

**DEVELOPMENT AND IMPACT ASSESSMENT
OF CONSUMER MEDICATION INFORMATION
ON HEALTH OUTCOMES AMONG TYPE II
DIABETES MELLITUS PATIENTS IN QATAR**

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UNIVERSITI SAINS MALAYSIA

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by

EMAD ELDIN OSMAN ALI MUNSOUR

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LIST OF ABBREVIATIONS

ADA	American diabetes association
CIA	Central intelligence agency
CIS	Clinical information system
CLT	Cognitive load theory
CMI	Consumer medicine information
CTDEI	Culturally tailored diabetes educational intervention
CVA	Cerebrovascular accident
CVD	Cardiovascular disease
DGP	Drug guide for patient
DM	Diabetes mellitus
ED	Emergency department
EEC	European economic community
EHR	Electronic health record
EMA	European medicine agency
EQIP	Ensuring quality information for patients
FDA	Food and drug administration

FKGL	Flesch-Kincaid grade level
FRE	Flesch Reading Ease
GCC	Gulf cooperation council
GSDP	General secretariat for development planning
HbA1c	Glycated hemoglobin
HCP	Healthcare professional
HL	Health literacy
HSU	Health state utility
IDF	International diabetes federation
MDPS	Ministry of development planning and statistics
ME	Middle East
MENA	Middle East and North Africa
MHRA	Medicines & healthcare products regulatory agency
MI	Myocardial infarction
MoPH	Ministry of public health
NCD	Non-communicable disease
NDRA	National drug regulatory authority

NHS	National health strategy
PI	Package insert
PIL	Patient information leaflet
PDCD	Pharmacy and drug control department
PRO	Patient reported outcome
QCHP	Qatar council for healthcare practitioners
QNV	Qatar national vision
QoL	Quality of life
QSA	Qatar statistics authority
RA	Regulatory agency
RCT	Randomized controlled trial
SCH	Supreme council of health
SmPC	Summary of product characteristics
T2DM	Type 2 diabetes mellitus
TGA	Therapeutic goods administration
UAE	United Arab Emirates
UK	United Kingdom

U.S.	Unites States
USD	United States dollar
VAS	Visual analogue scale
WHO	World health organization
WMI	Written medicine information

**PEMBANGUNAN DAN PENILAIAN KESAN MAKLUMAT UBATAN
PENGGUNA TERHADAP HASIL KESIHATAN DALAM KALANGAN
PESAKIT DIABETES MELLITUS JENIS II DI QATAR**

ABSTRAK

Literasi kesihatan (HL) sangat penting bagi penglibatan pesakit, tingkah laku pengambilan ubatan, dan dalam proses membuat keputusan mengenai rawatan. Pesakit dengan HL yang terhad mempunyai kesukaran untuk membaca dan mentafsirkan arahan ubatan yang digariskan dalam risalah maklumat pesakit (PIL). PIL ialah dokumen bertulis yang dihasilkan oleh pengilang farmaseutikal dan disertakan dengan ubat; kualitinya seringkali kurang memuaskan dan sukar difahami oleh pesakit. Di samping itu, tiada bukti yang didokumenkan bahawa PIL sedia ada mempertimbangkan perspektif budaya dan tingkah laku pelbagai populasi yang menetap di negara seperti Qatar. Objektif Fasa 1 tesis ini adalah untuk menilai kebolehbacaan dan kefahaman PIL yang dibekalkan dengan ubatan yang digunakan dalam rawatan diabetes mellitus Jenis II (T2DM) di Qatar dengan menggunakan skor "*Flesch Reading Ease*" (FRE) untuk kebolehbacaan, dan skor "*Flesch-Kincaid Gred Level*", "*Index Gunning-Fog*", serta "*SMOG Grading*" untuk kefahaman dari segi tahap gred sekolah. Sembilan (20%) PIL didapati dalam Bahasa Inggeris sahaja; 17.8% didapati dalam Bahasa Inggeris, Bahasa Arab, dan Perancis; serta 62.2% didapati dalam Bahasa Inggeris dan Arab. Skor purata FRE untuk 45 PIL tersebut ialah 37.71 (± 15.85), dan PIL yang paling mudah dibaca mempunyai skor FRE sebanyak 62. Tambahan pula, hanya 2.2% PIL mempunyai skor FRE yang memuaskan (iaitu 60-70% atau lebih tinggi). Semua PIL dapat difahami oleh sekurang-kurangnya pelajar gred 11 yang melebihi tahap gred 6 ke 8 disyorkan untuk

bacaan berkaitan kesihatan. Fasa 2 tesis ini bertujuan untuk membandingkan maklumat ubatan bertulis (WMI) bagi ubatan anti-diabetik yang dibenarkan untuk pemasaran di Qatar, Australia, dan Eropah menggunakan instrument-instrumen DISCERN dan “*Ensuring Quality Information for Patients*” (EQIP). Dua belas WMI yang masing-masing diluluskan oleh agensi pengawalseliaan masing-masing dipilih untuk penilaian kualiti. WMI dari Qatar tidak mengikuti format spesifik, manakala WMI dari Australia dan Eropah masing-masing mengikuti format maklumat ubat pengguna (CMI) dan PIL. Terdapat perbezaan yang signifikan ($p \leq 0.001$) antara skor EQIP WMI dari Qatar dengan Australia dan Eropah. Kualiti dan kandungan WMI sangat berbeza antara negara, manakala Australia dan Eropah mempamerkan amalan terbaik. Penemuan pada fasa 2 mencadangkan keperluan untuk menyelaraskan garis panduan pembangunan WMI bagi memastikan piawaian global WMI yang mesra pesakit. Bagi mengatasi masalah yang berkaitan dengan kekurangan WMI di Qatar seperti yang dikaji secara berasingan (Fasa 1) dan dibandingkan dengan negara-negara maju (Fasa 2), kami berhasrat untuk membangunkan dan mengesahkan CMI yang disesuaikan dalam enam bahasa yang paling kerap digunakan di Qatar, dan mengkaji kesannya terhadap pesakit T2DM. Fasa 3 terdiri daripada pembangunan dan pengesahan CMI yang disesuaikan ini serta kajian intervensi terkawal rawak, di mana pesakit kumpulan intervensi menerima CMI yang disesuaikan dan pesakit kumpulan kawalan menerima penjagaan biasa. Hasil utama kajian ini adalah pematuhan ubatan, kawalan glisemik dan kualiti hidup berkaitan kesihatan yang diukur pada selang tiga bulan [iaitu baseline (T_0), susulan pertama (T_3), dan lawatan susulan kedua (T_6)]. Penyediaan CMI dapat menambahbaik hasil kesihatan para pesakit T2DM di Qatar seperti mana diukur dengan indikator pematuhan ubatan dan kualiti hidup. Perkembangan dan

penyediaan maklumat perubatan yang disesuaikan kepada pesakit adalah peluang yang baik untuk ahli farmasi sebagai pakar terapi ubat untuk menyampaikan informasi farmakoterapeutikal yang sesuai, yang kemudiannya akan membawa kepada penambahbaikan hasil kesihatan para penerima.

**DEVELOPMENT AND IMPACT ASSESSMENT OF CONSUMER
MEDICATION INFORMATION ON HEALTH OUTCOMES AMONG TYPE
II DIABETES MELLITUS PATIENTS IN QATAR**

ABSTRACT

Health literacy (HL) is fundamental to patient engagement, medication-taking behavior, and decision-making about treatment. Patients with limited HL have difficulty in reading and interpreting medication instructions outlined in the patient information leaflets (PILs). PIL is the written document produced by the pharmaceutical manufacturers and packed with the medicine; they are often of poor quality and hard to comprehend by the patients. Additionally, no documented evidence that the available PILs consider cultural and behavioral perspectives of diverse populations residing in a country like Qatar. The objective of Phase 1 of this thesis was to evaluate the readability and comprehensibility of PILs supplied with medications used for the treatment of type 2 diabetes mellitus (T2DM) in Qatar using the Flesch Reading Ease (FRE) score for readability, and Flesch-Kincaid Grade Level, Gunning-Fog Index, and SMOG Grading for comprehensibility in terms of school grade levels. Nine (20%) of the PILs were in English only; 17.8% were in English, Arabic, and French; and 62.2% were in English and Arabic. The mean FRE score of the 45 PILs was 37.71 (± 15.85), and the most readable PIL had FRE score of 62. Furthermore, only 2.2% of PILs had acceptable FRE readability scores (i.e. 60-70% or higher). All the PILs could be comprehended by at least an 11th grade student, which exceeded the recommended 6th to 8th grade level for health-related materials. Phase 2 of this thesis aimed at comparing written medicine information (WMI) of antidiabetic medications authorized for marketing in Qatar, Australia, and

Europe using the DISCERN instrument and the Ensuring Quality Information for Patients (EQIP) tool. Twelve WMI each approved by respective regulatory agency were selected for the quality evaluation. WMI from Qatar did not follow a specific format, while those from Australia and Europe followed the consumer medication information (CMI) and PIL formats, respectively. There were significant differences ($p \leq 0.001$) between the EQIP scores of WMI from Qatar vs. Australia and Europe. The quality and content of WMI were highly variable between countries, while Australia and Europe exhibited best practices. Phase 2 suggested the need for harmonization of the guidelines for the development of WMI to ensure global standardization of patient-friendly WMI. In order to overcome the issue related to the shortcomings of WMI in Qatar as tested independently (Phase 1) and as compared with the counterparts from developed countries (Phase 2), we aimed to develop and validate a customized CMI in six most common languages in Qatar and test their impact on outcomes of T2DM patients. Phase 3 comprised the development and validation of the customized CMI and a randomized controlled intervention study, in which the intervention group patients received customized CMI and the control group patients received usual care. The primary outcomes of this study were medication adherence, glycemic control and health-related quality of life measured at three months intervals [i.e. baseline (T0), first follow up (T3), and second follow up visit (T6)]. The provision of CMI improved the health outcomes of T2DM patients in Qatar as measured by medication adherence and quality of life indicators. Development and provision of customized medicine information to the patient is a great opportunity for the pharmacists as medication therapy experts to communicate appropriate pharmacotherapeutic information, which will subsequently lead to improved health outcomes of the recipients.

CHAPTER 1

INTRODUCTION

1.1 Background

The Institute of Medicine (IOM) report defined health literacy (HL) as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (Kindig, Panzer, & Nielsen-Bohlman, 2004). Similarly, the World Health Organization (WHO) defined HL as “the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health” (WHO, 2017a). Limited HL is a global issue that deserves careful attention and vigilance from the medical community, community leaders, and policymakers all over the world (McCormack, Haun, Sorensen, & Valerio, 2013). The WHO global strategy on diet, physical activity, and health highlights the need to improve HL levels and mandates incorporating HL in adult education programs (WHO, 2004). If people’s ability to access and effectively utilize health information is improved, then HL can contribute to their empowerment (WHO, 2017a).

The increasing prevalence of limited HL is a serious dilemma worldwide even in developed countries, especially among minorities and underprivileged populations. Generally, the proportion of the population in developed countries lacking functional literacy skills ranges between 7% and 47%, whereas in developing countries these figures are much higher (D. Nutbeam, 2008). European surveys have reported a high prevalence (47%) of inadequate and problematic HL across the continent (Sorensen et al., 2015; WHO Regional Office for Europe, 2013). In the

United States, only 12% of adults exhibited proficient HL, while 55% of Canadian adults aged between 16 and 65 years and up to 57% of Irish adults scored low levels of HL (Health, Services, Prevention, & Promotion, 2010; Murray, 2007; Sahm, Wolf, Curtis, & McCarthy, 2012). The HL levels of adults aged 15–49 years old in 14 sub-Saharan African countries varied from 8.5% in Niger to 63.9% in Namibia (McClintock, Schrauben, Andrews, & Wiebe, 2017).

Literature on HL levels in the Middle East (ME) is very limited and data are very scanty. However, one would assume that HL levels in the ME would be relatively lower than those reported in the developed nations. Despite many countries having no data on HL, they are facing challenges related to development and public health, which can be affected by the public HL level (United Nations Economic and Social Council, 2010). If people cannot obtain, process, and understand basic health information, they will not be able to look after themselves well or make good decisions concerning their health (Coulter & Ellins, 2007). HL is fundamental to patient engagement, medication-taking behavior, patient empowerment, and decision-making about treatment and medicines. There is a documented association between disease knowledge and HL among patient with chronic diseases (Gazmararian, Williams, Peel, & Baker, 2003). Chronic disease patients are vulnerable to the impact of HL as documented by a study in the Netherlands, where 50% and 20% of patients have difficulties with regard to critical HL and communicative HL, respectively (Heijmans, Waverijn, Rademakers, van der Vaart, & Rijken, 2015). Inadequate HL is common among patients with chronic conditions including diabetes and is considered a barrier for improving health outcomes (Al Sayah, Majumdar, Williams, Robertson, & Johnson, 2013).

HL is an important contributor to health outcomes and has received increased attention (Y.-M. Lee, Yu, You, & Son, 2017). HL among patients with type 2 diabetes mellitus (T2DM) is recognized as an important modifiable psychosocial factor that contributes to their self-management behaviors (Bailey et al., 2014). There is an indirect effect of HL on diabetes self-care (Reisi et al., 2016). Furthermore, HL is associated with glycemic control; glycated hemoglobin (HbA1c) levels are related to adverse complications (Tseng, Liao, Wen, & Chuang, 2017). Limited HL has been independently associated with a greater prevalence of diabetes (Bains & Egede, 2011; Sudore et al., 2006). Several studies have explored the relationship between HL and diabetes-related knowledge and consistently found higher HL to be associated with greater diabetes-specific knowledge (Al Sayah et al., 2013; Bains & Egede, 2011; Angela G Brega et al., 2012; A. G. Brega et al., 2012; Mancuso, 2010; McCleary-Jones, 2010; Powell, Hill, & Clancy, 2007). A study conducted in the United Arab Emirates (UAE) reported the negative impact of limited literacy of diabetic patients' knowledge on their disease (Al-Maskari et al., 2013).

Limited HL is a marker for oral communication problems, particularly in the technical and explanatory aspects of clinician-patient dialogue; patients with limited HL were more likely to report worse communication with clinicians, explanation of conditions, and understanding of the process of care (U. Sarkar et al., 2008; Dean Schillinger, Bindman, Wang, Stewart, & Piette, 2004). Diabetic patients with limited HL had low rates of comprehension of the medical terminology used in their visits (Castro, Wilson, Wang, & Schillinger, 2007). Inappropriate HL is associated with larger gaps in medicine supply and inadequate use of antidiabetic therapy (Osborn et al., 2011). Effective educational strategies have increased knowledge, as well as adherence to medications, treatment satisfaction, and diet among T2DM patients (R.

Negarandeh, H. Mahmoodi, H. Noktehdan, R. Heshmat, & E. Shakibazadeh, 2013; White et al., 2015). Patients with limited HL experienced very poor HbA1c (HbA1c > 9.5%); in another study, the patients had greater than 1% higher absolute difference in HbA1c than those with greater than high school literacy (Powell et al., 2007; D. Schillinger et al., 2002). Self-efficacy and self-care behaviors are influenced by the HL contributing to the HbA1c of T2DM patients (Y. J. Lee et al., 2016). Recent studies have found a linkage between the numeracy component of HL and HbA1c (Cavanaugh et al., 2008; Marden et al., 2012). In a US-based study, patients with low HL displayed a misperception of their diabetes control, and their last two Hb1Ac measurements were > 8.0% (Ferguson et al., 2015).

In addition, limited HL was associated with two-fold greater odds of patients reporting microvascular and macrovascular complications of diabetes, such as retinopathy and cerebrovascular disease (D. Schillinger et al., 2002). Another study found that patients with diabetes and limited HL measured using the Short Test of Functional Health Literacy in Adults (S-TOFHLA) had 50% greater odds of having coexisting heart failure (Laramée, Morris, & Littenberg, 2007). HL and numeracy are each associated with greater diabetes self-efficacy, and greater diabetes self-efficacy is associated with lower HbA1c levels (Ishikawa, Takeuchi, & Yano, 2008; Osborn, Cavanaugh, Wallston, & Rothman, 2010). Some recent studies have shown an association between HL and self-care behavior (diet, exercise, foot care, blood glucose testing, etc.) (Angela G Brega et al., 2012; Cavanaugh et al., 2008; Vassy et al., 2012; White et al., 2010). Furthermore, patients with limited HL have difficulty in reading patient information leaflets (PILs) and, hence, interpreting the medication instructions (van Beusekom, Grootens-Wiegers, Bos, Guchelaar, & van den Broek, 2016).

About 67% and 80% of patients world-wide received prescription drugs after visiting physicians' offices and emergency departments (ED), respectively (Graber, Hershop, & Graber, 2017). In the United States, the persons using at least one drug and three or more prescription drugs in the past 30 days were 48.9% and 23.1%, respectively (National Center for Health Statistics, 2016). Furthermore, the therapeutic drug use in the United States for 2014 is described in Table 1.1.

Table 1.1: Therapeutic drug use in the United States

Location	Number of drugs provided	Percentage of visits that involved drug therapy	Most prescribed drug classes
Physician office	3.2 billion	75.2	Analgesics Antihyperlipidemic agents Antidepressants
Hospital outpatient department	329.2 million	72.5	Analgesics Antidiabetic agents Antihyperlipidemic agents
Hospital emergency department	317.6 million	79.6	Analgesics Antiemetic or antivertigo agents Minerals and electrolytes

Source: (CDC, 2014b).

Patients with appropriate information about their treatment contribute to the provision of safe, effective, and quality products (Vahdat, Hamzehgardeshi, Hessam, & Hamzehgardeshi, 2014). Written medicine information (WMI) is intended for patients who have been prescribed medication as an essential part of patient education worldwide (M. M. Koo, Krass, & Aslani, 2005). Patients regard WMI as a reliable and important source of information about their medicine (Narhi, 2007). The PIL (also known as the package leaflet, PL) is the leaflet that is packed with the medicine; it is produced by the pharmaceutical manufacturers and is the patient-

friendly version of the summary of product characteristics (SmPC) (Hamrosi, Aslani, & Raynor, 2014; The electronic Medicines Compendium (eMC)).

In Australia, consumer medicine information (CMI) is legally required to be supplied with all prescription and pharmacist-only medicines (Aslani, 2007). For the purpose of this thesis, we use the term WMI to represent both PILs and CMI. Patient education is essential for improving drug adherence and optimizing medicine use (M. M. Koo, Krass, & Aslani, 2003). Patients who have gained knowledge about their own treatment(s) will build self-confidence and hence better communicate their concerns and preferences (Chen, Mullins, Novak, & Thomas, 2016). The expectations of patients about receiving appropriate treatment information and their involvement in decision-making has evolved in many developing countries (Young, Tordoff, & Smith, 2017b). In the US, a third party other than the manufacturer prepares the CMI; CMI is provided with medication with the objective of improving treatment adherence, communicating side effects and drug interactions, and reducing the liability of drug companies, prescribers, and pharmacists (Sage, Blalock, & Carpenter, 2017). The majority of PILs in the United Kingdom (UK) do not contain the rationale or duration of the treatment; the scope of treatment as preventive, curative, or symptomatic is not covered (Dickinson, Raynor, Knapp, & MacDonald, 2017). In Japan, the drug guide for patients (DGP) is for patients with at least high school education, while health care professionals are provided with a package insert (PI); the content of the DGP should comply with that of the product information (PI) of the same drug (Yamamoto et al., 2017).

Furthermore, good information about a given medicine is mandatory for patients to make informed decisions from the context of understanding the benefits and harms of each prescribed treatment (D. K. Raynor, Blenkinsopp, et al., 2007).

Well-written PILs improve patients' satisfaction and knowledge regardless of the clinical situation; PILs contribute to better treatment adherence, especially in the short term (Sustersic, Gauchet, Foote, & Bosson, 2017). The content of PILs should be in understandable lay language, clearly legible with words of few syllables, and consistent with the prescribing information (UK-MHRA, 2012). Patients with limited HLs have difficulty in reading PILs and hence interpreting the medication instructions (van Beusekom et al., 2016).

1.2 Problem Statement

Patients are eligible to make better decisions about their healthcare and better use their medicines when they are well-informed about the medications they take. Access to useful written information about medicines is important to ensuring the appropriate use of these products. It is part of a pharmacist's professional role to ensure that patients receive useful, reader-friendly, and high-quality information about their medicines. Patient counseling and education sessions about disease and medication(s) are the pharmacist's responsibility to help ensure positive outcomes like quality of life (QoL) and glycemic control (Glasgow, Peebles, & Skovlund, 2008). A number of published studies have demonstrated the effectiveness of pharmacists' intervention and case management in improving HbA1c and other outcomes among patients with diabetes (Choe et al., 2005; Collins, Limone, Scholle, & Coleman, 2011; Farsaei, Sabzghabae, Zargarzadeh, & Amini, 2011; Suppakitiporn, Chindavijak, & Onsanit, 2005; Wubben & Vivian, 2008). Patients want more information about their medicines; they prefer to obtain information from a range of sources and value the PIL more than any other source except their doctor

and pharmacist (Hamrosi, Raynor, & Aslani, 2013b; UK-MHRA, 2012). The PIL is an important source of drug information, as most patients read the leaflet; nearly a third of the patients surveyed in one study stated that information about adverse effects had made them make a decision about consuming their medicine (Horwitz, Reuther, & Andersen, 2009). The PILs are usually packed with the dispensed medicines, and the information they contain is produced by the manufacturer and regulated by law. Therefore, they are both easily available and authoritative. Unfortunately, PILs are often of poor quality and hard to comprehend by the patients; in the United States, most leaflets do not meet quality criteria (Winterstein, Linden, Lee, Fernandez, & Kimberlin, 2010). It is important for pharmacists to become familiar with the criteria for evaluating these leaflets and to take necessary action to improve their quality (Svarstad, Bultman, Mount, & Tabak, 2003).

Additionally, in the ME region, there is no documented or even anecdotal evidence that the available PILs are developed to consider cultural, behavioral, and psychological perspectives of Arabic and other language-speaking patients residing in those countries. Furthermore, it is not mandatory under the regulations of some ME countries for manufacturers to present PILs in Arabic. Similarly, the availability, quality, and regulation of PILs in Qatar mirror those of other ME countries. Important and mandatory elements such as readability, comprehensibility, communicative focus, and user-testing are not well established for residents of this region. Traditionally, PILs were associated with branded medicines as per the manufacturer's guidelines. Lee and colleagues defined the limitations associated with PIL use are brand specificity where PIL are not common for all brand and generic drug, and PILs do not explain the multiple-drug regimens used in the pharmacological management of T2DM (D. Y. Lee, Armour, & Krass, 2007).

PILs are a tool necessary for health education, especially with chronic diseases such as diabetes mellitus (DM). The prevalence of DM in the ME region is very high and knowledge about the disease is very limited, requiring a great deal of effort from healthcare providers and researchers alike (Abuyassin & Laher, 2016). One viable option to circumvent the limitations of PILs is the use of consumer-tailored information in the form of the CMI to enhance comprehension and the overall outcomes of care. The CMI is defined by US Food and Drug Administration (FDA) as written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing. The provision of CMI in colloquial Arabic and other Asian languages as part of a tailored education intervention will assist patients in achieving better readability, comprehensibility, and treatment outcomes (including adherence, HbA1c, fasting plasma glucose, and QoL). There are existing guidelines that help CMI developers to ensure that the information contained is valid and useful to the consumers.

1.3 Rationale of the Study

Anecdotally, PILs in the ME region are of questionable quality, readability, and comprehensibility; are not well regulated; and are available only in Arabic and/or English languages (languages that are not widely spoken by the predominant population). The preferred language for the PILs was Arabic for most of the consumers (89.6%) in a Palestinian study (Al-Ramahi, Zaid, Kettana, Sweileh, & Al-Jabi, 2012). Currently, existing PILs are not being accompanied with patient-tailored

written information. Patients reported that the current leaflets are lengthy and they prefer short, comprehensive, and individually tailored medicine information (Dickinson et al., 2013; Hamrosi, Aslani, et al., 2014).

The majorities of the immigrant workforce in Qatar is of a low literacy level and speak neither Arabic nor English, which highlights the need to develop comprehensive, patient-tailored multilingual CMI targeting the majority of the populace of Qatar. This should encompass English, Arabic, and the other most widely spoken languages in the country (Hindi, Malayalam, Tamil, and Urdu). There has been no previous study documenting the quality, readability, and comprehensibility of PILs available in Qatar. The proposed study is to evaluate the quality of existing PILs, develop CMI that is scientifically rigorous, and evaluate the impact of the developed CMI on comprehensibility, readability, adherence to medications, and other outcomes of DM.

In this intervention study, DM is chosen because of its high prevalence as a non-communicable disease (NCD) of public health importance in Qatar and the greater ME. The overall prevalence of DM among the adult Qatari population is 16.7% (Haj Bakri & Al-Thani, 2013). The prevalence of diabetes is estimated to exceed 15% in Qatar as compared to 11% in the United States, and the increasing trend in prevalence is predicted to continue; by 2030, the number of people in Qatar with diabetes is expected to increase by 130%. Diabetes is the largest preventable risk factor for myocardial infarction (MI) and cerebrovascular accident (CVA) among the highly diverse population of Qatar (Mushlin et al., 2012). A study in Qatar identified levels of adherence to guideline recommendations, the need for additional documentation, and criteria with low adherence that might be a focus of educational intervention and a starting point for targeted pharmaceutical care (Issam

Diab, Julienne Johnson, & Hudson, 2013). Another study in Qatar (Mohamed, Al-Lenjawi, Amuna, Zotor, & Elmahdi, 2013) demonstrated the effectiveness of culturally sensitive, structured, group-based diabetes education in enhancing biomedical and behavioral outcomes in patients with diabetes. Formal in-patient diabetes education was independently associated with a lower frequency of all-cause hospital readmission within 30 days (Healy, Black, Harris, Lorenz, & Dungan, 2013). There was generally poor practice of regularly inspecting one's feet to detect signs of neuropathy, taking medication in relation to meals, modifying doses when necessary, and setting goals for therapy among Qatari patients with T2DM (Kheir, Greer, Yousif, Al Geed, & Al Okkah, 2011)

1.4 Objectives

1.4.1 General objective

The aim of this study was to evaluate the impact of the developed CMI intervention among patients with T2DM in tertiary care setting in Qatar.

1.4.2 Specific objectives

The specific objectives of this PhD thesis are as follows:

1. To evaluate the readability and comprehensibility of PILs of antidiabetic drugs prescribed for T2DM patients in Qatar (Phase 1).

2. To compare WMI of antidiabetic medications authorized for marketing in Qatar, Australia, and Europe using different quality criteria (Phase 2).
3. To develop patient-tailored CMI for T2DM patients in Qatar (Phase 3).
4. To evaluate the impact of the developed CMI on medication-taking behavior (adherence) of the study population (Phase 3).
5. To evaluate the impact of the developed CMI on glycemic control of the study population (Phase 3).
6. To evaluate the impact of the developed CMI on the health-related QoL (HR-QoL) of the study population (Phase 3).

1.5 Significance of the Study

This study has many important implications for healthcare policy makers and the quality assurance staff within healthcare systems and can provide useful data to explore the current quality of PILs accompanying antidiabetic medications in Qatar.

It will provide baseline data that can be used in the future evaluation and modification of PILs and patient-related educational materials.

1. This study addresses one of the national health priorities of the Qatar national research strategy (QNRS)—2012 (Qatar National Research Fund, 2012), to “Develop and implement comprehensive research programs to improve services, behaviors and outcomes related to diabetes type II.”
2. This study complies with one of the objectives outlined in the National Health Strategy (NHS) 2011–2016 (Supreme Council of Health [SCH], 2012) of ensuring that education and counseling are made available to T2DM patients.

1.6 Thesis Overview

This research project consisted of three phases. Phase 1 evaluated the quality of the PILs of antidiabetic medication(s) marketed in Qatar. Phase 2 compared Qatar's WMI for antidiabetic medications with those approved by stringent regulatory agencies, i.e., in Europe and Australia. Phase 3 developed and consolidated the tailored CMI for antidiabetic medications and evaluated their impact on T2DM patients. This thesis has six chapters, including this one, which are summarized as follows:

CHAPTER 1: This chapter is a general introduction providing basic information about HL. The chapter outlined the epidemiology of HL and its impact on patients with diabetes and related outcomes. The problem statement highlighted the issues related to WMI and its quality limitations worldwide and in the ME in particular. The rationale of the study expressed the diversity of Qatar's population and the need to provide medicine information in Arabic and different Asian languages. The prevalence of DM in Qatar was also documented. This chapter outlined the general and specific objectives of the study as well the significance of this research project.

CHAPTER 2: This chapter, an overview of the literature, provides essential information about the healthcare system in Qatar, including the organization, provision of care, expenditure and financing, and pharmaceutical profile. A general description of HL, including its relationship with health information and pharmacotherapy literacy, is provided. The chapter further outlines the different types of WMI and their details from different parts of the world. Literature on HL and its impact on medication adherence and glycemic control are explored. Chapter 2 also discusses certain concepts pertaining to health-related quality of life, i.e., its measurement and the impact on it of diabetes.

CHAPTER 3: This chapter describes quantitative analytical methods to evaluate quality aspects (the readability and comprehensibility) of the WMI for antidiabetic medications in Qatar using different formulas advanced in the literature. Chapter 3 also analyzes the number of words and quality aspects in the WMI for a commonly used antidiabetic medication, metformin. This chapter also discusses the inadequate quality and layout parameters of Qatar-based WMI. The conclusion reached in this phase of this study indicates a need for further investigations, which is described in the subsequent chapter.

CHAPTER 4: This chapter reports a comparative evaluation of Qatar's WMI against those approved by stringent drug regulatory agencies, the European Medicines Agency (EMA) and Australia's Therapeutic Goods Administration (TGA). The samples considered for this study were the WMI for the same brand medication from the three sources, Qatar, Australia, and Europe, to avoid the variation found in the WMI of the same generic product manufactured by different companies. The evaluation tools used in this study were the DISCERN instrument and the Ensuring Quality Information for Patients (EQIP) instrument in addition to the readability and comprehensibility formulas.

The results of this phase are discussed in connection with the lower quality of the WMI of the same company's medications as marketed in Qatar than as marketed in Europe and Australia. The findings of this chapter document the need to conduct further research, which is explained in the next chapter (Chapter 5).

CHAPTER 5: The aim of this chapter was to develop patient-tailored CMI following US FDA guidance on useful written CMI. The documents were developed in English language, then validated and translated into five different languages—Arabic, Hindi, Malayalam, Tamil, and Urdu. The impact of these documents was

pilot-tested on certain clinical and humanistic outcomes—glycemic control, medication adherence, and HR-QoL—of 140 randomized T2DM patients in Qatar.

CHAPTER 6: This chapter integrates the findings of the three phases described previously for each individual chapter. The recommendations for further studies related to this project from the context of the ME region are also documented. This chapter provides the overall conclusion reached by the researchers and suggests the basis for developing and implementing a strategy for improving WMI in the ME.

CHAPTER 2

LITERATURE REVIEW

2.1 The Healthcare System in Qatar

The state of Qatar is a Middle Eastern country located in the eastern part of the Arabian Peninsula that covers an area of approximately 11,606 km²; the total population by end of December 2018 is 2,674,320 (Central Intelligence Agency [CIA], 2017; Ministry of Development Planning and Statistics [MDPS], 2019). Around 15% of population is Qatari, while the rest are expatriates, which makes it the world's second-highest migrant population (M. H. Al-Thani et al., 2014; Koch, 2016). Doha is the capital city and the major urban area, home to more than 957,000 inhabitants in 2015 (MDPS, 2017). Indians (25%) accounted for the country's largest foreign population, with expatriates from Pakistan (10%), Sri Lanka (7%) and other Arab Nations (20%) are the other residents (Fahy, 2018).

As one of the wealthiest and smallest countries, Qatar's healthcare system is emerging and has witnessed significant changes since it came into existence (Goodman, 2015). The government has promulgated the Qatar National Vision (QNV) 2030, which states, "To improve the health of Qatar's population, Qatar aspires to develop an integrated system for healthcare, managed according to world-class standards. This system will meet the needs of existing and future generations and provide service for an increasingly healthy and lengthy life for all citizens. All health services will be accessible to the entire population" (General Secretariat For Development Planning [GSDP], 2008). The national health authority is charged with

implementing the NHS which aims to achieve the following health sector goals set in QNV 2030 (. SCH, 2014):

- A comprehensive world-class healthcare system whose services are accessible to the whole population.
- An integrated system of healthcare offering high-quality services.
- Preventive healthcare, taking into account the differing needs of men, women, and children.
- A skilled national workforce capable of providing high-quality health services.
- A national health policy that sets and monitors standards
- Effective and affordable services.
- High-caliber research directed at improving the effectiveness and quality of healthcare.

Qatar is the one of the world's highest-ranking nations in per capita wealth, i.e., Gross Domestic Product (GDP) at Purchasing Power Parity (PPP) per capita; its current value is US Dollar (USD) 140,649.2 (The World Bank, 2014). The annual government expenditures on health account for 5.83% of total government expenditures and represent 85.75% of the total expenditures on health, with private health expenditures making up the remaining 14.25% (WHO, 2016a). The annual expenditure on health was USD 2,106.4 per capita in 2014 (The World Bank, 2016).

2.1.1 Health system organization and provision of health-care

Because of its strong economic status, Qatar aims at achieving a world-class health care system (K. Corman & Hickey, 2014). Qatar's healthcare system ranked

first among ME countries and in 13th place in the world by the Legatum Prosperity Index in 2017 (HMC, 2018). Health care is 100% funded domestically, where the government is responsible for buying 86% of health care; 7% is spent by households and the remaining 7% by others (WHO, 2014). The key health system organization in Qatar comprises the following:

(i) Ministry of Public Health (MoPH)

A government body that oversees and regulates the medical marketplace and promotes and supports the health care financing program that provides access to all (Ministry of Public Health [MoPH], 2016). The MoPH is responsible for providing and improving the necessary work force and funding that is efficient, balanced, fair, and sustainable (WHO, 2006).

(ii) Hamad Medical Corporation (HMC)

The Hamad Medical Corporation (HMC) is the main national provider of secondary and tertiary healthcare in Qatar (Hamad Medical Corporation, 2016). HMC delivers 90% of acute service in Qatar through its eight Joint Commission International (JCI)-accredited hospitals (Hamad Medical Corporation [HMC], 2015).

(iii) Primary Health Care Corporation (PHCC)

The PHCC operates more than 23 primary health care centers located in many parts of the state of Qatar (Primary Health Care Corporation, 2016).

(iv) Others

The following points of care are described by (MoPH-Qatar, 2018) as follows

1. Private hospitals: includes privately-owned institutes like Al Emadi Hospital, Doha Clinic Hospital, and Al Ahli Hospital.
2. Sidra Medicine: medical center providing patient care for women, children, and young persons.
3. Aspetar: a specialized orthopedic and sports medicine hospital.

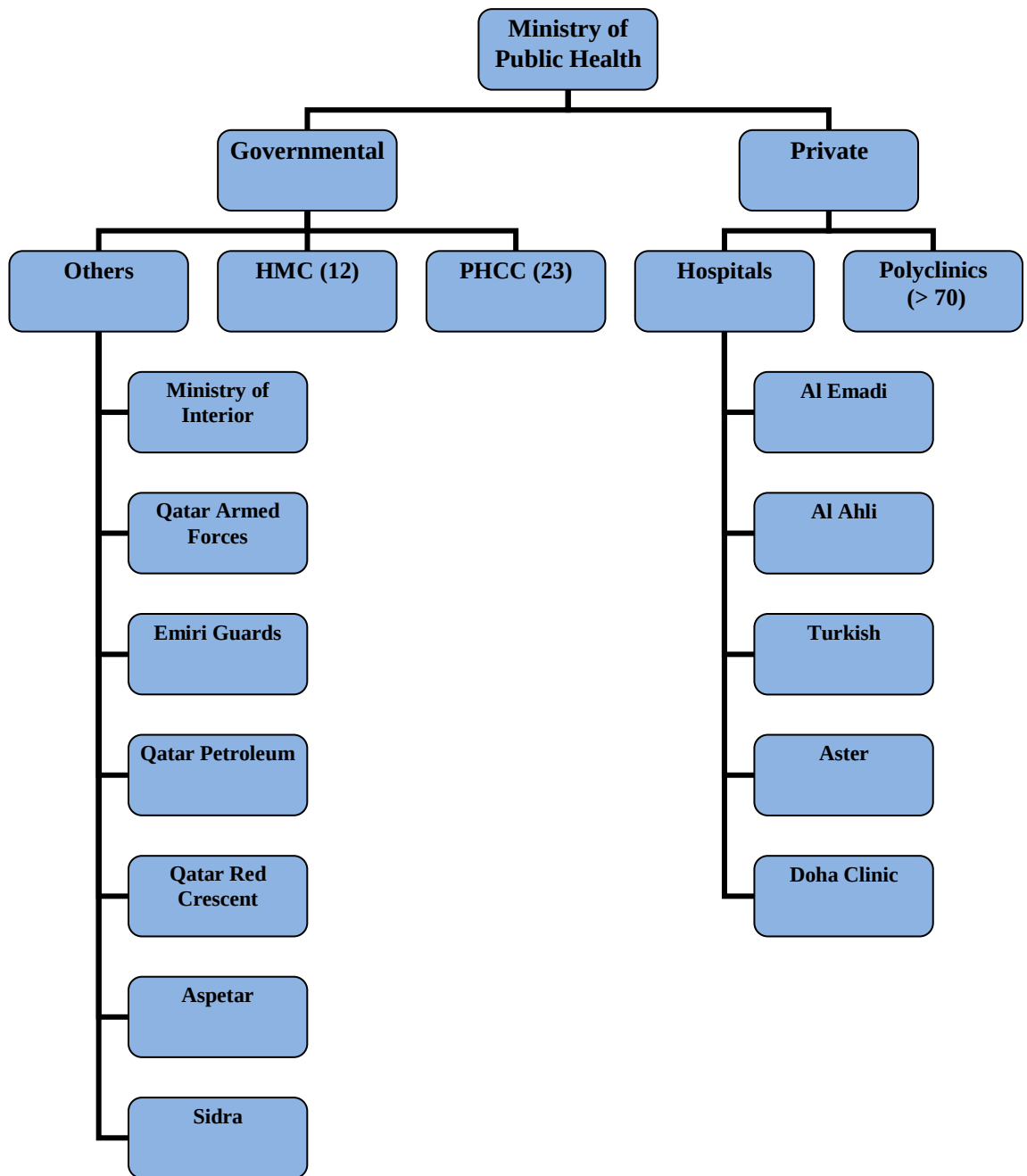


Figure 2.1: The structure of the healthcare system of the state of Qatar

Source: (Al Hail et al., 2018)

2.1.2 Health-care expenditures and financing

A critical review article (Alkhamis, Hassan, & Cosgrove, 2014) states that health care financing in Qatar and in other Gulf Cooperation Council (GCC) countries has the following features:

- Large expatriate population compared to the national population.
- Huge expenditures on health care services.
- Underdeveloped healthcare systems.

Qatar's total healthcare expenditure in 2013 was 18.26 billion QAR (5 billion USD), which was an increase of 20.6%, i.e., 15.14 billion QAR, from 2012 (SCH, 2015). In 2013, General Government Health Expenditure (GGHE) was 6% of General Government Expenditure (GGE) and 84% of the Total Health Expenditure (THE), which is estimated at a value of USD 2043 per capita (WHO, 2013).

2.1.3 Pharmaceutical profile in Qatar

As per the Qatar Council for Healthcare Practitioners (QCHP), pharmacists licensed in Qatar number more than 2080; around 500 are HMC pharmacists and 300 are PHCC pharmacists (Qatar Council for Healthcare Practitioners, 2017). These pharmacists were responsible for processing 2,001,310 prescriptions at health centers and more than 6,075,839 prescriptions at HMC hospitals (SCH, 2014). Before 2006, there was no school of pharmaceutical sciences in Qatar, and hence most pharmacy practitioners were expatriates. This structure is expected to change with the opening of the only college of pharmacy in the country at Qatar University that accepts its first class in September 2007 (Kheir & Fahey, 2011). In general, dispensing of

medication against a medical prescription remains the principal function of the pharmacist, and no patient records are available for the community pharmacy (M. S. El Hajj, Al-Saeed, & Khaja, 2016). There is no independent professional pharmacists' association or syndicate to contribute to the development and advancement of the practice in the country (Wilbur, 2010).

The government introduced the NHS 2011–2016 to set general health policy and promote all parts of health sector in Qatar in order to achieve the best health results for clients (Supreme Council of Health [SCH], 2012). The practice of pharmacy in Qatar has caught the attention of the policy makers who approved NHS 2011–2016, which highlighted the following issues related to the pharmacy profession via the Pharmacy and Drug Control Department (PDCD) (. SCH, 2014):

- A community pharmacy strategy that supports the role of pharmacists in providing pharmaceutical care and other services that is geographically convenient and accessible to patients.
- A Qatar national formulary and Qatar national drug coding.
- An education program for healthcare professionals (HCPs) encouraging the use of generic medicines.
- Strengthening the national drug regulatory authority (NDRA) by adopting rigorous medical device regulation.

The PDCD is the governmental body responsible for developing and executing the national drug policy throughout state of Qatar, and it functions under the legal framework of the MoPH (MoPH-Qatar, 2017b). The PDCD controls the operation of pharmaceutical establishments and use of narcotic substances; in addition to ensuring the safety, efficacy, and quality of pharmaceuticals, herbals,

food supplements, medicated cosmetics, and other products through the following sections:

- Drug Registration Section.
- Drug Quality Control Laboratory.
- Drug Release Section.
- Inspection and Narcotic Section.

The estimated pharmaceutical market size in Qatar was about USD 395 million, USD 524 million, and USD 554 million in 2010, 2015, and 2016, respectively (Business Monitor International, 2017; Ibrahim, 2015b). Due to insufficient local manufacturing, Qatar imports most of its needed pharmaceuticals from developed countries (Maguy Saffouh El Hajj, Kheir, Zaidan, & Jewesson, 2011). The pharmaceutical procurement for the governmental sector involved participation in regional GCC tenders, local tenders, and direct purchase when necessary (Ibrahim, 2015a).

2.2 Diabetes Mellitus

DM is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (American Diabetes Association, 2009, 2010). There is an increased risk of cardiovascular disease (CVD) due to DM, as described by the Framingham Heart Study (Fox et al., 2007). An estimated 1.5 million deaths in 2012 were reported to be directly caused by diabetes and more than 80% of diabetes deaths occur in low- and

middle-income countries (Mathers & Loncar, 2006). The prevalence of diabetes in 2014 was 422 million adults worldwide, and by 2040 the number of people with diabetes is projected to be 642 million (International Diabetes Federation [IDF], 2015; WHO, 2016b). As per a study published in 2011, 347 million people worldwide have diabetes, and this number is expected to reach 380 million by 2025 and 439 million by 2030; the projected healthcare expenditure is projected to rise sharply to USD 561 billion in 2030 (Danaei et al., 2011; "The global challenge of diabetes," 2008; Shaw, Sicree, & Zimmet, 2010; P. Zhang et al., 2010). There 29.1 million people (9.3% of the population) with diabetes in the United States (CDC, 2014a).

The prevalence of diabetes has risen in the countries of the Middle East and North Africa (MENA) region due to rapid economic development and urbanization; changes in lifestyle that have led to reduced levels of physical activity, increased intake of refined carbohydrates, and a rise in obesity; and the ageing of their populations (Alhyas, McKay, Balasanthiran, & Majeed, 2011; Alhyas, McKay, & Majeed, 2012). The prevalence of diabetes among adults in MENA region is 9.2%, which is equivalent to 34.6 million, and this number is expected to escalate to about 60 million and 67.9 million by 2030 and 2035, respectively (Majeed et al., 2014; Whiting, Guariguata, Weil, & Shaw, 2011). An estimated 10% of deaths in the MENA region were attributable to diabetes, and the cumulative spending to treat diabetes was \$12 billion and \$13 billion in 2012 and 2013, respectively (IDF, 2012, 2013; Whiting et al., 2011). Table 2.1 lists the top countries for diabetes prevalence in the MENA region (IDF, 2017).