ASSESSMENT OF PATTERN, PRACTICE AND WASTAGE OF MEDICINE-USE AMONG UNDERGRADUATE STUDENTS OF UNIVERSITI SAINS MALAYSIA

ASHUTOSH KUMAR VERMA

UNIVERSITI SAINS MALAYSIA

2018

ASSESSMENT OF PATTERN, PRACTICE AND WASTAGE OF MEDICINE-USE AMONG UNDERGRADUATE STUDENTS OF UNIVERSITI SAINS MALAYSIA

by

ASHUTOSH KUMAR VERMA

Thesis submitted in fulfilment of the requirements for the degree of Master of Science

January 2018

DEDICATION

To the Glory of Almighty

To my loving parents, sister, friends;

For their support, encouragement, care and love

"Karmany evadhikaras te ma phalesu kadachana ma karma-phala-hetur bhur ma te sango'stv akarmani" Bhagwat Gita: Chapter Two verse 47

ACKNOWLEDGEMENT

First of all, I'm grateful to almighty for his ashirwad that provided me strength and patience to sustain and complete this path. With this thesis a new research journey has began. I would like to express my deepest gratitude to my main supervisor, Professor Dr. Mohamed Azmi Ahmad Hassali for his continuous coaching and advice. He has supported me in every way possible since the start of my work as postgraduate student. Sincere thanks to my co-supervisor Dr. Fahad Saleem who not only guided me, also supported as a friend. They both both made my student life easier and less stressful with their encouragement and care. Their sincere help and supervision were real motivation for my research.

I'm thankful to my fellow postgraduates, staff of Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia and my friends who had given positive attitudes and supports. Finally, deepest gratitude to my loving parents Mr. Parashuram Verma and Mrs. Mithilesh Verma who stood by me always to strengthen and comfort me throughout the journey. Thank you my dear for being there to support and backup.

TABLE OF CONTENTS

ACK	NOWLEDGEMENT	ii	
LIST	OF TABLES	vi	
LIST	LIST OF FIGURES		
LIST	OF ABBREVIATIONS	viii	
ABS	ТРАК	ix	
ABS	TRACT	xi	
СНА	PTER 1: INTRODUCTION	1	
1.1	Background	1	
1.2	Rationale of the Study	4	
1.3	Research Objectives	5	
1.4	Thesis Overview	6	
СНА	CHAPTER 2: LITERATURE REVIEW		
2.1	Quality Use of Medicine (QUM)	7	
2.2	Markers of QUM	7	
2.3	World Scenario on the Use of Medicines	8	
2.4	Concept of QUM and drug wastage	9	
2.5	Impact of irresponsible use of medicines and drug expenditure	10	
2.6	Medication use and wastage in developed and developing countries	13	
2.7	Healthcare system and financing in Malaysia	14	
2.8	Healthcare system and financing in Universiti Sains Malaysia	15	
CHA	CHAPTER 3: RESEARCH METHODOLOGY		
3.1	Research methods	18	
	3.1.1 Research layout	18	

	3.1.2	Ethical consideration	18
3.2	Metho	dology - Phase I	19
	3.2.1	Study design	19
	3.2.2	Study instrument	19
		3.2.2(a) Questionnaire	19
		3.2.2(b) Pilot study	20
	3.2.3	Study setting	21
	3.2.4	Sample size	21
	3.2.5	Sampling technique	23
	3.2.6	Data collection	24
	3.2.7	Data management	24
		3.2.7(a) Data entry and data cleaning	24
		3.2.7(b) Data analysis	25
3.3	Metho	dology - Phase II	26
	3.3.1	Study design	26
	3.3.2	Study instrument	26
		3.3.2(a) Questionnaire	26
		3.3.2(b) Pilot study	27
	3.3.3	Study setting	27
	3.3.4	Sample size	28
	3.3.5	Sampling technique	29
	3.3.6	Data collection	29
	3.3.7	Data management	31
		3.3.7(a) Data entry and data cleaning	31
		3.3.7(b) Data analysis	31

CHAPTER 4: RESULT AND DISCUSSION - PHASE I				
4.1	Demographics and descriptive analysis	32		
4.2	Awareness of use of medicine	34		
4.3	Perceptions towards medicine labelling	34		
4.4	Assessment of mediciation compliance	35		
4.5	Association between awareness of use of medicines and demographics	36		
4.6	Association between perception towards medicine labelling and	37		
	demographics			
4.7	Discussion	39		
CHAPTER 5: RESULT AND DISCUSSION - PHASE II		44		
5.1	Demographics and descriptive analysis	44		
5.2	Descriptive results: Health services and medicine use	45		
5.3	Descriptive results: Storage of medicine	48		
5.4	Extent of medication wastage and costs (According to therapeutic	50		
	class)			
5.5	Discussion	52		
СНАР	PTER 6: CONCLUSIONS AND RECOMMENDATIONS	55		
6.1	Conclusions	55		
6.2	Recommendations	56		
6.3	Future direction	56		
REFERENCES				
APPENDICES				

LIST OF TABLES

		Page
Table 4.1	Demographics and descriptive characteristics	33
Table 4.2	Awareness of use of medicine	34
Table 4.3	Perceptions towards medicine labelling	35
Table 4.4	Assessment of medication compliance	35
Table 4.5	Association between awareness towards use of medicines and	37
	demographics	
Table 4.6	Association between perception towards medicine labelling and	38
	demographics	
Table 5.1	Demographic characteristics	45
Table 5.2	Descriptive results: Health services and medicine use	46
Table 5.3	Descriptive results: Storage of medicine	49
Table 5.4	Extent of medication wastage and costs (According to	50
	therapeutic class)	

LIST OF FIGURES

		Page
Figure 2.1	Data on avoidable costs and range of variation in between high,	11
	middle and low income countries	
Figure 2.2	Total healthcare expenditure of Malaysia (2006-2014)	15
Figure 5.1	Medications found at respondents' residence	51

LIST OF ABBREVIATIONS

Quality Use of Medicine QUM Rational Use of Medicine **RUM** Universiti Sains Malaysia **USM** Ringgit Malaysia RM Over The Counter OTC World Health Organisation WHO Organisation for Economic Co-operation and Development **OECD** World Bank WB United States Dollar **USD** National Survey on Use of Medicine **NSUM** Design Effect **DEFF** Statistical Package for Social Sciences **SPSS**

PENILAIAN POLA, PRAKTIS DAN PEMBAZIRAN UBATAN DALAM KALANGAN MAHASISWA UNIVERSITI SAINS MALAYSIA

ABSTRAK

Ubat-ubatan sangat berfaedah apabila digunakan secara bertanggungjawab tetapi kegunaan negatif boleh menyebabkan kebimbangan. Amalan tidak rasional ini sering dikaitkan dengan risiko kesihatan dan beban ekonomi. Peningkatan kos ubat juga dikaitkan dengan faktor-faktor seperti penggunaan ubatan yang tidak rasional dan aspek tingkah laku pengguna yang membawa kepada pembaziran. Kebanyakan pembaziran ubatan adalah disebabkan pengguna tidak mematuhi pengambilan ubatubatan seperti yang ditetapkan oleh doktor mereka. Di Malaysia seperti yang dilaporkan oleh Kajian Kebangsaan Penggunaan Perubatan (2012 dan 2015), lebih daripada separuh penduduk tidak memahami penggunaan ubat yang sesuai di mana sebahagian besar mereka adalah terdiri dari golongan muda dan pelajar. Penggunaan ubat-ubatan yang tidak bertanggungjawab adalah beban utama dalam sistem penjagaan kesihatan fiskal di Universiti Sains Malaysia (USM). Oleh itu, kajian ini dirancang bertujuan untuk menilai corak, amalan dan pembaziran penggunaan ubatubatan dalam kalangan mahasiswa. Kajian ini dibahagikan kepada Fasa I dan Fasa II. Kedua-dua fasa menggunakan reka bentuk kajian rentas keratan deskriptif. Penyelidikan bermula dengan Fasa I di mana responden didekati dengan mudah di tempat awam. Kajian ini berakhir dengan Tahap II, dimana responden yang berpotensi dipilih (pelajar yang menjalani rawatan atau menggunakan produk farmaseutikal dan / atau bersetuju untuk mengambil bahagian) telah didekati untuk proses semakan temuduga dan kajian semula perubatan di kediaman mereka (asrama universiti). Saiz sampel yang dikira untuk fasa I masing-masing adalah 925 dan 272

untuk fasa II. Data telah diurus dan dianalisis menggunakan perisian Pakej Statistik Untuk Sains Sosial (SPSS®) versi Windows® 22. Ujian statistik yang bersesuaian mengikut sifat data digunakan bagi tujuan ini. Dari segi penggunaan ubat, 41.2% (n=381) mengamalkan kaedah swa-pengubatan dan 74.3% (n=687) mempunyai maklumat terhad mengenai penggunaan ubat. Kumpulan etnik dikaitkan dengan keupayaan responden untuk membezakan bahan aktif dan nama jenama ubat, penggunaan ubat, kesedaran tentang kesan sampingan, dan pengetahuan mengenai penyimpanan ubat (p<0.05). Kawan, keluarga, dan jiran (90.2%) diikuti oleh Internet (83.0%) dilihat sebagai sumber utama maklumat berkaitan ubat-ubatan. Majoriti responden 72.6% (n=672) melaporkan bahawa mereka memerlukan kaunseling tambahan daripada ahli farmasi dan 74.7% (n=691) memerlukan maklumat berkaitan perubatan yang tertulis. Dalam fasa II kajian, lebih separuh daripada responden (54.0%, n=202) melaporkan maklumat malinformasi dari dispenser, sedangkan 47.6% (n=178) tidak menyedari tentang langkah berjaga-jaga untuk mencegah interaksi dadah. Majoriti responden tidak mematuhi terapi (64.9%; n=280). Sebaliknya, 58.8% (n=220) ubat yang diulang atau digunakan semula dan preskripsi lama (74.6%; n=278). Mereka juga menyimpan ubat-ubatan kiri untuk kegunaan masa depan (46%; n=172) atau melemparkan dalam tong sampah (42.5%; n=159). Sejumlah 5516 dos ubat didapati terbuang yang termasuk 5273 tidak luput dan 243 ubat tamat tempoh bernilai RM1318.18 seperti yang dikenakan kepada pusat kesihatan USM. Penemuan kajian ini menunjukkan bahawa terdapat keperluan untuk mendidik dan mewujudkan kesedaran di kalangan pelajar untuk mempromosikan amalan penggunaan ubat yang berkualiti dan bertanggungjawab.

ASSESSMENT OF PATTERN, PRACTICE AND WASTAGE OF MEDICINE-USE AMONG UNDERGRADUATE STUDENTS OF

UNIVERSITI SAINS MALAYSIA

ABSTRACT

Medicines are boon when used responsibly but irresponsible uses are cause for concern. Another health risk is associated with inappropriate drug use. This irrational practice often associated with risk on health and economic burden. The increase in the cost of drugs is also linked to factors such as irrational drug use and consumer behavioural aspects that lead to wastage. Majority of drug wastage is due to sub-consumption of medicine when consumers do not finish the medications prescribed by their doctors. In Malaysia as reported by National Survey on Use of Medicine (2012 and 2015), more than half of the population does not understand the proper use of medicine where a large proportion is young and studying. Irresponsible use of medicine and medication wastage is the major burden on the fiscally restrained health care system at Universiti Sains Malaysia (USM). Thus, a study was designed intended to assess pattern, practice and wastage of medicine use among undergraduate students. This research was divided into Phase I and Phase II. Both phases employed a descriptive cross-sectional study design. Research starts with Phase I where respondents were approached conveniently at places of public interest. The study ended with Phase II, where selected potential respondents (students undergoing treatment or using a pharmaceutical product(s) and/or agreed to participate) were approached for personal interview and medicine review process at their residences (university hostels). The calculated sample size for phase I was 925 and 272 for phase II respectively. Data were managed and analysed using Statistical

Package for Social Sciences (SPSS®) software for Windows® version 22 using appropriate statistical test as per nature of data. In terms of medication usage, 41.2% (n=381) preferred self-medication and 74.3% (n=687) had limited information about medicine use. Ethnicity was significantly associated with the ability of respondents to differentiate active ingredients and brand names of a medicine, medicine use, awareness of side effects, and knowledge about medicine storage (p < 0.05). Friends, family, and neighbours (90.2%) followed by the Internet (83.0%) were seen as major sources of medicine-related information. Majority (72.6%; n=672) respondents had reported that they need additional counselling from pharmacists and 74.7% (n=691) needed written medicine-related information. In phase II the study, over half of the respondents (54.0%, n=202) reported malinformation from the dispensing officer/pharmacist, whereas 47.6% (n=178) were unaware of precautions to prevent drug interactions. Majority of the respondents were non-compliant to therapies (64.9%; n=280). On other hand, 58.8% (n=220) repeated or reused medication and old prescription (74.6%; n=278). They also stored left over medicines for future use (46%; n=172) or threw in dustbin (42.5%; n=159). A total of 5516 doses of medicines were found wasted which included 5273 non-expired and 243 expired medicines total worth of RM1318.18 as per costing to USM health centre. The findings of the present study highlighted important issues lying among the students related to quality and responsible use of medicine. Based on the findings it's suggested that there is a need to educate and create awareness among students to promote the practice of quality and responsible use of medicine. Substantial quantities of prescribed medicines with potential to cause harm or be misused were present. The management of these unused medicines, and in particular controlled drugs, is currently inadequate and further work is required.

CHAPTER 1: INTRODUCTION

1.1 Background

Along with introduction of new ailments, researchers have introduced answers to them in form of medicines. If we look back towards last two decades, we can see many folds change in development of healthcare. Healthcare system came into existence to provide proper healthcare facilities to all. Around the globe we can see, each country is having their healthcare system. Quality Use of Medicine (QUM) is one of central objective of developed countries like Australia and been adopted my Malaysia too (Pharmaceutical Service Division, 2013). There are countries, which provide healthcare facilities to public and cost borne by the state.

The concept of QUM was first embarked in National Medicines Policy of Australia in the year 1999 and defined it as "selecting management options wisely, choosing a suitable medicine if a medicine is considered necessary and using the medicine safely and effectively" (Commonwealth Department of Health and Ageing, 2002). Rational use of medicine (RUM) as: "Patients receive medication appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and the lowest cost to them and their community" (World Health Organization, 2001).

The increase in the diverse and huge use of pharmaceuticals worldwide often leads to inappropriate use. It had been reported that, globally more than 50% of all medicines were prescribed, dispensed or sold inappropriately, while 50% of patients

1

fail to take them correctly (World Health Organization, 2002). Irrational drug use was a major public health problem worldwide, with extensive economic implications (Ambwani and Mathur, 2006).

The major health risk associated with the behaviour of inappropriate or irrational pharmaceutical drugs use by consumers was drug induced illness which could have been avoided by better patient care. The mechanisms that lead to drug induced illness were errors in dispensing or administration of drugs or poor compliance by the patient resulting in under use, over use, misuse or complete cessation of the therapy that render patient complete cure (Avorn, 2008). Besides, self-medication practices that can lead to occurrence of adverse drug reactions, including drugs interactions or even accidental drug poisoning. Another health risk which was associated with inappropriate drug use, was the occurrence of increasing microbial resistance to anti-microbial medicines, contributing to higher morbidity and mortality a problem wide spread in the world (Khor, 2005).

This irrational practice often associated with risk on health and economic burden to government since increase in the number of drugs available had incredible complicated the choice of appropriate drug for particular indication (Dong et al., 1999, Lee, 1991). The increase in the cost of drugs was often linked to factors such as higher medical service utilization rates, irrational drug use as well as consumer behavioural aspects that lead to wastage. Thus, improving drug use would have important financial and public health benefits by reducing the cost of treatment and medication (Tepper and Lied, 2004, Morgan, 2002, Fairman, 2000).

Majority of drug wastage was due to sub-consumption of medicine when consumers do not finish the medications prescribed by their doctors (Ali and Ibrahim, 2009, Ruhoy and Daughton, 2008). Many reasons for wasted medications like perception by subjects that a medical condition had resolved or that a medication was ineffective (Morgan, 2001). This behaviour can lead to delay in treatment, disease progression, treatment of ensuing complications, and include exacerbation or prolongation of illness, uncontrolled chronic disease, hospitalization, disability, and death (Ambwani and Mathur, 2006, Anonymous, 1991, Sorensen et al., 2005), besides, the increase in the cost of treatment. Moreover, it can lead to drug expiration and if the drug was reused again by patient without awareness of its expiration date, this can result in accidental drug poisoning or even death (Abramowicz, 2002). In addition, wasted medicines if not handled properly during disposal they will affect the environment and medications that go to a landfill may leach to the groundwater system (Siler et al., 2008, Division of Quality Assurance, 2016).

Irresponsible use of medicine and drug wastage poses a significant health problem. It endangers human life and health, results in the non-optimal utilization of resources and causes considerable loss of money (Abou-Auda, 2003). This study contributes to identify the factors that affect medicines use including drug wastage at Universiti Sains Malaysia (USM) main campus and to examine the behaviours of the students (i.e. consumers) that contribute to such wastage. The outcomes of this study can act as guide to policy makers for promoting responsible use of medicines.

1.2 Rationale of the study

Irresponsible use of medicine and medication wastage was major burden on the fiscally restrained health care system in USM and still there as evidenced by the increase in budget every year exponantially. Thus, appropriate medication use and prescription was needed to decrease costs attributable to such waste. The wide availability and accessibility of medications and their prescription in all USM related clinics may contribute to increased risk of drug wastage.

The USM Health Centre and its panel clinics provide out-patient treatment to over 20,000 students, staff and dependents. These health facilities were manpowered by local doctors, paramedics, administrative and relevant staff. Services provided include out-patient treatment and dental care at the USM Health Centre. In addition, this centre refers serious cases like surgery, eye problems, antenatal and maternity care to Penang General Hospital or other speciality hospital. Recurrent costs were funded primarily by payments from student's fees for services, including medicines. The students have unlimited access to treatment at the outpatient department. The pharmacies at the Health Centre and panel clinics dispensed all types of medications at adequate rate to patient seeked treatment at those clinics. This places a heavy financial burden on the USM health system with annual increase of students' intake. Thus, the prevalence of drug misuse and wastage if not contained will further aggravate the financial situation to the health system (World Health Organization, 2006). In literature review it was reported by majority that students stored medications in their room, practiced self medication and were also non-adherent to therapy (Saeed et al., 2014, Patil et al., 2014, Lv et al., 2014, Kumar et al., 2013,

Loknath et al., 2012, Correa da Silva et al., 2012, Ali et al., 2010). Cognizant of the fact, this study was conducted in 2015-16. The study involved a cross-sectional survey of USM undergraduate students' community aimed at the aspects of medicines use including assessment of extent of medication wastage by students, identifying the types of unused medicines and examine students' behaviours that leads to this wastage.

The findings of this study will help policy makers of Universiti Sains Malaysia to formulate necessary strategies to enhance the implementation of Quality Use of Medicine.

1.3 Research objectives

Like other countries, in Malaysia public hospital and primary health care clinic serve as the main entry point for most of the out patients. This service in USM is provided by USM Health Centre and linked Panel Clinics to its students and staffs. There was lack of published studies on the issues of inappropriate use of medicines leading to wastage in Malaysia from the perspective of both quality use and usage practice. Hence, the study objectives were as follows:

- To assess current pattern, practice and awareness of medicines-use among undergraduate students of USM.
- 2. To identify the healthcare services usage, medication storage and cost of wastage of prescribed therapies among undergraduate students of USM.

1.4 Thesis overview

This thesis is organized in the following sequence to address the study objectives:

- Chapter 2 presents literature review commence with overview on the QUM followed by literature reporting knowledge, perception, awareness, usage pattern of medication among students, wastage of medication involved and its costing reported.
- 2. Chapter 3 describes the research methodology employed. This chapter starts with layout of research and further explains the methodology in phase I and phase II of the study.
- **3.** Chapter 4 reports the results of phase I of the study and proceeds with its discussion.
- **4.** Chapter 5 reports the results of phase II of the study and proceeds with its discussion.
- **5.** Chapter 6 concludes the major findings of this study, limitations and recommendations for future studies.

CHAPTER 2: LITERATURE REVIEW

2.1 Quality Use of Medicine (QUM)

QUM was one of the central objectives of Malaysia's National Medicines Policy (Pharmaceutical Service Division, 2013). Objective of QUM can be achieved by using the medicines responsibly. This concept was termed as "Responsible Use of Medicines" which implies that the activities, capabilities, and existing resources of health system stakeholders were aligned to ensure patients receive the right medicines at the right time, use them appropriately, and benefit from them (Aitken and Gorokhovich, 2012).

2.2 Markers of QUM

According to the definition and recommendations from literature (Department of Health. Australia), following markers could be set:

Selecting management (health/disease) options wisely: Considering the place of medicines in treating illness and maintaining health and recognising that there may be better ways than medicine to manage many disorders. E.g.: preventive measure, rehabilitation methods, lifestyle modification, complementary therapy etc.

Choosing suitable medicines if a medicine is considered necessary: The best available option is selected by taking into account the individual, clinical condition, risks and benefits, dosage, length of treatment, any co-existing condition(s), other

therapies, monitoring considerations, costs for the individual, the community and the health system as a whole.

Using medicines safely and effectively: The best possible results can be obtained by monitoring outcomes, minimising misuse, improving people's ability to solve problems related to medication, such as negative effects or managing multiple medications, improper storage, and drug wastage.

These markers of QUM apply equally to decisions about medication-use by individuals and decisions that affect the health of the population.

2.3 World Scenario on the Use of Medicines

To achieve the objectives of QUM, patients must be involved in their therapeutic plans along with the healthcare professionals (Soleymani et al., 2009). This participation helps the patients to learn more about their treatment and hence positively affect outcomes of therapy (Department of Health. Australia). Studies reported that poorly involved and informed patients lack rational towards QUM and were more prone to irrational practices (Parkes and Coper, 1997, Mohd-Tahir et al., 2015). Inline to such irrational use, self-medication was rated as one major issue and was frequently reported around the globe (Norris, 2007, Ellis and Mullan, 2009, Kumar et al., 2013). Although self-medication was considered safe when practiced professionally, however lack of such qualified information can cause serious effects (Bennadi, 2013). Medicine-related knowledge influences medication-taking behaviour whereby low-level leads to inappropriate use of medicine (Hsiao et al.,

2006). Additionally, risk of making a wrong diagnosis, inappropriate medicine use and adverse effects are other disadvantages of self-medication (Patil et al., 2014).

The youth was particularly affected where 86.6% of males practiced self-medication which was increasingly higher when compared to a study in the same region (Saeed et al., 2014). Furthermore, a survey of 19 European countries reported young age, higher education and presence of a chronic disease to be associated with higher rates of self-medication (Grigoryan et al., 2006). Additionally, among medical students in Coastal South India, the prevalence of self-medication was 78.6% (Kumar et al., 2013).

2.4 Concept of QUM and drug wastage

Drug wastage was defined as "any drug product, either prescription or non-prescription (OTC), which was never fully consumed" (Abou-Auda, 2003). This definition explicitly pertains to partially or totally unused drugs as well as expired medicines. As noted earlier, the definition on the QUM implicitly infers that doctors should prescribe the right drug, the correct dose at an affordable price with clear information and instructions about the drug to the patient or his/her guardian. Thus, by default, this implies that the irresponsible use involves the prescription of medications in a way that is not compliant with the responsible mode.

2.5 Impact of irresponsible use of medicines and drug expenditure

Irresponsible & irrational use of drugs can relate to poor or negative health outcomes, increase adverse events and health costs among healthcare consumers around the world (Hardon, 1987, Homedes and Ugalde, 1993, Del Rio et al., 1997, Grand et al., 1999, Hardon et al., 2004). Several countries across the globe (both the developing and developed) are affected by drug wastage that emerges as the result of availability of greater quantities and varieties of pharmaceuticals in these countries followed by irrational use. It was reported that the pharmaceuticals market all over the world expanding rapidly. Global drug expenditure in 1985 was estimated at US\$100 billion, having doubled over the previous decade; by 1992 the world market was estimated at US\$226 billion or about US\$40 per capita, and it was estimated US\$400 billion in 2002 or US\$60 per capita (Homedes and Ugalde, 2001).

Inappropriate and irrational use of medication leads to the medication wastage. Global modelling analysis of the avoidable cost opportunity based on best available data (WHO, WB, OECD, IMS Health) from 186 different countries focused on 6 levers (Aitken and Valkova, 2013): Patient non-adherence; Untimely medicine use; Antibiotic misuse and overuse; Medication errors; Suboptimal generic use; Mismanaged poly-pharmacy.

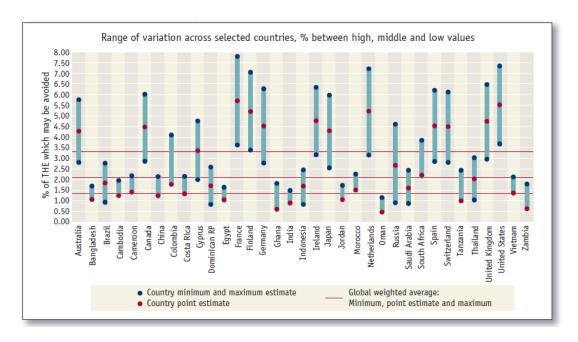


Figure 2.1 Data on avoidable costs and range of variation in between high, middle and low income countries (Malaysian data is not available here). (Adopted from (Aitken and Valkova, 2013))

In US, the annual prescription drug expenditure growth rate was 19.7% in 1999, 18.3% in 2000, 17.8% in 2001 and 16.9% in 2002 and it rise to approximately 19% in 2003. In fact, the US\$154.5 billion retail drug expenditure in 2001 exceeded US\$ 300 billion in 2005 (Covington, 2003). It is clear from these figures that prescription drug expenditure double in every 48 to 54 months and this trend is projected to continue (Tepper and Lied, 2004). Moreover, other related data show that for the 1985-2001 periods, Medicaid fiscal expenditures for prescribed drugs increased from US\$2.3 to US\$24.7 billion, approximately a 10 fold increase (Tepper and Lied, 2004). California Board of Pharmacy in United States for instance had reported that half of the prescriptions taken each year were used inappropriately and 96% of patients nationwide fail to ask questions about how to use their medications (Hempel, 2004). IMS Institute for Healthcare Informatics reported avoidable U.S.

healthcare costs add up to \$213 billion in annual budget. The \$200 Billion cost can be avoided by using medicines more responsibly (Aitken and Valkova, 2013). In UK, total expenditure on drugs in 2002 was US\$6.8 billion, with drug wastage accounting for loss as amounting for approximately US\$37.6 million yearly (Jesson et al., 2005). A report by the Department of Health, UK estimates that unused prescription medicines cost the NHS around £300 million every year, with an estimated £110 million worth of medicine returned to pharmacies, £90 million worth of unused prescriptions being stored in homes (Medicine Waste UK, 2016). In Canada, medication use and its costs have increased over the last few years. In 1995, spending on pharmaceuticals reached US\$9.1 billion while from 1992 to 1995 the number of prescriptions increased by 19 million. As the average age of the population increases, the number of prescription per patient will also inevitably increase (Boivin, 1997).

Twenty-five to sixty-five percent of total health expenditure was spent on pharmaceuticals in developing countries although government health budgets were insufficient to purchase enough medicines and poor people often cannot afford to buy them on their own. For instance, drug expenditure in Thailand account for 30% of total health expenditure (Pongcharoensuk et al., 2004) and in Nepal the percentage of health care expenditures that was spent on drugs accounts about 86% in urban areas and 74% in rural areas (Hotchkiss et al., 1998). Furthermore, 25% of total health expenditure was spent on drugs in South Africa and US\$1.5 billion on pharmaceuticals (Orrell and Kishuna, 1997). Irrational drug use reflected in medication wastage has been reported as one of the most important causes of

increase health care costs. Some studies describing status of such wastes is presented in following table.

2.6 Medication use and wastage in developed and developing countries

Medication use problems and wastage is a concerning issue in many developing as well as developed countries around the globe. In Saudi Arabia medication wastage was estimated to be 25.8% and 41.3% in other Gulf countries i.e. families there spent nearly USD150 million in total on medications that they never consumed (Abou-Auda, 2003). Another study from Texas reported pills worth over USD26, 000 were collected from residences. An Iranian household study found 238.5 on average where real medication wastage was estimated to be 38.8% (Zargarzadeh et al., 2005). A medicine return program was conducted in Birmingham where 3765 medicinal items were returned including 73.9% prescription-only medicines and 9.5% controlled drugs (Mackridge et al., 2007). A similar medicine return program was done in Spain where the estimated total cost of the collected drugs was €8,539.9 in which over 75% had been paid by the public health system (Coma et al., 2008). A one year cost-containment study conducted in Italy reported economic loss of 4.8% of the annual drug expenditure due to medicine waste (Fasola et al., 2008). A cross sectional survey among university students in Nigeria revealed that 66.0% of respondents stored medicines in their room, out of which 37.1% were leftover medicines. Substantial amounts of unused, prescribed medicines with potential to cause harm or for misuse were reported in community. The management of these unused medicines is currently inadequate and further work is required.

2.7 Healthcare system and financing in Malaysia

Malaysia is a tropical country situated in Southeast Asia, bordering Thailand to the north, to west is the Strait of Malacca, to east is the South China Sea, and the Island of Singapore to the south. The northern one third of the Island of Borneo is also part of the country as East Malaysia, bordering Indonesia to the south, the South China Sea to the north, and to east is the Sulu Sea and Celebes Sea (Verma et al., 2015). Malaysia consists of 13 states and a federal territory covering an area of 330,252 km². Malaysia is a developing country in Asia with multi-ethnic population projecting to 31.7 million by year 2016 (Department of Statistics Malaysia, 2016).

At present, Malaysia has a two-tier health care system consisting of the public and private sectors. The Ministry of Health is the main provider of health care services in the country (Healthcare, 2014). Health care services are also provided by other ministries in the country that includes Ministry of Higher Education, Ministry of Defense, Department of Aboriginal (Orang Asli) Affairs, Department of Social Welfare, Ministry of Home Affairs and Ministry of Housing (Jaafar et al., 2013). As of December 2015, there are 143 public hospitals, 209 private hospitals, 1061 public clinics, 1808 community clinics, and 6675 private clinics (Planning Division Health Informatics Centre, 2016).

The public health care system largely funded by the government and financed mainly from public tax revenue (Planning Division Health Informatics Centre, 2016). The private health care sector provides services on a non-subsidized, fee-for-service basis, and mainly serves for those who can afford to pay. Health care services by

private sectors are funded mainly by private health insurance, consumers' out-of-pocket payment, and non-profit institution (Jaafar et al., 2013).

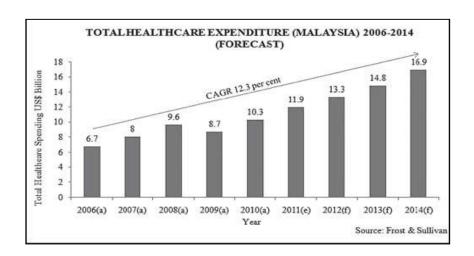


Figure 2.2 Total healthcare expenditure of Malaysia (2006-2014) (Adopted from (Frost and Sullivan, Malaysia 2014))

In Malaysia Total Health Expenditure (THE) was about RM 11 Billion in year 2000 which increased to about RM 34 Billion in year 2010 (Jaafar et al., 2013), about RM 17 Billion in 2012 (Health Informatics Centre Planning and Development Division, 2012) and to about RM 50 Billion in 2014 (Planning Division Health Informatics Centre, 2016). There can be many reasons. Low awareness level pertaining to drugs and drug use among the public is one of the reason for current crisis of medication wastage, which is one of the factors that contribute to the problem of increasing healthcare costs.

2.8 Healthcare system and financing in Universiti Sains Malaysia

The health care services in USM are primarily provided by the USM Health Centre and additionally by linked panel clinics (located at various locations outside campus) to its students and staffs. Serious cases are referred to specialized department at Penang General Hospital. In lieu of all these services, USM do not charge any extra fee. There has been a substantial increase in drug expenditure during the last few years with students counting for the largest share. If nothing is done to rectify this pattern, expenditure is expected to escalate even more as more money is spent on treatment using expensive drugs. This would eventually lead to budgetary shortfalls as expenditure outstrips income.

The availability and accessibility of medicines by all patients increases the probability of being involved in inappropriate drug use and drug wastage (Homedes and Ugalde, 2001). This is because each prescription written by doctors in all clinics that serve USM main campus community is dispensed completely and if the proper uses of these medications are not explained correctly and fully by the doctors and dispensers concerned, there will be drug misuse by consumers leading to medication wastage (World Health Organization, 2006).

Other medication wastage involved drugs that could be purchased over the counter (OTC) in the private pharmacies, although this will not affect USM health expenditure directly but can have adverse effect on students' health if not used responsibly. Furthermore this can increase patient number in USM Health Centre which indirectly affects USM drug cost. In addition, many patients could take OTC drugs prescribed for other patients as improper self-treatment (Okumura et al., 2002). Besides, the availability of OTC medicines from near-by Retail/Community Pharmacies could be a major factor that determines the incidence of acute

intoxication and drug misuse (Williams and Kokotailo, 2006). Thus, strategies to identify, resolve and prevent this problem must be adopted.

Based on these preliminary findings, a study was designed with the intent to assess pattern, practice medicine use among undergraduate student. And, to identify the healthcare services usage, medication storage and cost of wastage of prescribed therapies among them. The study was designed to help policy makers in USM to stem this irresponsible use of medicines and escalating cost. This study describes the pattern of medication usage as well as types and extent of medication wastage in USM.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Research Methods

3.1.1 Research Layout

The full research was divided into Phase I and Phase II. Both phases employed a descriptive cross-sectional study design. Research starts with Phase I where pattern and practice medicine use. Furthermore, students will be asked about their current medications or any other form of pharmaceutical product being consumed and ended with Phase II where selected potential respondents (students undergoing treatment or using pharmaceutical product(s) and/or agreed to participate) were approached for personal interview and medicine review process at their residencies (university hostels).

3.1.2 Ethical Consideration

The study was approved by Human research ethics committee (JEPeM), USM, Malaysia via approval number 1515841. Written informed consent of participation was taken. Confidentiality and anonymity was guaranteed.

3.2 Methodology - Phase I

3.2.1 Study Design

A descriptive, cross-sectional study design was employed to conduct this phase of study. In addition to the demographic information, the research tool focused on medication use pattern, access to medication, perception and awareness on use of medicine and sources of information about medication.

3.2.2 Study Instrument

3.2.2a Questionnaire

The questionnaire was adopted and modified from A National Survey on the Use of Medicines (NSUM) by Malaysian Consumers 2012 (Hassali et al., 2013, Hassali et al., 2016). The questionnaire was consisting of total 29 closed ended questions divided into 5 sections. All sections addressed demographic information, medication use pattern, access to medication, perception and awareness of use of medicine and sources of information about medication.

In the beginning of questionnaire explanatory statement of the study and informed consent was given stating purpose of the study and confidentiality of the respondents' identification data. Section 1 was about demographic characteristics of the respondents. The respondents were queried for their name (optional), age, gender, ethnic group, school and year of their study.

Section 2 of questionnaire was about respondents' access to medicine. It was concerned about respondents' action in case of experiencing health problems and where they usually obtained there medicines from.

Section 3 of questionnaire addressed respondents' perception and awareness on the use of medicines. This section was further divided into 3 parts where respondents were asked about their perceptions towards medicine labelling; awareness towards appropriate use of medicines and their medication compliance respectively in part 1, part 2 and part 3.

Section 4 of questionnaire assessed responents' sources of medicine information. Respondents were asked about their person of choice in any concern about medicines, easy source of medicine information, need of written medicine information and requirement of additional counselling from pharmacist as per their current knowledge.

Section 5 was concerned about respondents' current medication (if any) and their willingness to participate in Phase II of this study.

3.2.2b Pilot Study

The questionnaire was piloted on 30 participants. Face and content validity were established by the experts at the Discipline of Social & Administrative Pharmacy, School of Pharmaceutical Sciences, USM. For reliability assessment, the

questionnaire was considered reliable with a Cronbachs' alpha of 0.75 (Santos, 1999).

3.2.3 Study Setting

Universiti Sains Malaysia is a leading public university with its 4 campuses situated in different states of Malaysia. The study was conducted in USM main campus located in state of Penang (Universiti Sains Malaysia, 2015). Every year, USM main campus enrols about 11000 students collectively in various undergraduate courses in 14 schools with multicultural backgrounds and multi-ethnic origins from country and abroad. USM main campus had 7 hostels for accommodating undergraduate students as per information obtained from housing unit (UPPU). The study was conducted among these undergraduate students living in hostels in USM main campus.

3.2.4 Sample Size

Sample size calculations can be a source of confusion because different individuals may arrive at different recommended sample sizes, primarily because sample size calculations are based on a number of decisions and estimates. There may also be slight differences between hand calculated sample size estimates and computer-based calculations due to rounding and slight variations in sample size formulae, but these differences should be minor. In target population the total number of undergraduate students accommodated in hostels was 8920 during the data collection conducted in year 2014. The hostel and student data was obtained from the housing unit (UPPU).

Sample size was calculated by using an equation based on 95% confidence intervals, 5% margin of error and estimated design effect of 2 using following sample size equation (Gorstein et al., 2007).

$$n = \frac{z^2 p (1 - p) (DEFF)}{d^2}$$

Where,

 \mathbf{n} = Sample size.

z = Level of confidence (where z is 1.96 for 95% confidence interval)

p = Estimate of expected proportion (p = 0.5 or 50%)

d = Desired level of precision (Precision of $\pm 5\%$ be acceptable, d = 0.05)

DEFF = Estimated design effect (Here, DEFF = 2)

If the expected proportion p for an indicator is not known, usually the value of 0.5 (or 50%) is used because it produces the largest sample size (for given values of d and DEFF).

The level of absolute precision d specifies the width of the confidence interval, e.g., +0.03 (i.e., +3%), +0.05 (i.e., +5%) or +0.10 (i.e., +10%). The selection of a value for d may depend on the expected proportion and the purpose of the survey.

The sample size required for a population distributed in clusters is almost always larger than that required for surveys using simple random sampling because of the design effect (DEFF). If the prevalence or coverage of a particular indicator is similar in each cluster, the DEFF will be around one, which means the variability is the same as would have been with simple random sampling methods. The greater the clusters differ from one another, the larger the DEFF. As the DEFF increases the sample size must be increased to maintain a desired level of precision. Target population for this study were scattered in 14 schools of different fields and variable level of attitude, knowledge and perceptions. Therefore, DEFF of 2 was used to magnify the sample size to maintain desired level of precision.

The sample size calculated from the formula was 768. Additional 20% (n=157) dropout rate was added. Hence, minimum sample size needed was 925.

3.2.5 Sampling Technique

There are 7 hostels in USM main campus accommodating undergraduate students. Prior to data collection number of preliminary visits were made to the hostels and other areas of public interest to identify the potential places where targeted respondents can be approached for their participation in the study. The potential places identified were hostels, school cafes, library, hostel cafes, sports complexes etc. The criteria for inclusion of respondent was the participant should be current fulltime undergraduate student in USM main campus living in USM main campus hostel, aged 18 years and above, Malaysian citizen and can read, write and speak English and Bahasa Malaysia. Non-probability convenience sampling technique was used to approach respondents. A non-probability sampling techniques is that respondents are selected with subjective judgement of the researcher and do not need randomisation. Further, snowball technique was also employed to reach the potential respondents.

3.2.6 Data Collection

The pre-validated and piloted questionnaire was used for the data collection. Ten male and 10 female data collectors were recruited and provided required training. Data collectors did not belong to any of the respondent cluster.

Data collectors approached to the potential respondents at pre-identified places as mentioned section 3.2.5. First they explained the purpose of study, ethical consideration. Qualified respondent upon agreeing to participate in study, written informed consent was taken. Self-administered questionnaire was given to participant to answer. Once respondent was done, data collector cross checked for any missed response and completeness.

The process of data collection was continued until the required number sample size was achieved. Section 5 of the questionnaire was about any current treatment status and participant's willingness to participate in Phase II of this study. Willing participants were asked for their residential hostel address and contact number

3.2.7 Data Management

3.2.7a Data Entry and Data Cleaning

The data collected was processed using the Statistical Package for Social Sciences (SPSS®) software for Windows® version 22. Each data collection form was uniquely