A STUDY ASSESSING PRESCRIBING QUALITY OF UNIVERSITI SAINS MALAYSIA'S PRIMARY CARE PROVIDERS AND EVALUATION OF ITS IMPACT USING ANDERSEN'S MODEL AND PROPENSITY SCORE METHOD

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by

ABDULLAH AHMED HASSAN AL-DAHBALI

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Dedicated to

My Beloved Mother Mrs. Safia Abdullah Dhabali

My late Father Mr. Ahmed Hassan Dhabali

My beloved Wife Mrs. Safia Ahmed Dhabali

My Daughters

Rasha & Shadha

&

My Sons

Abdulwahab, Abdullah & Abdulrahman

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ACE	Angiotensin-Converting Enzyme
ADP	Allergenic Drug prescription
ATC	Anatomical Therapeutic Chemical
BB	Beta Blocker
CCB	Calcium-Channel Blocker
CDI	Chronic Disease Index
CDS	Chronic Disease Score
DCI	Drug Contraindication
DDD	Defined Daily Dose
DDI	Drug-drug Interaction
DHP	Dihydropyridine
DOP	Drug over-prescription
DRM	Drug-Related Morbidity
DRP	Drug-Related Problem
EP	Exposed Patient or Exposure Prevalence
FFS	Fee-For-Service
ICD	International Classification of Diseases
ICD-9	International Classification of Diseases-Version 9
Inh.	Inhalation
IOM	Institute of Medicine
LTTG	Long Term Therapeutic Group
LTTGI	Long Term Therapeutic Groups Index

MADRAC	Malaysian Adverse Drug Reactions Advisory Committee
MAI	Medication Appropriate Index
MAPE	Mean Absolute Prediction error
MPE	Mean Prediction Error
NICE	National Institute for Clinical Excellence
OLS	Orinary Least Square
PACT	Prescribing Analysis and Cost
PAI	Prescribing Appropriateness Index
PD	Pharmacologic Duplication
PDRM	Preventable Drug-Related Morbidity
PIM	Potentially Inappropriate Medication
PR	Prediction Ratio
RAS	Renin-Angiotensin System
Rx	Prescription
UK	United Kingdom
URTI	Upper Respiratory Tract Infection
US	United States
USM	Universiti Sains Malaysia
USMHC	Universiti Sains Malaysia's Health Centre
USMPC	Universiti Sains Malaysia's Panel of Clinics
WHO	World Health Organization
WMD	Weighted Means Difference/ Weighted Proportions Difference
WLS	Weighted Ordinary Least Square

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Kajian Penilaian Kualiti Mempreskripsi oleh Pengamal Perubatan Primer Universiti Sains Malaysia dan Penilaian Impak Menggunakan Model Andersen dan Kaedah Skor Kecenderungan

ABSTRAK

Peningkatan kos penjagaan kesihatan adalah masalah di seluruh dunia. Menilai dan memperbaiki kualiti sepatutnya menjadi salah satu agenda reformasi dan kawalan kos perkhidmatan penjagaan kesihatan. Mempreskripsi ubat adalah salah satu perkhidmatan penjagaan kesihatan yang memerlukan penilaian dan penambahbaikan secara berterusan. Namun, kaedah yang sedia ada untuk menilai kesesuaian pempreskripsian menghadapi banyak kekurangan termasuklah daripada segi kesahan ramalan. Kajian ini menilai corak pempreskripsian oleh penyedia penjagaan kesihatan asas di Universiti Sains Malaysia (USM). USM menawarkan khidmat penjagaan kesihatan asas kepada benefisiarinya. Penilaian telah dilakukan pada peringkat makro di mana teras petunjuk pempreskripsian dan metodologi dos harian yang tetap (DDD) yang telah digunapakai oleh Pertubuhan Kesihatan Sedunia (WHO) dikira daripada data akademik tahunan pengguna perkhidmatan ini. Penilaian juga telah dilakukan pada peringkat mikro (pesakit) di mana masalah berkaitan drug (DRP) berhubung dengan keselamatan pempreskripsian telah dikenalpasti di dalam setiap preskripsi yang dikeluarkan dalam dua tahun akademik. Kenyataan yang mewakili kejadian DRP telah dibangun dan disahkan. Setiap kenyataan adalah senario klinikal di mana drug telah dipreskripsi tetapi perakuan sumber informasi daripada pihak berkuasa drug adalah bertentangan dengan preskripsi tersebut. Berdasarkan model penggunaan penjagaan kesihatan Anderson, satu rangka kerja

telah dibangunkan untuk menilai kesan pendedahan pesakit terhadap DRP dan kaitannya dengan bilangan lawatan penjagaan asas. Analisis komponen regresi digunakan untuk menilai kesan ini. Komponen status kesihatan daripada model Anderson telah dianggarkan daripada beberapa jenis drug yang diambil oleh pesakit. Bagi mengkaji hubungan kesan- akibat di antara pendedahan dan peningkatan bilangan lawatan, teknik statistik skor kecenderungan (PS) telah digunakan selepas percubaan dan anggaran yang sesuai dilakukan. Memandangkan bahawa majoriti benefisiari USM adalah muda dan sihat, penilaian peringkat makro menunjukkan adanya isu-isu berpotensi dalam pempreskripsian drug berbanding corak yang dijangkakan. Tambahan pula, prevalens DRP adalah tinggi dengan beberapa kumpulan drug terutamanya antihistamin dan drug gastrousus. Analisis regresi menunjukkan bahawa pendedahan pesakit kepada DRP mempunyai kesan ketidakbergantungan yang positif kepada peningkatan dalam lawatan penjagaan kesihatan asas selepas mengawal kovariat, termasuk status kesihatan.. Sifat yang menyebabkan kesan ini telah disahkan di dalam analisis PS di mana pesakit yang terdedah mempunyai jumlah purata 6.5 kali lawatan berbanding dengan kawalan. Kesimpulannya, kajian ini telah membuktikan bahawa adanya isu-isu yang berpotensi di dalam pempreskripsian drug. Pendedahan kepada DRP telah dihubungkan kepada penggunaan penjagaan kesihatan yang tinggi. Intervensi juga adalah perlu untuk mengelakkan potensi berlakunya morbiditi berkaitan drug dan bagi mengurangkan kos penjagaan kesihatan.

A STUDY ASSESSING PRESCRIBING QUALITY OF UNIVERSITI SAINS MALAYSIA'S PRIMARY CARE PROVIDERS AND EVALUATION OF ITS IMPACT USING ANDERSEN'S MODEL AND PROPENSITY SCORE METHOD

ABSTRACT

Escalation of healthcare cost is a world-wide problem. Assessing and improving the quality of healthcare services should be a part of any agenda for healthcare reforms and cost containment. Drug prescribing is one of healthcare services that requires continuous assessment and improvement. However, available tools for assessing prescribing appropriateness have many shortcomings including lack of predictive validity. This study evaluates the prescribing pattern of Universiti Sains Malaysia's (USM's) primary healthcare providers. USM offers primary healthcare services to its beneficiaries. The evaluation was performed at a macro level where the core prescribing indicators and the defined daily dose (DDD) methodologies adopted by the World Health Organization (WHO) were calculated from an academic year data of service users. Evaluation was also performed at a micro level (the patient) where drug-related problems (DRP) pertaining to the safety of prescribing were identified in each drug prescription issued within two academic years. Statements representing DRP event were developed and validated. Each statement is a clinical scenario in which a drug was prescribed while the authoritative drug information sources recommend against its prescribing. Based on Andersen's healthcare utilization model, a framework was developed to evaluate the effect of patient's exposure to DRPs on the number of primary care visits. Regression analysis

was used to evaluate this effect. The health status component of Andersen's model was estimated from some of the drugs used by the patients. To study the cause-effect relationship between exposure and increment in number of visits, the propensity score (PS) statistical technique was applied after proper estimation and testing. In view of the fact that the majority of USM's beneficiaries are in young and healthy ages, the macro level evaluation has shown potential issues in drug prescribing compared to the expected pattern. Moreover, the prevalence of DRP was high with some drug groups especially antihistamines and gastrointestinal drugs. Regression analysis has shown that the exposure of patients to DRPs has an independent positive effect on the increase in primary care visits after controlling for other covariates, including the health status. The causal nature of this effect was confirmed in the PS analyses where the exposed patients had, on average, 6.5 visits more than their controls. In conclusion, the study has documented potential issues in drug prescribing. Exposure to DRPs was linked to higher utilization of healthcare. Intervention is warranted to prevent the potential drug-related morbidities and to decrease healthcare cost.

CHAPTER ONE

INTRODUCTION

1.1 Thesis Overview

This thesis consists of four parts. **Part One** is a classical study that investigated drug prescribing in clinics that offer primary healthcare services to beneficiaries of Universiti Sains Malaysia (USM). The data of part one, as well as that of the other parts, were obtained from USM computerized databases which keep electronic medical records (EMR) of patients. The defined daily dose (DDD) and the WHO core prescribing indicators were used in this part. These tools assess drug prescribing generally from aggregated data without the requirements of clinical details of the patients. Despite this, they can provide an overview on the situation. They can flag potential problems in drug prescribing that require further investigations. The findings of part one can serve as a baseline to which future prescribing patterns in these clinics can be compared from time to time or after any policy implementation. Results of part one showed potential issues in drug prescribing. The next step was to investigate whether these issues have an economic impact such as increasing the number of visits of patients to those clinics. This impact was studied using Andersen's model of healthcare utilization.

Andersen's model uses the patient as the unit of analysis, and conceptualizes healthcare utilization as a function of predisposing factors, enabling factors and needs factors of the patient. It also implicates healthcare quality as a determinant of healthcare use. While the predisposing factors and enabling factors are readily

available in the data, and the number of primary care visits of patients could be easily calculated, the needs factors and the quality of care required preparatory work before the model could be used. These two tasks were performed in the second part and the third part, respectively.

Part Two of this thesis deals with developing and validating an estimate of the needs factors of patients, the third input in the model. This estimate is called the long-term therapeutic group index (LTTGI). It is the number of therapeutic groups the patient uses, whereby these groups are used to treat disease conditions that take long time to cure or are not curable or go through exacerbation and remission or need continuous treatment or need repeated treatment courses. A panel of clinical pharmacists validated the use of these groups in such disease conditions.

Part Three assesses quality of prescribing using Donabedian's framework of healthcare quality assessment, focusing on the process component of quality. Specifically, prescribing appropriateness (at the patient level) was assessed. Hepler and Strand framework of drug-related morbidity (DRM) and drug-related problems (DRPs) states that: for a DRM to be preventable, it must be preceded by a recognizable and controllable DRP. In part three, statements on five categories of DRPs were developed and validated. These categories are overprescribing, allergenic prescription, drug interaction, contraindication, and pharmacologic duplication. Then, patients' EMR were screened for each of these statements. Finally, the DRP events scored-up for each patient. This score was incorporated into Andersen's model to represent prescribing quality.

At this stage, the components of Andersen's model has been made available. The relationship between exposure to these DRP categories and patients' visits was assessed within the model.

Part Four attempts to establish a cause-effect relationship between exposure to DRPs and increased healthcare utilization. That was achieved by applying the propensity score (PS) analyses. PS was estimated for each patient based on the number of DRP exposures. PS was then used to form matched pairs of patients whereby the two patients constituting any pair are closest in their PS values but farthest in their number of exposure to DRPs. Next, the pairs were dissociated into two groups; the exposed and the unexposed groups. Finally, the two groups were compared in the number of visits.

1.2 Background

Drug prescribing is probably the most common medical strategy in treating and preventing diseases affecting human beings. In a recent US' national ambulatory medical care survey (Cherry *et al.*, 2008), drugs were prescribed in 70% of physician's office visits. On average, 2.1 drugs were prescribed per visit.

New diseases are continually being discovered and new drugs are being invented and introduced into the pharmaceutical market. Randomized controlled trials propose benefits of new drugs and support potential new values of the already existing drugs for new medical indications.

Drug benefits have extended from treating and managing diseases to controlling the risk factors behind diseases. As examples, statin anti-hyperlipidemic drugs and aspirin are used for primary prevention of coronary heart disease, and aspirin and warfarin are used in primary prevention of ischemic stroke.

Furthermore, public access to healthcare and the availability of drugs is improving due to collaborations of countries and organizations. Elderly population present larger proportion of any community than any time before. All these factors

contribute to increasing drug prescribing and drug use among populations across the globe.

The quality of drugs in the pharmaceutical markets is better than any time before. Good manufacturing practice (GMP) is a pre-requisite to drug marketing in most countries. In addition, studies of bioequivalence on generic drug products are being implemented in developed countries and some of the developing countries as well. These regulations on marketing drugs have increased the confidence in both healthcare professionals and the general public that the marketed drugs have the capacity to effectively fight diseases.

The beneficial effects of drugs have been continuously shown, but drugs are not free of danger. A drug is double-edged sword. Parallel to the increase in drug use, numerous studies have shown that inappropriate use of drugs has led to an increase in adverse drug reactions and adverse drug events.

In the literature of patient-centered approach and pharmaceutical care, these adverse outcomes of drug use are referred to as drug-related morbidities (DRMs). A DRM is defined as “clinical or bio-social manifestation of unresolved drug-related problems.” (Hepler and Segal, 2003). A drug-related problem (DRP), in turn, is defined as “an event or a circumstance involving drug treatment that actually or potentially interferes with patient’s achievement of an optimum outcome of medical care” (Strand *et al.*, 1990). Eight categories of DRPs were identified. These categories are untreated indications, improper drug selection, sub-therapeutic dose, failure to receive drug, overdose, adverse drug reaction, drug interactions, and drug use without indication.

Drug-related problems are a worldwide concern. They cause morbidity and mortality (Ebbesen *et al.*, 2001, Buajordet *et al.*, 2001), increase rate of

hospitalization and hospitalization days (Roughead *et al.*, 1998, Kongkaew *et al.*, 2008, van der Hooft *et al.*, 2008, van der Hooft *et al.*, 2006), increase frequency of emergency visits (Yee *et al.*, 2005), increase primary care utilization and cost (Guerreiro *et al.*, 2005, Ernst and Grizzle, 2001, Johnson and Bootman, 1995), and lea to an overall increase in healthcare expenditure (Forster *et al.*, 2003, Gandhi *et al.*, 2003, Silverman *et al.*, 2003).

The magnitude of DRPs is so immense that it needs to be addressed. Though the elderly are the population most studied, the prevalence of DRPs is not low in the younger age groups. They involve all levels of healthcare. In residence homes of elderly in the US, large number of studies have found high prevalence of DRP (Lau *et al.*, 2004, Lau *et al.*, 2005). The situation in primary care is no better. Two studies in the US general practice and in community pharmacies of some European countries reported DRP prevalence as high as 61% and 64%, respectively (Paulino *et al.*, 2004, Strand *et al.*, 2004). A recent study in Spanish primary care of elderly reported a DRP prevalence of 46% (Gomez *et al.*, 2009). A study compared DRPs in primary care in Minnesota and Australia reported prevalence of 70% and 90%, respectively (Rao *et al.*, 2007).

1.2.1 Safety Issues in Drug Use

Following the release of the Institute of Medicine (IOM) report entitled “To Err Is Human: Building a Safer Health System” (Kohn LT, 1999), numerous efforts have been directed to ensure quality and safe health care systems. The report estimated an occurrence of 44000-98000 deaths in American inpatient care facilities each year due to medical errors; the share of medication errors were 7000 deaths. These findings put medical errors among the leading causes of mortality and one of the high cost diseases (Kohn LT, 1999). Since then, IOM has started series of

publications called “Quality chasm” which aim to improve the quality and safety of healthcare systems. The IOM framework categorizes health care quality into safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (Berwick, 2002, Institute of Medicine (U.S.). Committee on Quality of Health Care in America., 2001). Issues related to drug safety is one of the concerns in IOM quality chasm series (Aspden and Institute of Medicine (U.S.). Committee on Identifying and Preventing Medication Errors., 2007).

Similar efforts have been initiated in Europe. In the United Kingdom (UK), for example, the Department of Health has identified the needs to address medical errors (Donaldson, 2002). The focus of the UK’s government on quality improvement has resulted in the establishment of authorities such as the National Institute for Clinical Excellence (NICE) and the national performance framework. The purpose of these authorities is to measure and improve the quality in different areas of healthcare. Furthermore, and in relation to general practice specifically, Prescribing Analysis and Cost (PACT) database was established. PACT database allows the general practitioners to review their own prescribing and to compare with their peers. It is also used in research aiming to improve the quality of prescribing in general practice in the UK.

1.3 Overview on Healthcare Scheme of Universiti Sains Malaysia

Apart from hospital services offered by the Malaysian government for its population, Universiti Sains Malaysia (USM) offers primary healthcare services to its beneficiaries through its Health Center (USMHC) located at the main university campus in Penangand through a panel of private clinics (USMPC) and pharmacies. USM beneficiaries are staff of USM, their spouses and children as well as USM’s

students, their spouses and children. All beneficiaries have equal access to the healthcare services in USMHC. However, their access to the USMPC is not the same; staff and their dependants have unlimited access while students have limited access of 6 visits per year and student's dependants and pensioners do not have access to USMPC.

USMHC is owned by USM, and the healthcare providers are employees of USM. Panel clinics are private entities and are reimbursed by USM on the bases of fee-for-service (FFS). This FFS is capped to a ceiling according to the service provided. For consultation-only visits, USM reimburses USMPC with RM9. If an antibiotic has been prescribed, the reimbursement is RM14. If drugs other than antibiotics have been prescribed, the reimbursement becomes RM12.

While dispensing takes place in the pharmacy unit of the USMHC, most prescriptions issued by USMPC are dispensed by the respective clinics, since the Malaysian regulations allow private clinics to dispense prescriptions. However, if the patient chooses to obtain the prescribed medications from a pharmacy outside the clinic, dispensing will take place in one of the USM's panel pharmacies. Pharmacies send claims to USM, which then reimburses them for the prescriptions they dispensed.

1.4 Problem Statement

Escalation of healthcare cost is a worldwide problem. Any healthcare reforms aim to decrease the cost of healthcare. Healthcare escalation is multifactorial regardless of the context and healthcare system characteristics. However, many factors contributing to the cost escalation are controllable. Identifying these factors,

their causes, and the magnitude of their contribution in cost escalation is important in order to formulate relevant interventions towards cost containments.

Delivering quality healthcare is one of the means for cost containment. The need for quality assessment and improvement in healthcare is indisputable. Of healthcare services that need continuous quality assessment and improvement is drug prescribing.

Often, people benefit from drug therapy, but the potential of adverse outcomes are always present. These potential adverse outcomes range from minor adverse drug events to fatality. Research has shown that the cost of drug-related morbidities (DRM) and mortalities exceeds the cost of the drugs themselves (Guerreiro et al., 2005, Ernst and Grizzle, 2001, Johnson and Bootman, 1995). Adverse outcomes of drug therapy are costly; fortunately, most of them are preventable. Assuring safe and effective prescribing practice should be a priority in any quality improvement program.

Methods that assess the outcomes of exposure to drug-related problems (DRPs) require data-rich environment such as those in the hospital setting. In primary care setting, on the contrary, data on outcomes are often lacking. In such cases, assessing the quality of drug prescribing by assessing the prescribing pattern is more reliable. Assessing the prescribing pattern aims to identify DRPs in drug prescribing.

The validity of prescribing assessment methods relies on the strength of the link between the DRPs in the prescribing step of drug use and the drug therapy adverse outcomes (known as drug-related morbidity, DRM). The evidence that links safety-related prescribing assessment methods is not scientifically sound. Most assessment tools were developed through consensus-based approaches, and are

limited to elderly population. Even in cases of sound scientific evidence, operationalizing the assessment is hindered by data unavailability.

As stated earlier, the drug use in primary care is still far from being a system as conceptualized by pharmaceutical care philosophy. Drug use in primary care is a process with the inherent lack of the feedback loop (the monitoring step) that helps in detecting, resolving, and preventing DRPs. This affects both the effectiveness and the safety aspects of drug therapy. However, safety comes first, particularly in this instance. That is because effectiveness is always in the provider's mind and can be checked easily in the subsequent encounters by observing the signs and the symptoms of the disease being treated. Safety-related DRPs, on the other hand, has a relatively higher potential to go unrecognized. The result is events of DRM with consequent non-compliance, which definitely will adversely affect drug effectiveness. Furthermore, and in relation to the lack of monitoring step, safety-related DRP need to be defined more strictly, to allow the prescriber to judge the benefit and the risk of the majority of the prescriptions. Safety-related DRPs should be restricted to those prescribing events in which the potential risk of prescribing a drug outweighs any potential benefit from prescribing that drug.

Attempts to use indicators of inappropriate prescribing as quality assessment tool are devalued by the lack of predictive validity. That is, if the high prevalence of inappropriate prescribing reflects low quality, it is anticipated that it will result in negative healthcare outcomes (mortality, morbidity) and higher healthcare cost and utilization. However, the results of studies investigating this relationship are conflicting (Lin *et al.*, 2008, Jano and Aparasu, 2007, Fillenbaum *et al.*, 2004, Donna Marie Fick *et al.*, 2001). So, the questions are: do these indicators measure a wrong

thing? Or is it because of issues related to study designs, data validity, and data availability?

Exposure to DRPs is supposed to increase healthcare utilization of those who are exposed. Few studies have investigated this economic effect. Even, those studies did not investigate the causal nature of the effect. Ethically, no randomized experimental study can be carried out to investigate the causal effect of inappropriate prescribing on healthcare utilization.

The previously-mentioned issues were avoided in this thesis. This thesis has developed statements that assess the safety of prescribing in primary care practice. The statements were constructed from authoritative textbooks of therapeutics and drug information; these sources enhance the validity of the statements. This thesis has considered only prescribing events in which the risk of prescribing a drug outweighs any potential benefit. These statements were then validated by a panel of clinical pharmacists. The economic effect of exposure was assessed using Andersen's model of healthcare utilization. In relation to cause-effect relationship between the exposure and the healthcare utilization, this thesis used propensity score approach to study the causality in this relationship.

To the best of the researcher's knowledge, this is the first work to address measuring the causal effect of exposure to safety-related DRPs in the prescribing step of drug use on primary healthcare utilization by applying the propensity score.

1.5 Research Hypothesis

This study hypothesizes that exposure to DRPs in the the prescribing step of drug use leads to increase in healthcare utilization and cost. Such exposure causes harm to the exposed individuals. The harm may not be severe enough to lead to

emergency visit or hospitalization. However, it can be so annoying that the individuals will seek medical attention at primary care clinics. As a result, the exposed individuals will visit the primary care providers more frequently than their unexposed counterparts. That is to say, the exposure is a cause to an intermediate end (the annoying effect of exposure) which in turn is an intermediate cause to an ultimate end (the increase in the healthcare utilization, the number of visits and subsequently the cost).

Gandhi *et al.* (2000) found that most of the detected DRM events were neither life threatening nor led to hospitalization; and such DRMs are minor to the providers but not to the patients. Those authors commented that prescribers often overlook such DRM despite the fact that they annoy the patients, hence causing dissatisfaction and increase in primary health service utilization. Most of these "minor" DRM were preventable (PDRMs).

1.6 Study Objectives

1.6.1 General Aims

There are two primary aims to this thesis. The first is to assess the quality of prescribing of USM's primary care providers. The second is to evaluate the relationship between the quality of prescribing and primary care utilization.

1.6.2 Specific Objectives

1) To assess the quality of prescribing at a macro level (USM's Health Centre and USM's panel clinics) from the aggregates of prescribing data. This objective has been achieved by:
    a) Calculating the defined daily dose (DDD) rates.

b) Calculating the WHO core prescribing indicators.

2) Assessing the quality of prescribing at a micro level (the patient). This has been achieved by:
    a) Calculating the number of visits of each patient.
    b) Identifying socio-demographic factors of the patients.
    c) Estimating healthcare-related needs and health status of patients.
    d) Including this estimate in the Andersen's model of healthcare utilization in which the number of visits represent the utilization variable.
    e) Validating the inclusion of this estimate in the model.
    f) Identifying the number of times each patient has been exposed to the following drug-related problem categories:
        i. Drug Over-prescription
        ii. Drug-Drug Interaction
        iii. Drug Contraindication
        iv. Allergenic Drug Prescription
        v. Pharmacologic Duplication
3) Studying the prevalence of and the exposure rate to these DRP categories.
4) Identifying the drugs and drug classes in these DRP categories.
5) Studying the relationship between the number of exposures to DRPs and the number of primary care visits of patients.
6) Studying the causal effect of exposure to DRPs on the number of primary care visits of patients using propensity score analyses. These analyses included the following steps:
    a) Estimating the propensity score of exposure to DRPs.

b) Checking the estimated propensity score as a balancing score.

c) Producing matched groups of patients based on propensity score and the number of exposures to DRPs.

d) Comparing the number of visits between the two matched groups.

1.7 Rationale of the Study

There are concerns about the increase of healthcare cost and utilization in USM. To date, and to the best of the researcher's knowledge, no study has been performed to relate drug use problems to the cost and utilization. This study investigates the contribution of problems in drug use to the utilization of USM healthcare.

1.8 Significance of the Study

This study extends the finding of drug over-utilization (based on part1: drug utilization study) from a crude measure of utilization to the effect of utilization on the patient's overall health service utilization. In other word, this study uncovers some areas of expenditure related to drug use problems apart from the direct cost of drug over-utilization.

The contributions of this thesis are:

1) It describes drug prescribing pattern of USM's Health Centre and USM's panel clinics. These information can be used as a baseline against which comparisons can be made in the future; for example, after policy interventions related to drug prescribing.

2) It provides validated lists of some potential DRPs that occur in the prescribing step of drug use in the primary care. These lists have the potential to be used for the assessment of prescribing quality in the primary care setting.
3) It provides information on the prevalence of the above-mentioned DRPs in the USM's primary care system that offers healthcare to USM's beneficiaries.
4) It develops and validates a tool that estimates the health-related needs of individuals. This tool can be used to as an estimate of the health status of individuals in risk adjustment models of primary care utilization.
5) It tests the assumptions of the Andersen's model that the quality of healthcare provided has an effect on the healthcare utilization, as proposed by Andersen. It does so by applying the model with the incorporation of the exposure to DRPs as one of the determinants of the utilization.
6) It evaluated the causality of exposure to DRPs on the increased utilization of the exposed individuals.

1.9 The Scope of the Study

This thesis deals with evaluating the quality of prescribing in primary care. The quality of prescribing in this thesis refers to its technical meaning. As mentioned above, quality in medical care has a technical part as well as an artistic part. The artistic part of prescribing quality is not measured in this thesis. The study by Britten and colleagues suggested a tool for assessing the art component, and to some extent the technical component, of prescribing appropriateness (Britten *et al.*, 2003). That

study incorporated, by qualitative methods, the patient's perspectives into assessing the prescribing appropriateness.

In this thesis, drug prescribing was assessed at two levels. The first level was a macro-level. This macro-level assessment was gross in that it used the aggregate data on drug prescribing. Two well known tools were used in this assessment, the defined daily dose (DDD) and the WHO Core Prescribing Indicators. These two tools are more towards measuring rational drug prescribing than assessing the appropriateness of drug prescribing. Despite the grossness nature of this assessment using these two tools, potential issues in drug use can be highlighted in a timely and an inexpensive manner. They can highlight potential issues in drug prescribing that warrant further and deeper investigations.

The second prescribing assessment performed in this thesis was at a micro-level. It assessed the drug prescribing in relation to the patients for whom the drugs were prescribed. Unlike the DDD and the WHO indicators, the assessment at the micro-level targeted the appropriateness of drug prescribing in relation to patients' clinical data. This assessment of prescribing appropriateness relied on explicit statements. Each statement refers to an event in the prescribing step of drug use where such prescribing should not have occurred. Most of these statements are related to the safety of drug prescribing.

CHAPTER TWO

LITERATURE REVIEW

2.1 Chapter Overview

This chapter contains many sections. The main aim of this chapter is reviewing the literature regarding the quality assessment in medical care, especially the quality of drug prescribing. The first section (2.2) of this chapter deals with the concept of quality in medical care. It includes the methods and the procedures used in assessing the quality of medical care. The second section (2.3) concentrates on assessing the quality of drug prescribing. This second section includes extensive literature review of the tools that are widely used to assess prescribing appropriateness.

Three other topics are presented in brief at the end of this chapter. The third section (2.4) discusses the role of data availability in quality assessment. It focuses on how the dearth of data in primary care can be a barrier to the assessment of prescribing appropriateness. The fourth section (2.5) is a brief introduction to healthcare utilization models with special focus on the Andersen's model. Andersen's model is relevant because it is the conceptual framework adopted in this thesis. The last section (2.6) is about the propensity score. Propensity score is the statistical technique used in this thesis. The aim of its use was to analyze the causal nature of the effect of exposure to inappropriate prescribing on primary healthcare utilization.

2.2 Quality in Medical Care

Avedis Donabedian is among the first pioneers who called for the need to assess and improve the quality in healthcare (Donabedian, 1978). Along with Donabedian's framework of quality assessment in healthcare, IOM defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine (U.S.). Committee on Quality of Health Care in America., 1990). The "Current professional knowledge" in the above-mentioned definition refers to the ever-changing technical standards of medical care (Donabedian, 1997). The definition explicitly states that assessment of quality relies exclusively on examining how good a health service is, and the goodness of the services is judged by the current relevant professional knowledge. That is, the likelihood of good outcomes of medical care increases by applying the current, relevant technical knowledge in examining (and improving) health services (Pronovost *et al.*, 2004). The current professional knowledge refers to the scientific evidence by which the health services are judged.

The definition is also limited to the technical quality. Two quality components have been identified: technical (the perspective of clinicians), and art (human and cultural appropriateness, the patient's perspective) (Donabedian, 1997). Technical quality assessment is the business of clinical sciences while the artistic part is the business of social sciences. The technical quality means that the patient receives only the procedures, tests, or services for which probability of achieving the desired health outcomes exceed the potential risks by a sufficiently wide margin; and that each of these procedures or services is performed in a technically excellent manner. The art component of quality is determined by the values the patients carry;

patients would like to be involved in the decision of how the care is offered them (Brook *et al.*, 2000).

2.2.1 Assessing Quality in Medical Care

There are many frameworks to conceptualize quality in medical care. The Donabedian quality assessment framework is widely accepted by clinical professions as well as healthcare administration. It conceptualizes three dimensions of quality: structure, process and outcome (Donabedian, 1978). Accordingly, healthcare quality can be assessed by examining one or more of these dimensions. Under this framework, investigation on quality of care is a part of health systems research. The European Drug Utilization Research Quality Indicators Meeting (DURQUIM) has adopted this framework for quality improvement research (Hoven *et al.*, 2005).

The structure is the dimension that examines the attributes of settings where the care is delivered. Examining the structure deals with many aspects including the number of staff and their qualifications, availability of instruments and expertise, availability of drug lists, drugs, treatment protocols and treatment guidelines. The process is the dimension of quality that deals with how the care is delivered and it investigates whether “good” medical practices are followed. Criteria and standards are used to examine the process of care. The outcome dimension looks at the impact of the care on health status and wellbeing of individuals and community. The outcome of healthcare delivery is linked to both the structure and the process. It is thought that well-structured facilities provide good outcome of healthcare. It is also expected that good process in healthcare delivery results in good outcomes.

2.2.1.a Outcome Assessment

Outcome in healthcare is defined as the "primary changes in health status that can be attributed to the care" (Donabedian, 1978). Outcomes assessment can be defined as the evaluation of the impact of medical and non-medical interventions, the health care process, and the structure of the health care system on clinical, economic, and humanistic outcomes, such as patient health-related quality of life and patient satisfaction (Gandhi *et al.*, 1999).

It has always been argued that assessing the outcome of healthcare is the best way to judge the quality of delivered care. Some scholars have counter arguments that assessing outcome is a valid measure in technology assessment studies such as clinical trials but not in quality assessment. Quality assessment is an administrative technique that aims to improve quality in real healthcare setting (Donabedian, 1997).

There are certain situations in which the outcome is not a valid measure of quality (Brook *et al.*, 2000). First, there are factors unrelated to the care that have an effect on the outcome such as natural history of the disease, patient's physiologic factors and patient's age. In such instances, the outcome (good or bad) is not merely the result of good or bad care. In another word, the specificity is low (Flanagan *et al.*, 2004, Donabedian, 1997). Second, some outcomes take a lengthy time before they manifest. This makes judging the outcome from the care impractical. Furthermore, assessing the outcomes misses the opportunity of identifying the pattern of care that could be a potential underlying cause of undesired outcomes, if any. All these factors represent practical limitations of using the outcomes to assess the quality of medical care.

Another limitation of assessing the outcome as a valid measure of quality is that operationalisation of outcomes measures is difficult. In present day healthcare

systems, patients' clinical data as well as administrative data are stored in large computerized databases. Standardization of data entry, documentation of events related to patient care as well as computer programs are needed for the purpose of data retrieval from these databases. Research has shown that data related to the clinical outcomes of medical care suffer from unstandardized data entry and poor documentation especially in diagnoses coding and results of laboratory tests (Palmer, 1997, Gandhi *et al.*, 1999, Hammersley *et al.*, 2006, Harpe, 2009, Roth *et al.*, 2009). In their computer-assisted detection of preventable rug-related morbidity (PDRM) indicators, Hammersley and colleagues (2006) admitted the complexity of the queries and the need to detect the temporal relation between pattern of drug use and the PDRM. All these represent challenges and difficulties in using these data sources to assess the outcome of care, at least in the present time.

Another factor that can limit using outcome for quality assessment is the effect of diagnosis coding in computerized healthcare data. Previous research documented the significant role of the coding system on the accuracy of the findings. Honigman and colleagues (2001) investigated the effect of the diagnosis coding system on the accuracy of detecting adverse drug events (ADEs) in outpatients electronic medical records. The International Classification of Diseases (ICD-9-CM) system was the poorest in detecting ADEs, where database screening correctly identified only five events out of the 248 events identified by chart review (the positive predictive value was 2%). The study attributed this low accuracy to two reasons. First, the ICD codes of drug injuries (the E codes) were not used by physicians in the institution investigated. Second, the non-specific nature of ICD codes, which makes it not suitable for ADEs detection.

2.2.1.b Process Assessment

The second way of assessing the quality of care is by examining its process dimension. In some instances where measuring the outcome is impractical, not possible or unreliable, measuring the process of care offers a valuable alternative. Assessing the care process intents to know whether what is considered good knowledge has been applied. Examining process for quality assessment has its maximal validity when there is good evidence that links the process to the outcomes. These links must either have been demonstrated in clinical trials or have widely been accepted by professional experts (Mainz, 2003, Pronovost *et al.*, 2004). Care delivery concordant with the evidence derived from either of these two sources is called evidence-based practice. Another advantage of examining the process is that deficits in care delivery are identifiable and possibly correctable (Rubin *et al.*, 2001a). Examining the process of care assesses whether providers perform their professional tasks in concordance with achieving the desired aims of care and avoid practices that predispose patients to harm.

Assessing the process dimension as a measure of quality of care is acceptable to healthcare providers because they feel accountable for the care they deliver (Rubin *et al.*, 2001a, Rubin *et al.*, 2001b, Pronovost *et al.*, 2004, Pronovost *et al.*, 2005). In the era of electronic medical records (EMR), the process of care can be examined retrospectively with reasonable reliability (Palmer, 1997). Among the disadvantages of examining the process of care is that criteria and standards for judgment should be updated continuously.

2.2.1.c Structure Assessment

The third way of assessing the quality of care is to examine the setting in which the care is delivered, i.e. the structure. This approach investigates the availability and the adequacy of equipment, protocols and guidelines, staff and their qualifications, expertise as well as some managerial structures, operational programs and documentation systems. The advantage of this approach is the ease of getting the required information for quality assessment. Examining the structure, as a measure of quality, relies on the assumption that adequate structure produces good outcomes. However, the relationships between the structure and the outcome and between the structure and the process are not well established and cannot be guaranteed at all times. In their review, Brook and colleagues (2000) argued, referring to examples from the literature, against using structure measures alone to assess quality. They stated that the relationship between the structure and the process are “weak, inconsistent, and paradoxical”.

2.2.2 Quality Indicators, Criteria and Standards

To measure quality, regardless of its dimension, we need to define tools by which a dimension of quality can be measured. These tools are called indicators. Indicators are explicitly defined and measurable items that serve the purpose of quality assessment (Campbell *et al.,* 2003). A quality indicator is defined as a measurable element of practice performance for which there is evidence or consensus that it can be used to assess quality (Lawrence and Olesen, 1997). The European working party on quality in primary care (EQuiP) has adopted the previously-mentione definition of quality indicator (Haaijer-Ruskamp *et al.,* 2004).

In quality studies, quality indicators are usually applied retrospectively where each indicator is presented with numerator and denominator. For example, if the

number of post myocardial infarction patients who were prescribed aspirin is the numerator, the denominator would be number of patient with myocardial infarction without a contraindication to use aspirin. To operationalize quality indicators, criteria and standards have to be defined. The following are the definitions of these terms according to Campbell and colleagues (2003) with clarifying examples. Unlike indicators, criteria assess the care on case-by-case bases. A criterion is a systematically developed statement relating to a single medical act, and is so clearly defined that it is possible to say whether a good care has been provided. For example, if the patient had myocardial infarction event, was aspirin prescribed to him/her?

While criteria give an answer of “Yes” or “No” on each single case about whether a specific care was offered (or a specific outcome was achieved), standards set the extent of allowable deviation from the criteria. A standard is defined as the level of compliance with the indicator or the criterion. Standards are set according to the context in which the care takes place. A target standard is a predetermined level of compliance with the criteria (for example, 90% of patients who had myocardial infarction should be prescribed aspirin) unless contraindicated. The achieved standard is what was found from the indicator study (for example, only 80 % of patients who had myocardial infarction were prescribed aspirin provided that they do not have contraindication to aspirin).

After developing quality indicators and defining the standards, these parameters are applied to measure the quality. Defects detected are then corrected.

It should be noted that the way quality indicators are developed depends greatly on the way it will be used and on which stakeholders’ (professionals, managers, third party payers, patients, carers) perspectives they are intended to reflect (Campbell *et al.*, 2002, Campbell *et al.*, 2003). In addition to using them for

quality improvement, quality indicators can be used to monitor, reward, penalise, or compare care provision. Different stakeholders have different views of quality. Thus, when developing indicators to assess quality, these differences have to be taken into consideration (Rubin *et al.,* 2001b). Healthcare professionals usually focus on professional standards and outcomes of the care they provide. Managers look at efficiency, patients' satisfaction, accessibility of care and outcomes. From the patients' perspective, quality is often related to understanding attitude, communication skills, and clinical performance. It is also important to relate the quality indicator development to the dimension of care (structure, process or outcome) it will assess. The focus here is on the process of care. Process assessment has been the object of quality assessment and improvement (Brook *et al.*, 2000).

2.2.3 Methods of Developing Quality Indicators

There are three methods for indicator development. The first one is a non-systematic approach, which does not rely on evidences from the medical literature. It is based on the professional experience of developers of indicators. This approach offers easy and quick way to develop indicators. This approach is also suitable for areas like critical care where patient's conditions are so complex that it is difficult to fit under categories for which evidence exists. A disadvantage to this approach is that the level of disagreement between experts can be so high that the reliability and the validity of the developed indicator are questionable; hence higher number of reviewers is usually required at the time of its application (Rubin *et al.*, 2001b).

The second method is a systematic approach. It is based on scientific evidence derived from rigorously conducted studies. This approach should be adopted in developing indicators whenever possible. The stronger the evidence, the more beneficial will the indicator be in quality assessment and improvement