysian older adult patients. In addition, this study also aims to evaluate the complexity of medication regimens among Malaysian older adult patients and propose methods to simplify the regimen based on the current hospital formulary.

Procedures

We ask you to help us with your experience receiving treatment in SASMEC@IIUM outpatient clinic. We are inviting you to take part in this research project. If you accept, you will be asked to participate in our survey study. The questionnaire will be distributed in various outpatient clinics; preferably, the participant should answer the questionnaire via self-reported measures. There will be 3 THREE forms of the questionnaire available during the assessment: (1) Sociodemographic profile (patient's background); (2) Malaysian Medication Adherence Assessment Tool (MyMAAT) to assess medication adherence and (3) Treatment Satisfaction Questionnaire for Medication (TSQM) to evaluate treatment satisfaction. The estimated duration for answering the survey will be 5-10 minutes. The information recorded is **CONFIDENTIAL**, and no one else except the investigators named in this research will have access to the information documented.

Participant Selection

You are invited to participate in this research because you are fulfilling several selection criteria, such as outpatient age 65 years old and older, have been using at least 3 (THREE) prescribed chronic and long-term medications that are systemically acting. However, you will be excluded from the study if you cannot give proper informed consent (e.g., cognitive impairment), severe language barriers (e.g., cannot speak Malay and English), and are enrolled in another clinical research.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive at this healthcare facility will continue, and nothing will change. The choice that you make will have no bearing on your current received treatment. You may change your mind later and stop participating even if you agreed earlier.

Risks

There is a risk that you may feel uncomfortable talking about some of the topics. You do not have to answer any questions or participate in the survey if you don't wish to, which is also acceptable. You do not have to give us any reason for not responding to any question or refusing to participate in the session.

Benefits

There will be an indirect benefit if you agree and fully participate in this research. First of all, the data collected will be helpful for the various stakeholders, such as prescribers and pharmacists in a healthcare facility, manufacturers from the pharmaceutical industry and others to improve the quality use of medicine, which will enhance the pharmaceutical care services. Therefore, you as a patient, will satisfy with the treatment provided and adhere to the current medication regimen plan.

APPENDIX VI-C: INFORMED CONSENT FORM (ENGLISH)

ID NO: Version 1.0 dated 7 February 2023

Reimbursements
You will not be provided any incentive to take part in the research.

Confidentiality
We will not share information about you to anyone outside the research team. The information that we collect from this research project will be kept private. Any information about you will have a number instead of your name. Only the researchers will know your number, and we will lock that information up. It will not be shared with or given to anyone except the study investigators named in this information sheet.

Sharing the Results
Nothing that you tell us will be shared with anybody outside the research team, and nothing will be attributed to you by name. We will publish the results in conference proceedings and scientific journals so that other interested people may learn from the research. Your personal information will be kept private and confidential and will not be included in any report or publication.

Right to Refuse or Withdraw
You do not have to participate in this research if you do not wish to do so and choosing to participate will not affect the service and treatment provided in this hospital. You may stop participating during the session whenever you want.

Who to Contact
If you have any questions, you can ask the research investigators now or later. If you wish to ask questions later, you may contact any of the following:

1. Asst. Prof. Dr. Muhammad Eid Akkawi, Department of Pharmacy Practice, Kulliyyah of Pharmacy, phone no.: 0186675232, email: mhdeidak@iium.edu.my
2. Br. Mohammad Adam Al Haqimy Bin Mohammad Yunus, Kulliyyah of Pharmacy, phone no.: 0133826460, email: adamhaqimy98@gmail.com

This research has been reviewed and approved by the institutional review board, IIUM Research Ethics Committee, which is a committee whose task is to ensure that research participants are protected from harm. If you wish to find more about the institutional review board, contact:

IIUM Research Ethics Committee (IREC)
Research Management Center (RMC), Kuantan Campus Level 1,
Administrative Building (OCD),
IIUM Kuantan.
Tel. No.: 09-570 4413, email: irec@iium.edu.my

APPENDIX VI-D: INFORMED CONSENT FORM (ENGLISH)

ID NO: Version 1.0 dated 7 February 2023

Part II: Certificate of Consent

1. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.
2. I understand that the purpose of this research is to explore the association between medication regimen complexity, medication adherence and treatment satisfaction among Malaysian older adult
3. I understand that my participation in this project is for research purposes only.
4. I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.
5. I understand that I am free to decline to answer any specific items or questions in the survey.
6. I understand that my participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that I have provided.
7. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be protected and accessible only by the named researchers.
8. I agree to the use of anonymised quotes in publications.
9. I understand that after I sign and return this consent form, it will be retained by the researcher.

Participant Name: _____

Signature:_____ **Date:** _____

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent_____
Signature of Researcher /person taking the consent_____
Date _____

APPENDIX VII-A: INFORMED CONSENT FORM (MALAY)

ID NO: Versi 1.0 bertarikh 7 Februari 2023

Borang Persetujuan Termaklum

Borang persetujuan termaklum ini adalah untuk pesakit berstatus warga emas dari Klinik Pesakit Luar di Sultan Ahmad Shah Medical Centre@IIUM (SASMEC@IIUM), yang berumur 65 tahun dan ke atas dan mempunyai sekurang-kurangnya 3(TIGA) ubat kronik, dipanggil untuk mengambil bahagian dalam penyelidikan bertajuk "Hubungkait Antara Kerumitan Ubat-ubatan dalam Rawatan, Kepatuhan Terhadap Pengambilan Ubat dan Kepuasan Terhadap Rawatan di Kalangan Rakyat Malaysia yang Berwarga Emas".

Nama Ketua Penyelidik: Asst. Prof. Dr. Muhammad Eid Akkawi
Penyelidik Bersama: Br. Mohammad Adam Al Haqimy Bin Mohammad Yunus, Asst Prof. Dr. Abdul Rahman Fata Nahas
Nama Organisasi: Jabatan Amalan Farmasi, Kulliyyah Farmasi, Universiti Islam Antarabangsa Malaysia
Nama Penaja: Tiada
Nama Projek: "Hubungkait Antara Kerumitan Ubat-ubatan dalam Rawatan, Kepatuhan Terhadap Pengambilan Ubat dan Kepuasan Terhadap Rawatan di Kalangan Rakyat Malaysia yang Berwarga Emas"

Borang persetujuan termaklum ini mempunyai 2(DUA) bahagian:

- Lembaran Maklumat (untuk maklumat tentang kajian)
- Borang Persetujuan (untuk tandatangan jika bersetuju).

Bahagian 1: Lembaran Maklumat

Latar belakang Kajian

Aliran global meramalkan kenaikan pertumbuhan yang tinggi dalam populasi warga emas berumur 60 tahun dan keatas di kebanyakan negara-negara serantau. Di Malaysia, bilangan warga emas yang berumur lebih daripada 60 tahun telah berkembang lebih cepat berbanding golongan muda, iaitu meningkat dua kali ganda antara 1991 – 2010. Selain itu, jurang ini dijangka akan semakin meluas dari semasa ke semasa, dengan ramalan peningkatan kepada 7 juta (atau 17.6%) daripada jumlah penduduk 40 juta orang di Malaysia pada tahun 2040. Selain itu juga, sebilangan besar warga emas mempunyai pelbagai penyakit kronik dan memerlukan penjagaan kesihatan yang kompleks. Tambahan, populasi warga emas ini berkemungkinan menunjukkan kebergantungan dan permintaan yang lebih besar kepada perkhidmatan kesihatan berbanding golongan muda. Disebabkan oleh isu-isu ini, golongan warga emas ini semestinya akan menerima pelbagai ubat-ubatan yang ditetapkan oleh doktor. Justeru daripada pengambilan ubat-ubatan, ia akan menyebabkan masalah yang mungkin tidak dapat dielakkan seperti kesan advers ubat, interaksi antara ubat-ubatan dan interaksi antara ubat-penyakit. Akibat daripada masalah-masalah ini, pesakit akan mempunyai pematuhan yang rendah terhadap ubat-ubatan dan kepuasan yang rendah dengan rawatan mereka.

APPENDIX VII-B: INFORMED CONSENT FORM (MALAY)

ID NO: Versi 1.0 bertarikh 7 Februari 2023

Tujuan Penyelidikan

Secara amnya, penyelidikan ini bertujuan untuk menilai serta meneroka hubungkait antara kerumitan ubat-ubatan dalam rawatan, kepatuhan terhadap pengambilan ubat dan kepuasan terhadap rawatan di kalangan rakyat Malaysia yang berstatus warga emas. Di samping itu, kajian ini juga bertujuan untuk mencadangkan kaedah untuk memudahkan kerumitan ubat-ubatan, yang mana berpotensi untuk meningkatkan pematuhan terhadap pengambilan ubat serta kepuasan terhadap rawatan anda pada masa hadapan.

Prosedur

Kami memohon pertolongan anda dengan menceritakan pengalaman anda menerima rawatan di klinik pesakit luar di SASMEC@IIUM. Kami menjemput anda untuk mengambil bahagian dalam projek penyelidikan ini. Jika anda bersetuju, anda akan diminta untuk mengambil bahagian dalam kajian tinjauan kami (*survey study*). Borang soal selidik akan diedarkan di pelbagai klinik pesakit luar; sebaiknya, anda hendaklah menjawab sendiri soal selidik ini dengan jujur. Terdapat tiga bentuk soal selidik yang tersedia semasa penilaian: (1) Sosiodemografi (latar belakang pesakit); (2)Alat Pengukuran Tahap Kepatuhan Pesakit Terhadap Pengambilan Ubat Di Malaysia (MyMAAT) untuk menilai pematuhan pesakit terhadap ubat; (3) Soal Selidik Mengenai Kepuasan Terhadap Pengambilan Ubat dalam Rawatan (TSQM) untuk menilai kepuasan pesakit terhadap rawatan. Anggaran tempoh untuk menjawab tinjauan ini ialah 5-10 minit. Maklumat yang direkodkan adalah **SULIT**, dan tiada orang lain kecuali penyelidik yang dinamakan seperti diatas akan mempunyai akses kepada maklumat yang direkodkan.

Pemilihan Peserta

Anda dijemput untuk menyertai penyelidikan ini kerana anda memenuhi beberapa kriteria pemilihan, seperti pesakit di klinik pesakit luar di SAMEC@IIUM yang berumur 65 tahun ke atas, telah menggunakan sekurang-kurangnya 3 (TIGA) ubat kronik dan jangka panjang. Walau bagaimanapun, anda akan dikecualikan daripada penyelidikan ini jika anda tidak mampu memberikan persetujuan termaklum yang sewajarnya, tidak boleh bertutur dan memahami bahasa Melayu dan Inggeris, dan terlibat dalam penyelidikan klinikal lain.

Penyertaan Sukarela

Penyertaan anda dalam penyelidikan ini adalah secara sukarela. Ia adalah pilihan anda sama ada anda berminat untuk menyertai atau tidak. Jika anda memilih untuk tidak mengambil bahagian, semua perkhidmatan yang anda terima di sini masih diteruskan secara biasa, dan tiada apa yang akan berubah. Pilihan yang anda buat sama sekali tiada kaitan dengan rawatan yang anda terima sekarang. Ketika penyelidikan berlangsung, anda boleh berubah fikiran dan berhenti menyertai walaupun anda bersetuju pada awalnya

Risiko

Terdapat risiko bahawa anda mungkin berasa tidak selesa berkongsi maklumat tentang beberapa topik atau maklumat peribadi. Anda tidak perlu menjawab sebarang soalan atau mengambil bahagian dalam tinjauan jika anda tidak berminat. Anda tidak perlu memberi kami sebarang alasan untuk tidak menjawab sebarang soalan atau enggan menyertai penyelidikan ini.

Faedah

Beberapa faedah yang anda akan peroleh jika anda bersetuju dan mengambil bahagian sepenuhnya dalam penyelidikan ini. Pertama sekali, data yang dikumpulkan dalam penyelidikan ini akan membantu pelbagai pihak berkepentingan, seperti pakar perubatan dan ahli farmasi di sektor kesihatan awam, pengilang dari industri farmaseutikal dan lain-lain untuk meningkatkan kualiti penggunaan ubat, yang mana mampu

APPENDIX VII-C: INFORMED CONSENT FORM (MALAY)

untuk meningkatkan perkhidmatan kesihatan secara keseluruhan. Oleh itu, anda sebagai pesakit, akan berpuas hati dengan rawatan yang diberikan dan mampu untuk patuh terhadap pengambilan ubat.

Bayaran balik

Anda tidak akan diberikan apa-apa insentif jika anda mengambil bahagian di dalam penyelidikan ini.

Kerahsiaan

Kami tidak akan berkongsi maklumat berkaitan perihal anda kepada mana-mana pihak. Maklumat yang kami kumpulkan daripada projek penyelidikan ini akan dirahsiakan. Sebarang maklumat tentang anda akan mempunyai nombor tersendiri dan bukannya digelar dengan nama anda. Hanya penyelidik akan mengetahui nombor anda, dan kami akan mengunci maklumat ini ditempat yang selamat. Ia tidak akan dikongsi atau diberikan kepada sesiapa kecuali kumpulan penyelidik yang dinamakan dalam lembaran maklumat ini.

Perkongsian Keputusan

Apa-apa maklumat yang anda beritahu kepada kami tidak akan kongsi kepada mana-mana pihak atau sesiapa sahaja di luar kumpulan penyelidik. Kami akan menerbitkan keputusan dalam prosiding persidangan dan jurnal saintifik supaya sesiapa yang berminat boleh belajar daripada projek penyelidikan ini. Maklumat peribadi anda akan dirahsiakan dan sulit serta tidak akan disertakan dalam sebarang laporan atau penerbitan.

Hak Menolak atau Menarik Diri

Anda tidak perlu untuk mengambil bahagian dalam penyelidikan ini sekiranya anda tidak mahu berbuat sedemikian. Memilih untuk mengambil bahagian tidak akan menjejaskan perkhidmatan dan rawatan yang disediakan di hospital ini. Anda boleh berhenti mengambil bahagian semasa sesi penyelidikan ini berlangsung pada bila-bila masa anda mahu.

Siapa yang perlu dihubungi

Jika anda mempunyai sebarang soalan, anda boleh bertanya kepada penyiasat penyelidikan sekarang atau kemudian. Jika anda ingin bertanya soalan kemudian, anda boleh menghubungi individu yang berikut:

1. Asst. Prof. Dr. Muhammad Eid Akkawi, Department of Pharmacy Practice, Kulliyyah of Pharmacy, phone no.: 0186675232, email: mhdeidak@iium.edu.my
2. Br. Mohammad Adam Al Haqimy Bin Mohammad Yunus, Kulliyyah of Pharmacy, phone no.: 0133826460, email: adamhaqimy98@gmail.com

Kajian ini telah disemak dan diluluskan oleh yang lembaga semakan institusi, Jawatankuasa Etika Penyelidikan UIAM, iaitu jawatankuasa yang bertugas memastikan peserta kajian dilindungi daripada sebarang bahaya. Jika anda ingin mengetahui lebih lanjut mengenai lembaga semakan institusi tersebut, sila hubungi:

IIUM Research Ethics Committee (IREC)
Research Management Center (RMC), Kuantan Campus Level 1,
Administrative Building (OCD),
IIUM Kuantan.
Tel. No.: 09-570 4413, email: irec@iium.edu.my

APPENDIX VII-D: INFORMED CONSENT FORM (MALAY)

ID NO: Versi 1.0 bertarikh 7 Februari 2023

Bahagian II: Borang Persetujuan

1. Saya bersetuju untuk mengambil bahagian dalam kajian ini, butirannya telah diterangkan kepada saya, dan saya telah dibekalkan dengan kenyataan bertulis yang jelas untuk disimpan.
2. Saya faham bahawa tujuan penyelidikan ini adalah untuk menilai serta meneroka hubungkait antara kerumitan ubat-ubatan dalam rawatan, kepatuhan terhadap pengambilan ubat dan kepuasan terhadap rawatan di kalangan rakyat Malaysia yang berstatus warga emas
3. Saya faham bahawa penyertaan saya dalam projek ini ialah untuk tujuan penyelidikan sahaja.
4. Saya telah diberi peluang untuk bertanya soalan dan saya berpuas hati dengan jawapan yang diberikan.
5. Saya faham bahawa saya bebas untuk menolak daripada menjawab sebarang perkara atau soalan tertentu dalam temu bual
6. Saya faham bahawa penyertaan ini adalah secara sukarela dan saya bebas untuk menarik diri daripada projek ini pada bila-bila masa tanpa perlu memberikan penjelasan dan untuk menarik kembali mana-mana data saya yang belum dianalisis.
7. Saya telah dimaklumkan bahawa maklumat yang saya berikan akan dirahsiakan dan menjadi subjek yang dilindungi subjek daripada sebarang keperluan undang-undang; data saya akan dilindungi dan hanya boleh diakses oleh penyelidik yang disenaraikan di atas.
8. Saya faham bahawa selepas saya menandatangani dan mengembalikan borang kebenaran ini, ia akan disimpan oleh penyelidik.

Nama peserta: _____

Tandatangan:_____ **Tarikh:** _____

Kenyataan oleh yang penyelidik/orang menerima persetujuan

Saya mengesahkan bahawa peserta telah diberi peluang untuk bertanya soalan mengenai kajian tersebut, dan semua soalan yang ditanya oleh peserta telah dijawab dengan betul dan mengikut kemampuan saya. Saya mengesahkan individu tersebut tidak dipaksa untuk memberi persetujuan, dan persetujuan yang diberikan adalah secara bebas dan sukarela

Satu salinan daripada ini borang ini telah diberikan kepada peserta.

Nama Penyelidik/orang yang menerima persetujuan: _____
Tandatangan Penyelidik/ orang yang menerima persetujuan: _____
Tarikh _____

APPENDIX VIII-A: DATA COLLECTION SHEET (SOCIODEMOGRAPHIC PROFILE)

LATARBELAKANG PESERTA (SOSIODEMOGRAFI DAN KRITERIA KLINIKAL)

Nombor Pendaftaran :_____

Nombor Kad Pengenalan :_____

Umur :_____

Tarikh Lahir :_____

Jantina
- ☐ Lelaki
- ☐ Perempuan

Pendapatan Bulanan
- ☐ Kurang daripada RM 1000 sebulan
- ☐ RM 1000 hingga RM 2500
- ☐ RM 2501 hingga RM 4000
- ☐ RM 4001 hingga RM 4999
- ☐ > RM 5000

Bangsa
- ☐ Melayu
- ☐ Cina
- ☐ India
- ☐ Lain-lain:_____

Status Perkahwinan
- ☐ Berkahwin
- ☐ Bujang
- ☐ Lain-lain:_____

Tahap Pendidikan
- ☐ Kolej/Universiti
- ☐ Sekolah Menengah
- ☐ Sekolah Rendah
- ☐ Tiada Pendidikan Formal

Status Pekerjaan
- ☐ Kolej/Universiti
- ☐ Sekolah Menengah
- ☐ Sekolah Rendah
- ☐ Tiada Pendidikan Formal

APPENDIX VIII-B: DATA COLLECTION SHEET (SOCIODEMOGRAPHIC PROFILE)

Lokasi Penempatan	☐ Bandar ☐ Luar Bandar	
Pengurusan Ubat-Ubatan	☐ Pengurusan sendiri sepenuhnya ☐ Pengurusan sendiri (dengan bantuan pihak keluarga/penjaga) ☐ Bantuan pihak keluarga/penjaga sepenuhnya	
Senarai Penyakit Yang Dihadapi & Tempoh Berpenyakit	1. 2. 3. 4. 5. 6.	1. 2. 3. 4. 5. 6.
Bilangan ubat yang diambil	Sila nyatakan: _____	

APPENDIX VIII-C: DATA COLLECTION SHEET (TSQM FORM)

SOAL SELIDIK MENGENAI KEPUASAN TERHADAP PENGAMBILAN UBAT DALAM RAWATAN
TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION (TSQM)

Soal selidik ini dijalankan untuk mendapatkan maklumat kepuasan terhadap pengambilan ubat dalam rawatan oleh pesakit dan sebaik-baiknya diisi oleh pesakit/ penjaga. Soal selidik ini akan menilai kepuasan terhadap keberkesanan, kesan sampingan, kemudahan dan kepuasan secara menyeluruh terhadap pengambilan ubat dalam rawatan dalam tempoh dua hingga tiga minggu lepas, atau sejak kali terakhir pesakit mengambil ubat-ubatan.

***Sila bulatkan pada kotak yang berkenaan**

This questionnaire will ask you on the satisfaction related to medication taking in the treatment and should preferably be filled in by the patient/caregiver. This questionnaire will assess satisfaction with effectiveness, side effects, convenience and global satisfaction in treatment during the last two to three weeks, or since the last time the patient took medication.

** Please circle in the appropriate boxes.*

BAHAGIAN/*SECTION* 1: KEBERKESANAN/*EFFECTIVENESS*

1. Sejauh manakah anda berpuas hati dengan keupayaan ubat anda untuk mencegah atau merawat sesuatu penyakit?
   How satisfied or dissatisfied are you with the ability of the medication to prevent or treat the condition?

Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**

2. **Sejauh manakah anda berpuas hati dengan cara ubat anda melegakan gejala(simptom) penyakit?**
   How satisfied or dissatisfied are you with the way the medication relieves symptoms?

Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**

APPENDIX VIII-D: DATA COLLECTION SHEET (TSQM FORM)

BAHAGIAN/*SECTION 2*: KESAN SAMPINGAN/*SIDE EFFECTS*

3. Selepas mengambil ubat, adakah anda mengalami apa-apa kesan sampingan?
As a result of taking this medication, do you experience any side effects at all?

☐ *Ya/Yes* ☐ Tidak/*No*

4. Sejauh manakah anda tidak berpuas hati dengan kesan sampingan ubat yang mengganggu kesihatan fizikal dan keupayaan anda untuk berfungsi (contohnya, kekuatan, tahap tenaga)?
How dissatisfied are you by side effects that interfere with your physical health and ability to function (e.g., strength, energy levels)?

Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Agak Tidak Berpuas Hati/** *Somewhat Dissatisfied*	**Sedikit Tidak Berpuas Hati/** *Slightly Dissatisfied*	**Langsung Tiada Ketidakpuasan Hati/** *Not at all Dissatisfied*
1	**2**	**3**	**4**	**5**

5. **Sejauh manakah anda tidak berpuas hati dengan kesan sampingan ubat yang mengganggu fungsi mental anda (contohnya, keupayaan untuk berfikir dengan baik,sentiasa berjaga)?**
How dissatisfied are you by side effects that interfere with your mental function (e.g., ability to think clearly, stay awake)?

Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Agak Tidak Berpuas Hati/** *Somewhat Dissatisfied*	**Sedikit Tidak Berpuas Hati/** *Slightly Dissatisfied*	**Langsung Tiada Ketidakpuasan Hati/** *Not at all Dissatisfied*
1	**2**	**3**	**4**	**5**

6. **Sejauh manakah anda tidak berpuas hati dengan kesan sampingan ubat yang mengganggu perasaan atau emosi anda (contohnya, kebimbangan/ketakutan,kesedihan, kejengkelan/kemarahan)?**
How dissatisfied are you by side effects that interfere with your mood or emotions (e.g. anxiety/fear, sadness, irritation/anger)?

Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Agak Tidak Berpuas Hati/** *Somewhat Dissatisfied*	**Sedikit Tidak Berpuas Hati/** *Slightly Dissatisfied*	**Langsung Tiada Ketidakpuasan Hati/** *Not at all Dissatisfied*
1	**2**	**3**	**4**	**5**

APPENDIX VIII-E: DATA COLLECTION SHEET (TSQM FORM)

BAHAGIAN/*SECTION 3:* KEMUDAHAN/*CONVENIENT*

7. Sejauh manakah anda berpuas hati dengan betapa mudahnya cara penggunaan/pengambilan ubat anda? *How satisfied or dissatisfied are you with how easy the medication is to use?*						
Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**
8. Sejauh manakah anda berpuas hati dengan betapa mudahnya untuk merancang masa bagi setiap penggunaan/pengambilan ubat anda? *How satisfied or dissatisfied are you with how easy it is to plan when you will use the medication each time?*						
Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**
9. Sejauh manakah anda berpuas hati dengan kekerapan penggunaan/pengambilan ubat anda? *How satisfied or dissatisfied are you by how often you are expected to use/take the medication?*						
Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**

APPENDIX VIII-F: DATA COLLECTION SHEET (TSQM FORM)

BAHAGIAN/*SECTION 4:* KEPUASAN SECARA MENYELURUH/GLOBAL SATISFACTION

10. Sejauh manakah anda berpuas hati bahawa kebaikan tentang ubat anda mengatasi keburukannya? How satisfied are you that the good things about this medication outweigh the bad things?						
Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**
11. Dengan mengambil kira semua perkara, sejauh manakah anda berpuas hati terhadap ubat anda? *Taking all things into account, how satisfied or dissatisfied are you with this medication?*						
Sangat Tidak Berpuas Hati Sekali/ *Extremely Dissatisfied*	**Sangat Tidak Berpuas Hati/** *Very Dissatisfied*	**Tidak Berpuas Hati/** *Dissatisfied*	**Agak Berpuas Hati/** *Somewhat Satisfied*	**Berpuas Hati/** *Satisfied*	**Sangat Berpuas Hati/** *Very Satisfied*	**Sangat Berpuas Hati Sekali/** *Extremely Satisfied*
1	**2**	**3**	**4**	**5**	**6**	**7**

APPENDIX VIII-G: DATA COLLECTION SHEET (MYMAAT FORM)

ALAT PENGUKURAN TAHAP KEPATUHAN PESAKIT TERHADAP PENGAMBILAN UBAT DI MALAYSIA
MALAYSIA MEDICATION ADHERENCE ASSESSMENT TOOL (MyMAAT)

Hospital/ *Hospital*			
Nama Pesakit/ *Patient's Name*		**No. Pendaftaran/** *Reg. No.*	
		Tarikh/ *Date*	
No. KP/ *IC No.*		**Lokasi/** *Location*	

Bahagian I : Persepsi Tahap Kepatuhan Pesakit Terhadap Pengambilan Ubat-Ubatan
Part I : Perception on Patient's Adherence Towards Medication

Soal selidik ini dijalankan untuk mendapatkan maklumat mengenai amalan pengambilan ubat oleh pesakit dan sebaik-baiknya diisi oleh pesakit/ penjaga.
***Sila tandakan (√) pada kotak yang berkenaan.**

This survey will ask about your current practice related to medication taking and preferably to be filled by patient/ care taker.
** Please tick (√) in the appropriate boxes.*

Bil./ *No.*	**Perkara/** *Item*	**Skor/***Score*				
		Sangat Tidak Setuju/ *Strongly Disagree*	**Tidak Setuju/** *Disagree*	**Neutral/** *Neutral*	**Setuju/** *Agree*	**Sangat Setuju/** *Strongly Agree*
		5	**4**	**3**	**2**	**1**
1.	**Dalam sebulan yang lepas, saya kerap tidak mengambil ubat seperti yang diarahkan oleh doktor.** *In the past one month, I frequently failed to take my medication in accordance with the doctor's instruction.*					
2.	**Dalam sebulan yang lepas, saya mengurangkan pengambilan ubat apabila berasa sihat.** *In the past one month, I reduced my medication intake when I felt better.*					
3.	**Dalam sebulan yang lepas, saya mengambil ubat secara berselang-seli.** *In the past one month, I took my medication alternately.*					
4.	**Saya sering terlewat/terlepas untuk temujanji pengambilan ubat susulan di kaunter farmasi.** *I was often late on / missed the appointment date to get the supplies of my follow-up medication at the pharmacy counter.*					

APPENDIX VIII-H: DATA COLLECTION SHEET (MYMAAT FORM)

Bil./ *No.*	**Perkara/** *Item*	**Skor/***Score*				
		Sangat Tidak Setuju/ *Strongly Disagree*	**Tidak Setuju/** *Disagree*	**Neutral/** *Neutral*	**Setuju/** *Agree*	**Sangat Setuju/** *Strongly Agree*
		5	**4**	**3**	**2**	**1**
5.	**Daripada bekalan ubat yang diterima, saya mempunyai banyak lebihan ubat di rumah.** *I have excess supply of the prescribed medication at home.*					
6.	**Saya hanya mengambil sebahagian sahaja daripada ubat yang diberikan kerana merasakan ianya tidak perlu/tidak penting.** *I did not fully comply with the prescriptions because I felt it was unnecessary/insignificant.*					
7.	**Dalam sebulan yang lepas, saya sering terlupa untuk mengambil ubat saya.** *In the past one month, I frequently failed to remember to take my medication.*					
8.	**Saya sering mengurangkan pengambilan ubat kerana bimbang akan kesan sampingnya terhadap badan.** *I regularly take less medication than prescribed for fear of the side effects to my body.*					
9.	**Saya tidak mengambil ubat apabila tiada sesiapa mengingatkan saya.** *I will miss/not take my medication if no one reminds me to do so.*					
10.	**Saya tidak begitu pasti tentang dos ubat yang perlu diambil setiap hari.** *I am uncertain about my daily medication doses.*					
11.	**Saya tidak boleh menguruskan pengambilan ubat saya dengan baik.** *I am unable to manage my medication intake properly.*					
12.	**Ketiadaan sokongan atau pertolongan dari orang tersayang menyebabkan saya tidak bermotivasi untuk mengambil ubat yang diberikan oleh doktor.** *Without support or help from the loved ones, I lack motivation to take my medication as prescribed by the doctor.*					
	JUMLAH/ *TOTAL* **Skor minimum = 12; Skor maksimum = 60** *Minimum score = 12; Maximum score = 60*					

SOAL SELIDIK TAMAT/ ***END OF SURVEY***

TERIMA KASIH/ ***THANK YOU***

APPENDIX VIII-I: DATA COLLECTION SHEET (MYMAAT FORM)

ALAT PENGUKURAN TAHAP KEPATUHAN PESAKIT TERHADAP PENGAMBILAN UBAT DI MALAYSIA
MALAYSIA MEDICATION ADHERENCE ASSESSMENT TOOL (MyMAAT)

Bahagian II : Kategori Kepatuhan Pesakit Terhadap Pengambilan Ubat-Ubatan
Part II : Category of Patient's Adherence Towards Medication

Kategori kepatuhan mengikut jumlah skor adalah seperti berikut:
Patient's adherence category based on total score as stated below:

Kategori/ *Category*	**Jumlah Skor/** *Total Score*
Kepatuhan baik/ *Good adherence*	≥ 54
Kepatuhan sederhana dan lemah/ *Moderate and poor adherence*	< 54

Bahagian III : Rumusan Tahap Kepatuhan Pesakit Terhadap Pengambilan Ubat-Ubatan
Part III : Summary on Patient's Adherence Towards Medication

Untuk diisi oleh pegawai farmasi/ *To be filled by pharmacist.*

Jumlah Skor/ *Total Score*	
Kategori Kepatuhan/ *Adherence Category*	☐ **Kepatuhan baik/** *Good adherence* ☐ **Kepatuhan sederhana dan lemah/** *Moderate and poor adherence*
Nota Pegawai Farmasi/ *Pharmacist's Note*	

Tandatangan & Cop Pegawai Farmasi/ : *Pharmacist's Signature & Stamp*

Tarikh/ : *Date*

APPENDIX VIII-J: DATA COLLECTION SHEET (MRCI CALCULATION FORM)