An Exploratory Sequential Mixed Method Evaluation of General Practitioners, Pharmacists, Consumers and Pharmacy Students' Knowledge, Perception and Attitude on Contemporary Issues Surrounding Generic Medicine Use in Karachi, Pakistan

SHAZIA JAMSHED

Thesis submitted in the fulfillment of the requirements for the degree of Doctor of Philosophy

July 2011

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DEDICATION

My mother

Professor (Rtd.) Nuzhat Qasim

whose love, constant moral support, knowledgeable insight, and always prayerful approach towards ALLAH Subhanahu Wa-ta'ala makes this day possible

and

My Father Muhammed Qasim Sualeh and my better half Dr Jamshed Siddiqui to whom I am indebted for their broad mental horizon which nurtured confidence in me to complete this cumbersome task

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LIST OF ABBREVIATIONS

World Health Organization	WHO
Gross Domestic Product	GDP
Social Health Insurance	SHI
North West Frontier Province	NWFP
Health for All	HFA
Health Policy Task Force	HPTF
National Drug Policy	NDP
Ministry of Health	MoH
Essential Drug List	EDL
Price Recommendation Committee	PRC
Bachelor of Pharmacy	BPharm
Pakistan Pharmaceutical Manufacturer's Association	PPMA
International Non-proprietary Name	INN
Federal Drug & Administration	FDA
American Association of Retired Persons	AARP
Antiepileptic Drugs	AEDs
Reference Drug Program	RDP
General Practitioners	GPs
National Pharmaceutical Control Bureau	NPCB
Abbreviated New Drug Application	ANDA
Multisource Pharmaceuticals	MPs
Drug Product Selection	DPS
Interview Transcript Review	ITR

Medical Representatives	MRs
General Practitioners	GPs
Drug Regulatory Authority	DRA
Out Patient Departments	OPDs
Medication Therapy Management	MTM
Health Action International	HAI
United Nations Development Program	UNDP

Penilaian Menggunakan Kaedah Sekuensial Bercampur Ke Atas Pengamal Perubatan Umum, Ahli Farmasi, Konsumer dan Pelajar Farmasi Berkaitan Isu-Isu Kotemporari Sekitar Penggunaan Ubat Generik di Karachi, Pakistan

ABSTRAK

Negara membangun sedang bergelut dengan kos rawatan yang tinggi dan Pakistan juga tidak terlepas daripada isu ini. Ubat generik boleh memainkan peranan penting dalam mengurangkan kos rawatan serta perbelanjaan penjagaan kesihatan di Pakistan. Oleh itu, penting bagi memastikan pengetahuan, persepsi dan sikap pemegang taruh dalam hal ini. Kajian ini menggunakan penyelidikan kaedah-campur berjujukan yang mengaplikasikan pendekatan kualitatif dan kuantitatif. Data kualitatif dikumpul berdasarkan temu bual separa-struktur secara bersemuka dengan pengamal perubatan (*general practitioners,* GP), ahli farmasi, pengguna dan pelajar farmasi. Takat maksimum, suatu puncak yang tiada lagi maklumat baru diperoleh daripada temu bual tambahan, dicapai pada 11 bagi doktor, 11 bagi ahli farmasi, 29 bagi pengguna dan 28 bagi pelajar farmasi. Gabungan tema *a priori* dan tema daripada analisis memberikan maklumat tentang tahap pengetahuan ubat generik dalam kalangan GP, pengguna dan pelajar farmasi. Dari segi persepsi dan sikap, dengan mengabaikan pelajar, pendapat daripada pemegang taruh yang lain adalah pelbagai. Soal selidik yang diolah berdasarkan keputusan kualitatif serta carian literatur, kemudiannya diuji dan disahkan sebelum diedarkan kepada responden kecuali pengguna. Bagi pengguna. temu bual berinstrumen digunakan. Empat soal selidik yang berbeza digunakan dalam bahagian kuantitatif kajian ini. Statistik deskripsi dan statistik inferens yang sesuai dijalankan dalam setiap bahagian kajian ini. Kesignifikanan tahap *a priori* 0.05 digunakan. Soal selidik bagi GP diagihkan kepada 289 GP. Sejumlah 206 GP (71.3%) telah melengkapkan soal

selidik ini. Lebih daripada 70% (n=148; 71.8%) GP menunjukkan pemahaman yang betul bahawa ubat generik merupakan salinan daripada jenama ubat yang lain. Mereka juga menunjukkan persepsi dan sikap yang baik tentang preskribsi ubat. Lebih separuh daripada respondan sangat bersetuju bahawa wakil perubatan merupakan sumber maklumat yang baik (n=158; 76.7%) dan mempengaruhi keputusan preskribsi mereka (n=117; 56.8%). Soal selidik bagi ahli farmasi diedarkan kepada 51 ahli farmasi komuniti dan 150 ahli farmasi hospital. Sejumlah 152 (75.6%) soal selidik didapati berguna. Ahli farmasi menunjukkan persepsi dan sikap yang baik tentang ubat generik dan gantiannya. Lebih dua pertiga daripada respondan (n=117; 77.0%) menyatakan bahawa ubat generik secara teraputik sama dengan nama ubat. Lebih daripada dua pertiga respondan berpendapat bahawa ubat buatan tempatan mempunyai kesan yang sama seperti ubat berjenama (n=123; 80.9%) dan mereka lebih selesa untuk menukar nama jenama dalam preskripsi (n=138; 90.8%). Dalam bahagian ketiga kajian ini, sejumlah 300 soal selidik dijalankan secara temu bual dengan semua golongan pengguna, iaitu golongan berpendapatan tinggi, pertengahan dan rendah. Sebahagian besar pengguna tidak pernah mendengar tentang istilah ubat generik (n=207; 69%). Sebilangan kecil (kurang daripada separuh) respondan bersetuju (n=135; 44.0%) bahawa ubat generik adalah sama efektif seperti ubat berjenama. Majoriti daripada mereka bersetuju (n=254; 84.7%) bahawa preskribsi yang diberikan oleh doktor adalah yang terbaik bagi mereka. Dalam kajian di bilik darjah, sejumlah 236 soal selidik diedarkan dalam kalangan pelajar farmasi tahun akhir. Hanya separuh daripada respondan (n=118; 50.0%) menunjukkan pemahaman yang betul bahawa ubat generic mempunyai kesamaan biologi yang sama seperti ubat berjenama. Sehubungan dengan persepsi, pelajar farmasi menunjukkan keprihatinan yang tinggi

tentang ubat generik dan menganggap diri mereka sebagai seorang daripada profesional penjagaan kesihatan yang penting untuk memberi nasihat tentang ubat generic (n=233; 98.8%). Jurang atau tahap pengetahuan tentang ubat generak dikenal pasti dalam kalangan pemegang taruh. Persepsi dan sikap yang baik dikenal pasti dalam kalangan profesional penjagaan kesihatan, pelajar farmasi dan pengguna tentang penggunaan ubat generik.

An exploratory sequential mixed method evaluation of general practitioners, pharmacists, consumers and pharmacy students' knowledge, perception and attitude on contemporary issues surrounding generic medicine use in Karachi, Pakistan

ABSTRACT

Developing countries are struggling with the high cost of treatment and Pakistan is not an exception to this issue. Generic medicines could be instrumental in curtailing the cost of treatment and reduce healthcare expenditures in Pakistan. Therefore, it is imperative to ascertain the knowledge, perception and attitudes of different stakeholders in this regard. The study used a sequential mixed-method research in which the qualitative and quantitative approaches were applied. The qualitative data was collected through in-depth semi-structured, face-to-face interviews with general practitioners, pharmacists, consumers, and pharmacy students. Saturation point, a peak after which no new information was sought from additional interviews, was achieved at 11 for doctors, 11 for pharmacists, 29 for consumers and 28 for pharmacy students. A combination of *a priori* themes and emergent themes from content analysis identified gaps in knowledge of generic medicines among general practitioners, consumers, and pharmacy students. Likewise, in terms of perception and attitude, with the exception of students the opinions of all the stakeholders seem to be divided. The questionnaires which were formed on the basis of qualitative results as well as literature search were distributed and collected by hand after pretested and validated; except for consumers wherein interview-administered instrument was used. Four separate survey questionnaires were used in the quantitative part of the study. Appropriate descriptive and inferential statistics were performed in each part of the study. *A priori* significance level of 0.05 was used.

The survey questionnaire for general practitioners was distributed to 289 GPs. A total of 206 GPs (71.3%) completed the survey. More than 70% (n=148; 71.8%) of the general practitioners showed correct understanding that generic medicines are copy of the brand name medicines. General practitioners expressed good perception and attitude towards generic medicine prescribing. More than half of the respondents expressed their strong agreement that medical representative is a good source of information for them (n=158; 76.7%) and influence their prescribing decisions (n=117; 56.8%). The survey questionnaire for pharmacists was distributed to 51 community pharmacists and 150 hospital pharmacists. A total of 152 (75.6%) questionnaires were found to be usable. Pharmacists showed good perception and attitude towards generic medicine and its substitution. Two-thirds of the respondents (n=117; 77.0%) expressed their knowingness that generic medicines are therapeutically equivalent to brand name medicines. More than two-thirds of the respondents viewed that locally manufactured medicines are of same effectiveness as brand name medicines (n=123; 80.9%) and expressed their comforting attitude to change brand name in prescription (n=138; 90.8%). In the third part of the study, a total of 300 questionnaires were interview-administered to high income group, middle income group, and low income group consumers. A very large majority of consumers never heard the term generic medicines (n=207; 69%). Slightly less than half of the respondents agreed (n=135; 44.0%) that generic medicines are as effective as brand medicines. A very large majority agreed (n=254; 84.7%) that their doctor prescribes the best medicine for them. In a classroom survey, 236 questionnaires were distributed among final year pharmacy students. Only half of the respondents (n=118; 50.0%) showed correct understanding that generic medicines are bioequivalent to brand name medicines. With regard to perception, pharmacy

students showed high concern towards generic medicine and viewed themselves as one of the most important healthcare professional to give advice on generic medicines (n=233; 98.8%). Knowledge gaps were recognized among stakeholders towards generic medicines. Good perception and attitude were identified among healthcare professionals, pharmacy students and consumers towards generic medicine utilization.

CHAPTER ONE
General Introduction

1.1 Introduction

Medicines play a pivotal role in the process of human development as their rational utilization can decrease the morbidity and mortality as well as improve the quality of life (Cohen-Kohler, 2007). Healthcare expenditures become an increased burden and prices of medicines account for the majority of healthcare expenditures in developing countries (Quick, 1997). As price of medicine is one important obstacle to access of medicines (WHO, 2003), there seems to be inequitable access to medicines globally. World Health Organization (WHO) estimates that one third of the world population lacks access to essential medicines and more than 50% of the population of developing countries in Asia and Africa lacks access to basic essential medicines (WHO, 2004). In fact, access to medicines is characterized by many factors such as affordable prices, rational utilization, sustainable financing and reliable supply system but the most crucial element which restricts access to medicines is drug pricing (HAI, 2007). Therefore, to increase access to medicines, affordable price is one of the measures to counteract the global medicine gap. The issue of affordability is therefore, accordingly addressed by generic medicines, which is a cost containment strategy globally.

1.2 Definition of generic medicine

A "generic" medicine is a multisource pharmaceutical product which is meant to be interchangeable with the comparator product which is also known as proprietary, brand or innovator product (WHO, 2005). Interchangeable pharmaceutical products are considered to be therapeutically equivalent to innovator product i.e. when administered in the same dosage form and by the same route, they will produce the same desired effects exhibiting the same safety profile as innovator or brand product

(WHO, 2008b). Included in the definition of generic products are those marketed under a brand name, known as branded generics (Homedes & Ugalde, 2005). Generic medicine can also mean a product marketed under the drug's non-proprietary approved name, or it can mean a product marketed under a different brand (proprietary) name. It is, sometimes, used to mean any product from a company other than the innovator (research-based) manufacturer (Birkett, 2003). Generally, due to the cost effective nature, generic medicines offer major saving benefits in health-care expenditures (Hassali & Stewart 2004; Lofgren, 2004).

1.3 Pakistan

1.3.1 Demographics

The Islamic Republic of Pakistan has an approximate population of 158 million (DFID, 2007) with a population growth rate of 2% per annum (Khan, 2006). However, according the recent report of Ministry of Population Welfare, Islamabad, Pakistan, the population has increased five folds since last six decades and is estimated to be 171 million in mid 2009 (NPP, 2010). As far as the demographic characteristics are concerned, the population comprises of native people with rich cultural and linguistic diversity. With its four administrative provinces Sind, Punjab, Balochistan and North West Frontier Province (NWFP), recently renamed as Pakhtoon Khawa, the population is showing an uneven appearance in distribution. In the eastern provinces of Punjab and Sind there is an estimated 78.6% population while Balochistan, although being 44% of the total land area of the country, has only 5% of the population (Pakistan, 2008).

1.3.2 Healthcare system in Pakistan

The responsibility of Government of Pakistan is to give free national health care services to all strata of society including hospital care free of charge (Pakistan, 2005) The Ministry of Health is responsible in providing services, both curative as well as preventive but the recent institutional reform provides mandate to provinces for imparting healthcare services (Nishtar, 2010a).

At the primary care level, the government healthcare facilities are short of staff with poor supply of medicines. This results in patient's access to low-quality private clinics or to secondary and tertiary care facilities, which are coping up with primary care problems, and thus, further weaken the tertiary care services (Tarn *et al.*, 2008; Nishtar, 2010a). This, therefore, is reflective of compromised healthcare delivery system (Tarn *et al.*, 2008; Nishtar, 2010a).

1.3.3 Health care spending and drug expenditure

Public health expenditure is low in Pakistan; as 3.5% of the public budget is spent on health, and public health expenditure only accounts 0.7% of Gross Domestic Product (GDP). National public expenditure on health is USD 4 per capita while total expenditure on health is USD 18 per capita (ADB, 2005). The per capita drug spending in Pakistan is alarmingly low i.e. around USD 12.57 in 2008 and which is now more reduced to USD 9.84 in 2009. The private spending accounts for 86% of the total healthcare expenditure (BMI, 2010) . In terms of healthcare finances, more than 80% of the medicine expenditures are Out-of-Pocket (OOP).

1.3.4 Social health insurance

Social health insurance (SHI) schemes are considered realistic when national coverage is comparatively far-reaching, thus making it realistic for higher earners to fund lower earners. Like many developing countries, coverage under social health insurance schemes in Pakistan is drastically low, and avoidance of contribution is a problem. This is most likely because the scheme lacks the vital flexibility to cater the specific healthcare needs and diverse contributory competences of heterogeneous population groups. To be precise, SHI is still in the preliminary stage and covers only 5% of the population of Pakistan (ADB, 2005).

1.3.5 National health policy

In 1978, Pakistan decided to adopt the WHO strategy of "Health For All (HFA) by the year 2000" (Ali, 2000; Pakistan, 1997). The Government of Pakistan then declared its first plan for a National Health Policy (NHP) in January 1990 (Pakistan, 1990) which aimed to give universal health coverage in accordance with the strategy HFA 2000. In 1997 the NHP was renewed and upgraded in line with modern health standards (Pakistan, 1997). The Government of Pakistan put forward its third NHP in 2001 by accepting the need of a more detailed health policy to address health problems and improve life conditions. In 2008, Ministry of Health, has made a Health Policy Task Force (HPTF) and recently with their initiation the Ministry of Health (MoH) Government of Pakistan has stepped up efforts to articulate the NHP 2010 (Nishtar, 2010b).

1.3.6 National drug policy

In 1997 National Drug Policy (NDP) was announced but was failed to deliver quality-assured essential drugs to the people of Pakistan (Network, 1998; MOH, 1997). This is simply because of poor execution of the policy. Moreover, the interpretation of policy is generally observed for individual interest rather than public welfare (Nishtar, 2010a).

1.3.7 Pharmaceutical industry

Pakistan is a densely populated country with a notable economic progress and a rapidly evolving pharmaceutical market. The pharmaceutical industry in Pakistan is worth around USD 1.18 billion showing a yearly development of 9.4%. In a number of more than 650 registered pharmaceutical companies in Pakistan(BMI, 2010), there are about 31 multinationals enjoying over 53.3% of market share while the remaining 46.7% share is in the hands of national pharmaceutical units (IMS_Health, 2007). The pharmaceutical sector of Pakistan has strong influence on health sector and is a key generator of foreign exchange (BMI, 2011). It is foresighted that pharmaceutical sector of Pakistan has full potential to hike exports to more than USD 600 million by 2010 (Syed, 2007). Although, the market of pharmaceutical industry is expanding at the rate of 20 per cent annually, about half of the population has so far no access to modern medicines (Correspondent, 2008). At present the generic medicine market in Pakistan is 1.341 billion US dollars and this would be expected to reach new heights on account of long overdue new Essential Drug List (EDL) which will comprise of generic medicines only (BMI, 2010). Keeping in view the demand for cost effective generic medicines in the country for their quality utilization, this will strengthen through systematic plan of action.

1.4 Problem statement

In Pakistan 77% of the population has to endure out-of-pocket payment for healthcare services (WHO, 2000a; WHO, 2004). Affordability of medicines is a major issue in Pakistan, in which more than 44% of the population lives below the poverty line (Khan, 2006). In spite that the prices of medicines are fixed by the Federal Ministry of Health on the recommendation of Price Recommendation Committee (PRC), medicines enjoy a free system through which increment in prices is a common feature at regular intervals. Keeping in view the rising costs, the utilization of cost effective alternatives, which could be one of the best options in these scenarios, is notably low; i.e. the use of generics is even less than 50% (Memon, 2001). Underutilization of generic medicine and the factors affecting underutilization are neglected areas in Pakistan. Although there have been several studies from developed and developing countries addressing the factors responsible for underutilization of generic medicines, none has specifically focused in the context of Pakistan. With local pharmaceutical industry holds more than 50% of market share by volume coupled with the market of Pakistan flooded with branded generics, research into the factors affecting underutilization of generics is imperative. Moreover, government policies consider risk perceptions, and the perception of different stakeholders towards the efficacy and safety of products can affect the development and application of regulatory framework. Therefore, it was decided to conduct a cross-sectional, descriptive study by using both qualitative and quantitative research methods. Semi-structured interviews will be conducted to explore in-depth information from different stakeholders. These interviews will be analyzed to develop the items for quantitative instruments or questionnaires. These questionnaires will then be administered to different stakeholders. Moreover, to

change the established prescribing and dispensing behavior is a difficult task. The current study also attempts to interlink pharmacy students in their academic training towards generic medicine use. In order to sensitize the pharmacy students towards generic substitution and cost-effective dispensing during their academic training years this study is one such attempt and explores the understanding and perception of final year pharmacy students regarding generic medicines.

1.5 Rationale of the study

There are strong justifications for conducting this study. Increased generic drug use is an important means of controlling drug costs without compromising quality of care (Fischer & Avorn, 2004; Kohl & Shrank, 2007) and research suggests that overall drug spending could be reduced to more than 10% by using available generics (Haas *et al.*, 2005).

Several studies have been conducted globally regarding the perception and acceptance of generic drug use in health professionals. In the developing region very few studies have evaluated the views and attitudes of healthcare professionals and consumers in this regard; although generic drug utilization is found to be lower in this region (De Costa *et al.*, 2008; Naseeb & Nasser, 2005; Birkett, 2003).

In Pakistan during the fourth five-year plan a scheme of generic nomenclature i.e. Generic Name Act was launched. Inappropriate product strategies of domestic manufacturers as well as suspension of manufacturing licenses of 38 domestic manufacturers for the production of substandard drugs were observed at that time (Quraeshi *et al.*, 1983). Consequently, lack of confidence was developed for generic medicines (Quraeshi *et al.*, 1983). During the last decade World Health Organization (WHO) reported that less than 50% of the medicines are prescribed as generics in

Pakistan (WHO, 2004). In the context of present scenario of pharmaceutical market of Pakistan the total market share of domestic industry is 70-85% (by volume) and 55% (by value). In the preceding years, the patent expiry of some major innovators is going to benefit the generics-dominated domestic industry (BMI, 2010; PPMA, 2007). Therefore, it is pertinent to ascertain the knowledge, views and attitudes of healthcare professionals, pharmacy students and consumers towards generic medicine utilization. Factors preventing people from using generic medicines and making the prescribers and providers hesitant to prescribe and dispense generic medicines are unexplored arenas in the context of Pakistan. Keeping in view this background and the paucity of data, this study is aimed to explore the combination of factors affecting the utilization of generic medicines among the consumers as well as prescribing and substitution by healthcare providers.

1.6 Objectives

1.6.1 General objective

The study is aimed to develop a planned way for the quality use of generic medicines.

1.6.2 Specific objectives

In order to achieve the above aim this study was performed to

i) evaluate the knowledge, perception and attitude among general practitioners

ii) evaluate knowledge, perception and attitude among pharmacists

iii) evaluate knowledge, perception and attitude among consumers

iv) evaluate knowledge, perception and attitude among pharmacy students

1.7 Contribution of the study

Generic medicines will help to establish the relative importance of acceptance of generics in Pakistan where previously no study have addressed this issue. The evaluation of knowledge, perception and attitude of prescribers, providers and consumers will attempt to improve the understanding and views towards generic medicines among all stakeholders. The study will also help to highlight the issues hindering the use of generic medicines. This study will provide a framework within which the government would have an idea about different stakeholders understanding and perspectives on generic medicines and can bring forth educational outreach program for them, which in turn, can cause judicious use of generic medicines.

The study will sensitize the government to streamline the registration process for pharmaceuticals ensuring generic drugs must meet high-quality standards. This study will provide baseline data to the government to assist policy makers in developing appropriate strategies to promote the quality use of generic drugs, thus emphasizing the need for generic medicine policy. This study will help to construct strong alliance among provider, prescriber, and consumer who have a commitment to promote quality use of generic medicines.

In addition, exploring the understanding and views of pharmacy students about generic medicines will help pharmacy curriculum developers to include aspects on generic medicine issues in Doctor of Pharmacy (Pharm D) curriculum. This inclusion will not only support the initiation of substantial policy-related discussion but generate the importance of generic medicine utilization in pharmacy students, right before the start of their professional career.

1.8 Organization of the thesis

Chapter 2 of the thesis, the Literature review is an overview of the chronological outline of internationally conducted studies. This chapter gives a detailed analysis of the research studies evaluating the knowledge, perception and attitudes of general practitioners, pharmacists, consumers and pharmacy students towards the prescribing, dispensing and utilization of generic medicines in developed, transitional and developing economies.

Chapter 3 of the thesis, Research methodology gave a comprehensive account of both qualitative and quantitative methods used in the current research project. The chapter also highlighted the reasons to use both these methods in the current research project. In addition, to that, different sampling strategies and the issue of validity and reliability are also discussed.

Chapter 4 of the thesis, provided a description of the knowledge, perception and attitude of general practitioners towards generic medicine prescribing. This chapter included the methods, data analysis, results and discussions in a step-wise approach of qualitative method followed by quantitative method. The last part of this chapter gives a summarized view of the findings in the form of conclusion.

Chapter 5 of the thesis gave an explanation of the knowledge, perception and attitude of pharmacists towards generic medicine dispensing and generic substitution. A sequential approach of qualitative research followed by quantitative research was adopted. Each research is comprised of methods, data analysis, results and discussions. Conclusion is also included as the last part of this chapter.

Chapter 6 of the thesis provided a detailed description of the knowledge, perception and attitude of consumers towards generic medicine utilization. This section also

covered methods, data analysis, results and discussion under both qualitative and quantitative approach sequentially. Conclusion is the last section of this chapter.

Chapter 7 of the thesis evaluated the knowledge, perception, and attitude of pharmacy students towards generic medicine. This chapter highlighted both qualitative and quantitative approaches in a phase-wise manner. Both the research approaches comprised of methods, data analysis, results and discussions with conclusion as the last part of this chapter.

Chapter 8 drew an overall conclusion of the research project and highlighted recommendations as well as limitations in the study.

CHAPTER TWO
Literature Survey

The coherent framework for literature review followed a chronological development of the related studies. A literature review matrix (Garrard, 2007) was also created to assemble the information extracted from each study. The matrix is placed in the spreadsheet format in the Appendices section of thesis (Appendix 2-4).

2.1 Knowledge, perception and attitude of general practitioners

A large body of literature highlighted prescriber's knowledge, perception, attitude, practices, beliefs and opinions towards generic medicine prescribing. A thorough review of the previously published studies is compiled in the chronological order.

2.1.1 1980-1990

Bearden and Mason (1980) reported contributory factors which served as determinants to support generic drugs (Bearden & Mason, 1980). In this study the outcomes were reported as econometric models, conclusive of factors affecting physicians' prescribing decisions (Bearden & Mason, 1980).

In another study in USA more than 60% of the family physicians showed good confidence to prescribe generic medicines regularly. In spite of that only slightly more than one fourth of the respondents admitted to prescribe mostly generic drugs (Bower & Burkett, 1987). Interestingly, among those 26.9%, generic prescribing was more extensive among residency trained family physicians. They reported negligible role of drug company representatives as information providers but physicians were found to be voracious readers of New England Journal of Medicine and the Medical Letter (Bower & Burkett, 1987). The reason of linkage of extensive generic prescribing with reading of medical journals was not mentioned in the study.

In another study done in New Zealand the authors expressed uneasiness on the government proposal to allow generic substitution by pharmacists (Tilyard *et al.*, 1990). A survey of 200 general practitioners was conducted to investigate their views on the utilization of generic medications and generic substitution. One hundred and eighty-two completed questionnaires were included in the analysis. Although 67% of general practitioners admitted that they prescribe generic medicines, a large majority of them showed their disagreement towards generic substitution without doctors' consents. More than 25% of the respondents reported about generic-medicine related problems in 85 cases in their practice (Tilyard *et al.*, 1990). A few of these were related to being less safe and efficacious, which in turn, made the prescriber reluctant to prescribe with full confidence in generics.

2.1.2 1991-2000

There were only three studies published in this decade and encompassed only knowledge and attitudes of resident physicians and general practitioners towards generic medicine prescribing.

In a study done in USA knowledge and attitudes in a convenience sample of resident physicians towards generic drugs were evaluated. Three-quarters of the resident physicians believed that both generic and brand name medicines are of same efficacy. Despite that, it was noted that psychiatry residents were more inclined to prescribe brand name medicines (Shulkin *et al.*, 1992).

An attitudinal study in 39 General Practitioners in UK evaluated the attitude and behavior about generic drug prescribing and focused on five particular generic drugs and their branded counterparts (Turnbull & Parsons, 1993). Their attitudes were dependent on features of products like therapeutic category and dosage form

complexity. Diverse attitudes were reported depending on their practice characteristics. Physicians working without partners showed aversion to generic prescribing due to greater risk perception. Influence of brand loyalty and its implementation in practice were more marked among those GPs who frequently met more medical representatives as compared to their peers practicing in partnerships. The physicians with higher number of years practicing in general practice were more inclined to prescribe brand names (Turnbull & Parsons, 1993).

Another attitudinal study covering beliefs, knowledge and experiences with generic drugs and generic substitution was done in USA (Banahan & Kolassa, 1997). The overall mean score on attitudinal items indicated neutral attitudes regarding generic substitution and moderately high concerns about substitution of critical dose drugs. More than 40% of the physicians indicated strong acceptance of generic drugs and showed least concern for critical dose drugs (pro substitution group). Interestingly, in this study more than 50% of the physicians were classified as 'antisubstitution group'. The antisubstitution group perceived patients, managed care organizations, and prescription prices as pressurizing factors to allow and facilitate generic substitution. More than 60% of the physicians admitted to be ignorant about the variation in bioavailability of generic drugs allowed by Federal Drug & Administration (FDA) (Banahan & Kolassa, 1997).

2.1.3 2001-2010

A study conducted in early 2000 on 600 ambulatory general practitioners in South-Eastern France showed good willingness to prescribe generics (Paraponaris *et al.*, 2004). The response rate was found to be 55.76%. More than 75% of the general practitioners showed their inclination to write prescriptions using International Non

Proprietary Name (INN). Physicians' sources of information played a major role in decision to prescribe by INN. Moreover, different types of access to information inculcated willingness or reluctance to prescribe generics. This study also highlighted that GPs working in low-income settings have a deep insight to economic barriers with regard to the delivery of drugs and in an attempt to prevent this, they prescribe INN (Paraponaris *et al.*, 2004).

The American Association of Retired Persons (AARP) conducted web-based survey on the practicing physicians in United States (Barrett, 2005) . Electronic invitations were sent to 2,050 physicians. 425 surveys were completed. Based on these numbers, the response rate was 21%. Most of the physicians supported the use of generic substitutes, dependent on their availability and appropriateness. More than 70% of the physicians agreed to be knowledgeable about the price differences between generic and brand name drugs. Medical representatives from brand name drug companies often paid visits and give free drug samples on a weekly basis as reported by 80% of the physicians (Barrett, 2005). On the contrary representatives from the generic drug companies never visited the physicians. The physicians also denied receiving free samples from generic drug manufacturers. Most of the physicians admitted pressure by patients, insurance companies and healthcare plans in prescribing generic drugs (Barrett, 2005).

In a study conducted in Slovenia attitudes of GPs towards generic prescribing was evaluated (Kersnik & Peklar, 2006). Awareness regarding costs of prescribed drugs in the respondents found to be high and more than 75% of them admitted that escalated prices of prescribed drugs posed a major problem to sustain healthcare budget. Educational outreach to GPs inculcated generic prescribing practices in doctors. A very large number of respondents (97%) opined to welcome expert drug

consultant from insurance institute (Kersnik & Peklar, 2006). Moreover, in the study the respondents showed their willingness to use generic drugs provided they are found to be cheaper to up to 25-35% than the branded counterparts (Kersnik & Peklar, 2006).

In one of the studies in Malaysia 15 doctors employed in various government hospitals of Sarawak were interviewed (Run *et al.*, 2006). The study identified multitude of factors like the type of illness and drugs, the patient, the doctors, environment, and policies for doctors' prescribing decisions. Interestingly, the study did not highlight academic detailing as an important reason for prescribing drugs. Although in this study generic drugs were admitted as affordable, still lack of quality control and uncertain efficacy were perceived as hindering factors to prescribe generic drugs.

In-depth semi-structured qualitative interviews were conducted in 10 Australian GPs to seek their perception and attitude towards generic prescribing (Hassali *et al.*, 2006b) . Mixed attitudes were observed towards generic prescribing. Due to generic substitution policy some were wary about their personal role as prescriber and showed concern about patient confusion which may arise from substitution. All the respondents were unaware of the bioequivalence acceptability standards for generic drugs (Hassali *et al.*, 2006b) .

Generic substitution was instituted in Finland in early 2000 as a cost-containment measure. Finnish pharmacists were instructed to substitute the cheaper alternatives for prescribed medicines provided the customer or the physician did not ask to refrain from substitution (Heikkila *et al.*, 2007). Structured interviews with 25 GPs, 8 psychiatrists, 8 geriatrists, and 8 internists were conducted one year after the generic substitution introduced. Generic substitution as a good reform measure was opined

by more than 85% of the physicians while the rest considered generic substitution a failure reform (Heikkila *et al.*, 2007). More than 50% of the respondents considered beta blockers, lipid lowering agents and selective serotonin reuptake inhibitors not to be interchangeable with cheaper alternatives (Heikkila *et al.*, 2007) .

According to changes in Pharmacy Act in Jamaica in 1993 pharmacists were permitted to do generic substitution with some reservations. This was only allowed provided the physician did not mention 'no substitution' on prescription (Gossell-Williams, 2007) . In context to that a survey was conducted on 60 physicians from various specialties to explore their opinion about acceptance as well as to investigate their perception about generic drugs (Gossell-Williams, 2007) . Nearly half of the physicians indicated cost effectiveness of cheaper alternatives a major factor in prescribing generics. More than 30% of the physicians related clinical problems with generic substitutes in at least one of their patient. Good acceptance of generics was noted by responding physicians. Conclusively, physicians were willing to accept generic substitution provided their confidence in therapeutic equivalence can be built (Gossell-Williams, 2007).

In another study in US physicians cited major concerns for the efficacy and safety of generic alternatives of antiepileptic drugs (AED) (Berg *et al.*, 2008). More than 60% of the physicians revealed that a breakthrough seizure was elicited in their patients after switching from brand AED to generic AED (Berg *et al.*, 2008). Majority of the physicians (75%) showed their concern about the efficacy of generic AED. As patient's welfare is of prime importance more than 80% of the physicians were not in favor of allowing generic substitution without their consent (Berg *et al.*, 2008).

In British Columbia, Canada generic substitution policies were introduced in 1994. Drug benefit program for elderly adults 'PharmaCare' introduced a Reference Drug

Program (RDP). In RDP generic substitution is extrapolated to therapeutic substitution which means that drugs in reference drug group are considered to be interchangeable based on the equivalence of their clinical effectiveness and safety (Schneeweiss *et al.*, 2002). A telephonic interview-based study was designed to assess the opinion of GPs towards generic substitution and RDP in British Columbia. Precisely, GPs showed positive attitudes and beliefs about the economic appropriateness of generic substitution and RDP. In terms of clinical appropriateness of the programs they did not show much enthusiasm (Polinski *et al.*, 2008).

In a recently conducted study in Saudi Arabia, nearly all the physicians (n=471; 96%) showed good understanding about the therapeutic value of prescribed generic drugs (Alghasham, 2009). Majority of the respondents (88%) reported understanding of the price difference between generic and brand name drugs and most of them (75%) agreed that price difference is the determinant to switch easily to a generic prescription. Around 80% of the physicians supported generic substitution except in some certain situations where brand drugs are recommended. Interestingly, 75% of the physicians asserted that they have never been visited by pharmaceutical representatives of generic drug companies. Around half of the respondents (47%) favored generic substitution by the pharmacist only on the instruction of physicians. Around 50% of the physicians considered generic substitution a cost-containment strategy (Alghasham, 2009). Most physicians cited positive attitude towards the role of the government for checks and balances on the pharmaceutical industry as well as to persuade the physicians for generic prescribing. To be precise, this study highlighted good understanding and positive attitude of physicians towards generic prescribing (Alghasham, 2009).

In an attempt to explore the perceptions of physicians in Basrah, Iraq semi-structured qualitative interviews were conducted with 10 respondents (Sharrad *et al.*, 2009). Thematic content analysis identified multiple themes; mainly related to the factors affecting generic medicine prescribing. This study highlighted that the medicine availability in Iraqi market is a major factor in the prescribing decisions. All the physicians showed strong dissatisfaction over the plight of presence of counterfeit drugs in Iraq. Drug promotional strategies by the industries were accounted by the physicians to have a strong influence on prescribing decision. Majority of physicians were not in favor of generic substitution by the pharmacist in the absence of doctors or physicians consent and agreement. Conclusively, physicians were willing to prescribe generic medicines (Sharrad *et al.*, 2009).

In European countries generic medicine market exhibited a non-uniform pattern due to different policies (Simoens & Coster, 2006). As Greece exhibits a weak penetration of generic medicines in their pharmaceutical market a study was directed to explore to prescribing patterns of Greek physicians as well as the factors hindering and favoring their prescribing decisions (Tsiantou *et al.*, 2009). Factors as sources of information in prescribing were peer-reviewed publications, medical representatives and electronic databases. Around 75% of the physicians cited that sales representatives do not influence their prescribing decisions. Although patient complained about the drug cost, still physicians admitted that they do not interfere in their prescribing decisions. More than 70% of the respondents claimed that they seldom changed their prescribing habits except in few instances like manifestations of side effects, drug withdrawal of the market, etc. Insurance coverage and income of the patient coupled with drug cost were cited as major determinants of drug choice (Tsiantou *et al.*, 2009). Majority of the Greek physicians were in favor of

enforcement of INN system (n=725; 60.2%) as they showed positive perception towards the quality of generic medicine in Greece. Interestingly, in spite of all these facts Greek physicians did not prescribe generic medicines. Senior physicians showed higher probability of prescribing generics as compared to young ones. In a nutshell, a policy to promote generics in Greece can be a stimulus for physicians generic prescribing (Tsiantou *et al.*, 2009).

In another comparative detailed study among Greek and Cypriot physicians 'clinical effectiveness' was cited as the most important factor in their prescribing decisions (Theodorou *et al.*, 2009). Cost was cited as another highly important influential factor in more than 90% of the Greek physicians and 27% of Cypriot physicians. More than 65% of both Greek and Cypriot physician stated insurance coverage of the patients as one of the major determinants in prescribing. Although majority of the physicians from both the countries admitted quality, safety and effectiveness of generics as 'acceptable', still only Cypriot physicians generally prescribed them (Theodorou *et al.*, 2009) .

The New Malaysian National Medicine Policy recommended generic prescribing and substitution to improve the affordability of medicines. In context to that the physician is heavily burdened, and thus, a study was aimed to explore the understanding of GPs in Malaysia (Chua *et al.*, 2010). More than 85% of the GPs admitted to prescribe generics in their practice. Interestingly the respondents defective understanding of Malaysia's National Pharmaceutical Control Bureau (NPCB) regulatory limit for bioequivalence but nearly half of the GPs believed that a generic medicine is bioequivalent to brand name medicine (Chua *et al.*, 2010). More than 80% of the GPs believed that a standard guideline on brand substitution process is the need of time. Lucrative schemes in the form of product bonuses from drug companies, drug

promotion and socioeconomic factors were reported to influence the choice of prescribing (Chua *et al.*, 2010) .

2.1.4 Conclusion

In general physicians accepted generic substitution owing to policy pressure and economic scenarios but they still feel wary about the quality, reliability and 'switching phenomenon' of specific drug categories. These issues restrict the phenomenon of adoption of generic prescribing and substitution at its fullest, thus result in an increased burden on healthcare costs. In order to rectify the quality and reliability issues of generic medicines, co-operation among every stakeholder be it government, educator, professional organizations and consumer associations is of prime importance. Regulatory bodies should assure every stakeholder that generics are produced and kept according to the required standards. Professional organizations should declare their views from generic practices in their policy statements and consumer organizations must demand to be informed about the medicines they will pay for, especially in cases of OOPs.

To be precise and as evident from the cited studies, only a couple of studies have been conducted in transitional and developing economies and therefore, there is an urgent need to address the contemporary issues surrounding generic medicine prescribing in the context of Pakistan.

2.2 Knowledge, perception and attitudes of pharmacists towards generic medicine use and generic substitution

A large body of literature highlighted community and hospital pharmacist's knowledge, perception, attitude, practices, beliefs and opinions towards generic

medicine dispensing and substitution. A thorough review of the previously published studies encompassing these above variables is compiled under chronological order.

2.2.1 1980-1990

In order to reduce the burden of health expenditure from the consumer, Drug Product Selection (DPS) legislation was passed in US, which gave liberty to the pharmacist to substitute a generic drug to a brand-name written prescription (Goldberg *et al.*, 1979). Mason and Bearden conducted a study on 118 practicing pharmacists in the state of Alabama (Mason & Bearden, 1980). Majority of the pharmacists suggested that they should have the substitution rights and they considered themselves superiorly trained than physicians in drug product selection. In case of generic prescribing, which is a common modality by the physicians, most of the pharmacists perceived fewer risks for consumers. In case of generic dispensing most of the pharmacists were apprehensive about facing paramount potential for liability. Pharmacists expressed satisfaction to dispense drugs manufactured by reputable manufacturers (Mason & Bearden, 1980).

Similarly in the same period after the enactment of DPS legislation, Carroll and her associates conducted two studies in six different states of US to explore the perceived risks associated with the reluctant behavior of pharmacists towards generic substitution (Carroll *et al.*, 1986; Carroll & Wolfgang, 1991). In one of the study conducted in the state of Georgia, a random sample of 600 pharmacists was selected (Carroll *et al.*, 1986). A response rate of 69.5% was achieved. The analysis of 321 usable questionnaires highlighted the use of non-therapeutic and bioinequivalent products, concerns about quality, and time frame required to motivate the customer for substitution as most important perceived risks and generate reluctance in

pharmacist's behavior to substitute a product. Efforts on assuring the quality of generic products and their bioequivalence by sending promotional messages for comparative bioavailability data as well as building confidence in quality control steps taken by manufacturers were some of the suggested measures, which might lessen the reluctance of pharmacists to substitute generically (Carroll *et al.*, 1986). In another study Carroll and her associates mailed the questionnaire to 1,007 pharmacists in five different states of US i.e. Kentucky, New York, Mississippi, California, and Texas (Carroll & Wolfgang, 1991). With a response rate of 59%, 401 usable questionnaires were analyzed and gave the same results as the previous study done in Georgia. Precisely, pharmacist's behavioral decision to substitute seems to be governed by both expected benefits and expected risks (Carroll & Wolfgang, 1991).

In another study conducted in Ohio, factors were evaluated to explore the decision-making behavior of pharmacists in the selection of generic pharmaceuticals (Segal *et al.*, 1989). This study tried to identify the criteria that affect pharmacists' decisions to stock generic pharmaceuticals in pharmacies as well as to recommend them to patients. A random sample of 500 pharmacist-owners and managers of Ohio independent community pharmacies were invited to participate in the study. The questionnaire was developed after in depth interviews with 27-member Co-operative of Ohio Pharmacies (Segal *et al.*, 1989). The questionnaire was then mailed to all invited participants. A total of 298 usable questionnaires highlighted that more than 20% of the respondents disagreed or strongly disagreed that FDA approval is a guarantee of quality for generic products. More than 20% of the respondents considered FDA Orange Book extremely important or important as the determinant of overall quality of generic products. Promptness of shipment, consistent