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Priority Medicines Policy Issues for Qatar: Challenges and Opportunities

Nadeem Zia

A thesis submitted in partial fulfilment of the requirements for the degree of MSc Pharmaceutical Sciences (Research)



The University of Huddersfield

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Abstract

Qatar has a modern public and private healthcare system, and the state provides the majority of healthcare services free to its citizens. The aim of this study was to identify priority medicines policy issues, including the "use" and "access to medicines" in Qatar. In this qualitative study, opinions and knowledge about priority medicines policy issues in Qatar were explored. Fifty-five stakeholders in Qatar were contacted by face-to-face meetup, email, WhatsApp, and phone calls. Out of 55, 21 agreed to participate and they were from healthcare practices and academia. The recruitment method involved meeting with key stakeholders and using a snowball sampling procedure. The inclusion criteria included: (a) participants working or involved in Qatar's healthcare system for more than five years; (b) participants having experience or working knowledge of medicines policy, or different facets of medicines policy, use and access to medicines; and (c) participants well versed in the English language.

All participants were involved in semi-structured, audio-recorded interviews, which were then transcribed verbatim, coded and followed by thematic analysis to identify the common themes. The identified themes include (a) Defining Medicines Policy (b) Access to Medicines (c) Use of Medicines (d) Future Overall Health and Use of Medicines for Qatar. This study found challenges related to the availability of pharmaceuticals in Qatar, including the medicines registration process.

There is no comprehensive national medicines policy in Qatar, however, there are a number of rules, regulations, policies and procedures in place. The community pharmacy services provided are mostly "traditional" with little emphasis on pharmacists' extended roles and /or cognitive services. The study identifies several areas for improvement including extending the role of the pharmacist, improving the prescribing of antibiotics, medicines compliance and counselling for consumers, pharmacovigilance and implementation of generic medicines policies, as well as the need for a national health record database.

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After 25 years of pharmacy practice, my dream of completing an MSc has come true. My dream would not have become a reality without the guidance and enormous support of the supervisory team during our research, especially Professor Zaheer-Ud-Din Babar, Professor Mohamed Izham Mohamed Ibrahim and Dr Syed Shahzad Hassan. My supervisory team kept me motivated, mentoring me at every step, following up regularly and helping in a way that reduced stress by giving me timely advice and directions to complete the MSc thesis.

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LIST OF ABBREVIATIONS

CVD - Cardiovascular diseases

EMA – European Medicines Agency

EMEA - European Medicines Evaluation Agency

GCC - Gulf Cooperation Council

HMC - Hamad Medical Corporation

LMICs - Low-and Middle-Income Countries

MoPH - Ministry of Public Health

NCD - Non-Communicative diseases

NDS-1 - National Development Strategy 2011

NDS-2 - National Development Strategy 2018

PDCD - Pharmacy and Drug Control Department

NHS - National Health Strategy 2018-2022

QNV 2030 - Qatar National Vision 2030

SGDs - Sustainable Development Goals

WHO - World Health Organisation

CHAPTER 1

1 Introduction

As of 2020, the population of Qatar is 2.79 Million.[1] Qatar has a public and private healthcare system and provides modern healthcare services to its nationals and residents. The quality of healthcare in Qatar is very high.[2] The Qatar National Vision 2030 (QNV 2030), started in July 2008, has four pillars, including (a) economic development, (b) social development, (c) human development and (d) environmental development.[3] In 2011, the first National Development Strategy (NDS-1) was developed so that the Qatar National Vision 2030 goals could be achieved. The State of Qatar started its National Health Strategy 2018-2022 (Q-NHS 2018) in 2018 and the aim was to develop a comprehensive world-class healthcare system.[4] The vision of Q-NHS 2018 is to build the expansion of health services, and provide improvements in health and healthcare for everyone living in Qatar.[3, 5, 6] The Qatar NHS aims to achieve better health care and better value for all. The Qatar National Health Service (NHS) is led by the Ministry of Public Health, and the objective is to guide the healthcare system in Qatar.[6] The vision of Q-NHS is "Our Health Our Future" and is based on seven principles.[6]

The Q-NHS has 12 priority areas, including seven priority populations and five system-wide priorities. It is projected that Qatar will spend QAR 18.8 billion (USD5.2 billion) in 2020 on health.[5, 7] The seven principles of Qatar NHS 2018-2022 are action and empowerment, teamwork and collaboration, patient-centred care, accountability, patient safety, leadership, intelligence and empathy. The Qatar NHS population priorities are Healthy Children and Adolescents, Healthy Women Leading to Healthy Pregnancies, Healthy and Safe Employees, Mental Health and Well-being, Improved Health for People with Multiple Chronic Conditions, Health and Wellbeing for People with Special Needs and Healthy Ageing. The system-wide priorities are an Integrated Model of High-Quality Care and Service Delivery, Enhanced Health Promotion and Disease Prevention, Enhanced Health Protection, Health in All policies, and an Effective System of Governance and Leadership.[6]

There are seven Supporting Strategies and Frameworks for the Qatar NHS, including the Qatar Public Health Strategy, National Primary Health Strategy, National Diabetes Strategy, Qatar

National Dementia Plan, National E-Health and Data Management Strategy, Continuing Care Design Strategy and Qatar Health Facility Master Plan.[6]

1.1 Qatar Health and Health Problems

Qatar's population in May 2020 was 2.8 million, of which 73% are male and 27% female. Of 2.8 million people, 80% are expatriates and 20% Qatari nationals.[8] In Qatar, 11% of the population is aged between 15 and 25 years, 74% is aged between 25 and 65, and only 1% of the population is older than 65.[8] Qatar has a young population and expatriates from around the world, bringing multicultural beliefs and practices.

Wilbur et al. (2019) report that the State of Qatar provides healthcare services free of charge to all Qatar nationals.[9] The expatriates have subsidized healthcare services in the public sectors, and they only pay 20% of the cost of pharmaceuticals. Qatar is developing a healthcare system according to world-class standards to enhance the health of Qatari nationals and residents. The intentions are to enhance the health and extend the life expectancy of its population. All healthcare services are expected to be accessible and affordable to the all-inclusive population irrespective of nationality.[10, 11] Private healthcare in Qatar is through patient insurance, or otherwise, patients have to pay for services and products.[9, 12]

Qatar's most common diseases are Non-Communicable Diseases (NCD), including cardiovascular diseases (CVD), diabetes, cancer and chronic respiratory diseases. In Qatar, 69% of the people have cardiovascular disease, diabetes and cancer, 70% of Qatari adults are overweight, and 43.9% of the population have a low level of physical activity. Around 88% of Qatari children have dental cavities, and the estimated tobacco usage among men is 31.9% while among women, it is 1.2 %.[13-16]

In Qatar, there are 3.3 physicians for every 1,000 people. The ratio of healthcare providers is 7.5 for nurses, 0.6 for dentists, 1 for pharmacists and 3.5 for the other healthcare providers.[17] There are 1.3 hospital beds per 1,000 population. As of 2018, there were 327 private pharmacies in Qatar.[17] The most common cause of mortality in Qatar is cardiovascular diseases, including hypertension, diabetes and cholesterol, which accounted for 33.1% deaths during 2018,[18] while 16.6% of deaths were due to road accidents, falls, drowning, exposure to smoke, fire and

flames, and toxic substances, self-harm and assault. The third cause of mortality is neoplasms, which is responsible for 15.1% of deaths. The fourth reason is respiratory system diseases, and these are responsible for 11% of total deaths in Qatar.[18]

Diseases	Percentage of population	Mortality cases	Percentage of population	Healthcare Providers	For every 1,000 people
Cardiovascular, 69% diabetes, cancer		Cardiovascular Hypertension Diabetes cholesterol	33.1%	Physicians	3.3
Qatar adults overweight	70%	Road accidents, falls, drowning, Fire, toxic substances, Self-harm, assault	16.6%	Nurses	7.5
Low level of physical activity	43.9%	Neoplasms	15.1%	Pharmacists	1
Qatari children's dental cavities	88%	Respiratory system disease	11%	Dentists	0.6
Tobacco usage in man	31.9%			Other's healthcare	3.5
Tobacco usage in women	1.2%				

Table 1. Qatar morbidity and mortality status and health workforce

1.2 Qatar's National Medicines Policy

The State of Qatar has a National Health Strategy 2018-2022, which focuses on twelve priority areas and seven Support Strategies and Frameworks. The Support Strategies and Frameworks include the Qatar Public Health Strategy 2017-2022 and National Primary Health Strategy. The goal is to develop a comprehensive world-class healthcare system. [4] The MoPH is leading NHS 2018-2022, and the NHS is an all-encompassing vision for Qatar's health sector. In 2011, the State of Qatar launched its first edition of a National Health Strategy (NHS 2011), summarizing a comprehensive programme. The NHS 2011 was started to reform advanced patient-centred health services in all hospitals and clinics under the umbrella of Qatar National Vision 2030. [19]

Qatar's National Medicines Policy

The National Medicines Policy of a country provides guidance regarding the quality, safety, effectiveness, access and use of medicines.[20] There is a need for a generic medicines policy and guidelines in Qatar.[21] The government is supporting the use of generic medicines,[22] but it seems that Qatar does not have an official document named Qatar's national medicines policy. However, there is a set of regulations, policies and strategies related to medicines. These documents govern the use of and access to medicines in Qatar.[23]

The Pharmacy and Drug Control Department (PDCD) of MoPH recommends the medicines policy, developing pharmaceutical care, authorizing laws and regulations, governing the pharmacy profession, and registering medicines, pharmaceutical companies and factories in Qatar. The PDCD has four departments and sections, which are (1) Registration and Drug Pricing, (2) Quality of Medicines Laboratories, (3) Inspection and Narcotics and (4) Pharmacist Release. [24, 25] The PDCD abides by the laws and regulations of the Ministry of Foreign Affairs in Qatar for narcotic and psychotropic substances. Law No. 9 of 1987 is on the Control and Regulation of Narcotic Drugs and Dangerous Psychotropic Substances (NDDPS), while medicines pricing is governed by Law No. 1 of 1999 Amending Certain Provisions of Law No. 7 of 1990, Regulating and Controlling the Pricing of Medicines and Pharmaceuticals 1 / 1999. [26-28]

1.3 Pharmaceuticals and Pharmacy Systems

The pharmaceutical sector and public healthcare are governed by MoPH, including public and private pharmacies and medication warehouses.[9] In 2019, Qatar spent QAR 2.4 billion (USA 657 million) on medicines.[29] It is estimated that the prescription drug market will increase in the future due to demand for access to healthcare and increases in non-communicable diseases.[29] Qatar has public and private pharmacy systems. The Ministry of Public Health (MoPH) is responsible for Hamad Medical Corporation (HMC) pharmacies in hospitals. In the private sector, most hospitals and clinics have their own pharmacies, and there are companies with their own chain pharmacies and independent pharmacies. As of Sept 2017, there were 1.8 pharmacies per 10,000 population.[30]

1.4 Import of Medicines

The State of Qatar's pharmaceuticals sector is very much dependent on the import of pharmaceutical products. The pharmaceutical expenditure projection was estimated to be at USD 657 million in 2019 and USD 696 million in 2020. The Ministry of Public Health (MoPH) is willing to eliminate government controls over medicines pricing and to allow more imported medicines into Qatar.[10] Medicines are imported from many international pharmaceutical companies, for example, Roche, MSD, GSK, Novartis, Sanofi and AstraZeneca.[11] Although there is no government policy on the bioequivalence of generic medicines,[31] the government is promoting the use of these. Qatar Pharma is the leading local manufacturer in the country.[32] The Gulf Cooperation Council (GCC) states formed a Gulf Centralised Committee for Drug Registration (GCC-DR) to improve imports of and access to medicines in May 1999. The GCC-DR consists of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates and Yemen.[33, 34] After the Qatar blockade in 2017, most importers of medicines followed a procurement process without GCC-DR. In the State of Qatar, the highest drug authority is the Pharmacy & Drug Control Department (PDCD). Under the Ministry of Public Health (MOPH), the PDCD is responsible for ensuring the quality, safety and efficacy of any health product in Qatar.[35]

Local Manufacturing

Qatar Pharma began pharmaceutical production in 2009 in Qatar.[36] QLife Pharma is another domestic pharmaceutical manufacturing company which started in 2016 and is working to get US FDA approval of its drug products.[37] Other pharmaceutical companies include Qatar Al-Hayat, Q-Med; Al-Mutamayyiz Factory for pharmaceutical products, and Doha Factory for pharmaceutical products. There is a need to reduce dependence on imported pharmaceuticals [32, 38] and there are additional new local pharmaceutical manufacturers, including the Qatar Pharmaceutical Industries Company.[39]

1.4.1 Use of Medicines

The World Health Organization (WHO) recommends that the effective implementation of a medicines policy could increase the responsible use of medicines. [40] This could have a positive impact on medicines spending, patient health outcomes and medicines adherence. The use of medicines is an essential element of a country's national medicines policy. [40]

Aljayyousi et al. (2019) report the significant inappropriate antibiotic use in Qatar. [41] Eighty-two percent of the consumers were using medicines without a prescription, 45% did not complete the antibiotic course, and 23% were taking antibiotics from the pharmacy without a prescription. [41] It was observed that 85% of people in Qatar use antibiotics for upper respiratory tract infections. [41-43] Also, Jaam et al. (2018) found that patients with uncontrolled diabetes have a significantly higher medication nonadherence rate in Qatar. [44] This study concluded that there is a need to implement interventions to improve medicines adherence.

Abdulrhim et al. (2019) concluded that collaborated pharmaceutical care services and pharmacists' interventions would improve clinical outcomes in type 2 diabetes mellitus patients in Qatar.[45] The country also faces myriad challenges with regards to the use of medicines as more than 80% of the population is migrant.[46] Hence the migrant face challenges with regards to medicines access and use. This has also been seen in other countries where there is a migrant population. For example, Babar et al. (2013) have identified substantial difficulties in the use of medicines among the migrants' population in New Zealand.[47, 48]

1.4.2 Access to Medicines

Access to medicines is an essential element of pharmaceutical policy, including equitable access, availability and affordability of medicines, as well as cost-effective use of medicines. [49] Qatar's public hospitals and clinics provide free healthcare services for Qataris and subsidized healthcare and pharmaceutical services for expatriates. [9] In Qatar, multinational pharmaceutical companies have been successful in promoting more brand name consciousness for patients and physicians. This is for both prescription and over-the-counter medications.

Qatar imports medicines mainly from western countries, including Europe, UK, the USA and a small proportion from other countries. There are few challenges with regards to the registration and licensing of medicines in Qatar. This includes tender regulations, procurement processes, unpredictable consumption trends and physicians' preferences. [50] The availability of medicines is also affected by the time required to imports medicines in Qatar.

The regulatory review process of medicines involves 13 critical steps in Qatar which affect the processing time and cause delays in access.[34] The medicines registration process also impacts generic drug registration processes. On the other hand, generic manufacturers could have good business opportunities because by using generic medicines, Qatar can reduce its healthcare expenditure.[11]

The prices of medicines have been reduced by MoPH in recent years. Of 4600 registered medicines, the prices of 2873 (62.5%) have been reduced. [29] Globally it has been observed that a Generic Drug Policy (GDP) is an integral part of medicines policy, and it can be effective in reducing pharmaceutical expenditures. [51, 52]

Access to medicines can be improved by sharing information and experiences about policy implementation and procurement, including challenges. This is very valuable for countries. There is also strong evidence to use generic medicines, which can result in prices reduction, savings, and improves access overall. [53] Qatar can improve saving on the healthcare budget by learning lessons from other counties, especially GCC, and using generic medicines. An Australian study concluded that some patients did not fill prescriptions because of costs and due to high copayments. Those patients are the least adherent patients. [54] Therefore prescription costs are

linked with medicine adherence.[55] Access to medicines can also be improved with new knowledge related to pharmaceutical technologies, and electronic health records data.[56, 57]

Moreover, World Health Organisation (WHO) stated that access to essential medicines and vaccines remains to be a challenge in many countries. WHO developed a new strategy to focus on the challenges identified in providing access to safe, effective, affordable, and sustainable supplies of medicines and vaccines.[58] Medicines shortage was also identified as a major concern. There could be many reasons for medicines shortages and is prevalent globally including in Europe. A study in Europe observed that about 75% of respondents reporting weekly or daily medicine shortages.[59]. That affects the patient's access to medicines. This could also lead to adverse health outcomes, medication errors, as well as economic consequences for patients.[60]

1.5 Rationale of the Study

Medicines policy is an essential component of a country's healthcare system.[61, 62] Qatar is a country with a small population, and it has its own set of pharmaceutical-related challenges. This is in terms of both medicines use and access, as well as for a forward-looking approach. Qatar imports most of its medicines; hence there are issues related to pricing, medicines registration, as well as access and availability of medicines.[10, 63]

The rationale of this study is to identify broad medicines policy and pharmaceutical health system issues. Access to medicines is one such issue. Qatar imports most of it's medicines. As the medicines are imported, the prices are on the higher side, the taxes are added and there are also additional logistics and transportation costs. Moreover, the imported medicines registration process may take few months, which may affect access, availability, and affordability of medicines. Due to the reasons above WHO has favored the local production of medicines as it can improve the access and affordability of medicines. [64,65]

It is vital to identify priority medicines policy issues in a country so that better-informed medicine policies can be built. Several developed countries, including Australia and New Zealand, have

benefited from the development of priority medicines policies. This includes building cost-effective medicines policies. [66] Babar and Francis identified priority medicines policy issues for New Zealand, and [67] Mirza discussed the need to identify priority medicines policy issues for Saudi Arabia. [68]

Priority medicines is a terminology that is being borrowed from the 2013 WHO document. It has been further refined with Babar and Susan (2014).[67,69] This is linked to medicines policy issues identified in a country due to local disease burden and gaps in the health system.

Hence, in this context, this study has been planned to explore and get an understanding of priority medicines policy issues for Qatar. Determining and synthesizing priority medicines policy issues can provide a future direction towards medicines policy, access and use questions in the country. The study is conducted by exploring the opinion of stakeholders about priority medicines policy issues in Qatar.

Qatar National Vision 2030 (QNV2030) and National Health Strategy (Q-NHS) 2018-2022 recommends "Health for All". Moreover, this strategy also focused on better health outcomes. National medicines policies in a country also promote better health outcomes through the appropriate and responsible use of medicines. This study identifies the priority medicines policy issues that support the Q-NHS and Qatar National Vision 2030.

1.6 Objectives

The research aims to identify priority medicines policy issues for Qatar. The specific objectives are as follows:

- 1. To explore and identify key challenges affecting Qatar in terms of priority medicines policy issues, including medicines use and access.
- 2. To explore the futuristic approach in terms of overall medicines access and use in Qatar.

The study objectives are linked to medicines policy issues identified in a country due to local disease burden and gaps in the health system.[67]

CHAPTER 2

2 Literature Review

The following is a synthesis of the studies and literature on this topic.

2.1 Literature Search

A review of the literature published between January 2000 and June 2020 in the English language was performed from February 2019 to June 2020. It included studies, full-text articles, journal articles, reports and book chapters. The objective was to find all literature available on medicines policy issues, access to medicines and use published on Qatar. The keywords used were medicines policy, pharmaceutical policy, drug policy, medicines strategy, pharmaceutical strategy, drug strategy, medicines policy issues, access to medicines and use, affordability and availability, and Qatar.[70] The primary databases used were Scopus, Science Direct, Medline, PubMed and Google Scholar, book chapters were also reviewed.[52, 71, 72]

The global and local literature review cover key areas related to medicines policy, access to and use of medicines. It also covers issues related to medicines shortages, imports, pricing, licensing, medicines adherence, and counselling. This collectively feeds into identifying the gaps in medicines policy literature in the country. It also helps to frame the objectives and research question for this study, which is to "identify priority medicines policy issues". An exploratory qualitative design is used to uncover stakeholders' opinions as no formal medicines policy document is available in the country.

Synthesis of Literature Review

2.1.1 Medicines Policy

A national medicines policy is vital for the health system, as described by Almarsdóttir et al. (2019).[61] A medicines policy is a comprehensive national framework that focuses on and explains difficulties related to medicines. It provides guidelines for all the critical sectors in the pharmaceutical field, comprising both public and private sectors. The medicines policy sets goals for the government and all healthcare sectors, including the pharmaceutical sector, and pinpoints both general and the most critical strategies for those goals.[61]

Medicines policy covers medicine development, manufacturing, marketing, distribution, pricing and reimbursement, formulary management, pharmacovigilance, patient eligibility, prescribing practice and professional services, particularly pharmaceutical services. [73] Al-Essa et al. (2015) describe the foundation of any country's medicines regulation as a "national drug policy." [74] This will guarantee a sustainable pharmaceutical industry and benchmark medicines authorization process.[34, 74] Additionally, Ibrahim et al. (2017) state that in low-and middleincome countries (LMICs), there are high prices, low-quality medicines and lack of medicines access despite support from international agencies like the World Health Organization (WHO).[75] The Sustainable Development Goals (SGDs) of the World Health Organization (WHO) include four key components, including use of essential medicines, development of national standard treatment guidelines and a National Essential Medicines List (EML). A second component refers to affordability and availability, including access to essential medicines, use of unbiased available price information, allowing price competition, supporting bulk procurement, implementing generics policies, negotiating fair pricing and promoting local production of quality medicines. Another component considers sustainable financing, including a reduction in out-ofpocket expenditures, increased public funding, expansion of health insurance schemes, and exploration of external funding and financing mechanisms. [76, 77]

The medicines policy governs and manages marketing authorization, inspection and surveillance of market actors, pharmacovigilance, advertisement, provision of independent medicines information, and also deals with ensuring affordable access to medicines for patients.[78]

Norman (2015) describes three significant elements to pursuing pharmaceutical policy: effective skills, practical use of current systems to improve participation with policymakers and focusing on vital areas that improve health outcomes.[68]

A study by Newton et al. (2020) describes the need to control substandard and falsified medical products. Hence, Newton argues the need for "Effective regulatory supervision, robust authentication measures, and procurement policies supporting quality, as well as the need for trusted public engagement campaigns." [80] Additionally, Hafner et al. (2020) conclude that global public health issues like HIV and TB, and in recent times COVID-19, have emphasized the

importance of public health policies and must include plans for disease-specific programmes focusing on health outcomes and sustainable health systems. [81] Almarsdottir et al. (2019) also describe how pharmacy practice has been affected by national medicines policies, and the pharmacist has a vital role to play. [61] Pharmacists are active in healthcare; for example, they have developed pharmaceutical care services to improve pharmacy clinical services. [61, 82]

In 1998, the World Health Organization developed a document on National Medicines Policies (NMP), which was further revised in 2001. The document emphasized that governments should prioritize, develop and have an implementation plan for National Medicines Policies. [40, 83, 84] Wirtz et al. (2017) reported that by 2015, there were 95 countries who had developed a National Medicines Policy. [85] The components of a National Medicines Policy are discussed below based on findings from the literature.

2.1.1.1 Medicines supply chain and pricing

The World Health Organization has provided different stages for governments to control the pharmaceutical supply chain and recommend eight (8) methods to impact the manufacturers' prices. These are as follows: "(1) Price controls on the manufacturer; (2) Profit controls on the manufacturer; (3) Reference pricing and brand premiums; (4) Comparing pricing controls (international benchmarking); (5) Eliminating tariffs and taxes; (6) Fixed margins; (7) Digressive mark-ups; and (8) Capitation systems."[23]

Breen et al. (2020) have identified the risks for medicines supply chains, and the five most common risks are (1) fragmentation of Supply chain—no single source, multiple channels, no communication, unilateral decisions; (2) lack of visibility of stock; (3) unexpected increase in demand; (4) demand versus capacity; and (5) information flow or lack of information. [86]

2.1.1.2 Medicine prices in Qatar

In Qatar, The Ministry of Public Health (MoPH) controls medicine pricing. The Pharmacy and Drug Control Department (PDCD) negotiates with pharmaceutical companies and other stakeholders to propose medicines for reimbursement, which are then authorized by the Ministry of Finance. Qatar has applied a free-market system to manage the high prices of medicines and guarantee a

better supply chain for all registered and licensed importers. The MoPH fixes prices of medicines at private pharmacies against the council's initial price control mechanisms.[10] The public and private sectors have different purchasing and pricing processes. The public sector is publicly funded, and medicines are acquired via various channels. This is mainly by Gulf Cooperation Council (GCC) bulk procurement, agreements directly with local manufacturers, or local agents. The medicines pricing method in the public sector is not publicly available; however, prices of medicine have been found to be considerably lower in the public sector as compared to the private sector.[23]

Abdel Rida et al. (2019) concluded that pharmaceutical pricing in Qatar is primarily established on external reference pricing (ERP) and mark-up regulations.[23] Qatar may take into account the economic evaluation and therapeutic importance of medicine to set the price.[23, 87] However, in other counties, medicines pricing policies have not been successful because of inadequate administration of regulation, absence of governance, low monitoring, corruption and a lack of full compliance with the stakeholders.[88]

Vogler (2018) suggests that the policymakers should consider a range of measures when developing pricing policies, including (1) a mix of pricing policies; (2) enforcement; (3) evaluation and reviews; and (4) transparency.[78, 89] Hasan et al. (2018) argue that High-Cost Medicines (HMCs) coverage should be built on an evidence base and pharmacoeconomic analysis, with all stakeholders participating in the evaluation.[90]

2.1.2 Access to Medicines

High price medicines are a challenge for most countries. Babar et al. (2019) point out that high prices of new cancer medicines affect access to medicines, and it is also observed that the prices of the same cancer medicines in high-income countries show a big price differential.[91] Hasan et al. (2019) explain that all high-cost medications present health and economic challenges for healthcare organizations and may involve issues regarding affordability and critical decision-making for coverage and reimbursement.[92] Nowadays, healthcare software appraisal has also become a crucial health policy tool for decision-making and controlling high-cost medications. By

using these health technology assessments, patients' access to cost-effective treatment can be made feasible.[92]

2.1.2.1 Generic medicines and biosimilars in Qatar

A community pharmacy study in Qatar has found that 89% of pharmacists agreed that "Health authorities in Qatar should implement bioequivalence policies before a generic product is marketed." The majority of the respondents also agreed that "Community Pharmacists should be allowed to perform generic substitution without consulting the prescribing physician."[31] Awaisu (2014) concluded that a large percentage of community pharmacists in Qatar had basic knowledge about generic medicines; however, they do require knowledge on practical and regulatory aspects of bioequivalence and pharmacokinetics.[31] The study also showed that a training programme should be established to improve the quality and uptake of generic medicines in Qatar. Rehman et al. (2018) and Khan (2019) state that the biosimilars provide more treatment options and possible cost savings in healthcare.[93, 94, 95] The new generation of biologicals or biosimilars is also available in the global market. However, prescribing of biosimilars should be evidence-based. All the above studies conducted in Qatar showed that there is a need to establish a generic medicine policy for the country.

2.1.2.2 Community pharmacies and access to medicines in Qatar

Wilbur et al. (2019) discussed access to medicines and community pharmacies in Qatar.[9] The community pharmacy services are mostly "traditional" with no pharmacists having extended roles or cognitive services. However, community pharmacy has not developed the essential steps to be recognized as an essential source for public health and primary health care in Qatar. Ibrahim et al. (2016) report that the community pharmacists in Qatar spend little time providing counselling with an average of two to three minutes, whereas the literature suggests that the appropriate length of time for providing counselling should be longer than this. [96] In addition, Jaam et al. (2018) identified that the rate of medication nonadherence, including patients with uncontrolled diabetes, is significantly high. [44] This study emphasises that there is a need for targeted implementation strategies to increase medication adherence in high-risk patients in Qatar.

2.1.3 Use of Medicines

2.1.3.1 Use of medicines issues

Babar and Scahill (2017) point out that the use of medicines is an essential area for patients, consumers and healthcare professionals.[97] Use of medicines studies and research areas include perceptions, beliefs, knowledge and attitudes, as well as studies on medication adherence, prescribing, dispensing, concordance and compliance. Globally, antibiotic resistance is growing due to the increase in patients' stays in hospital. This means an increase in operations-related infection and a substantial increase in healthcare costs.[98] Shaikhan et al. (2018) concluded that antimicrobials are commonly overprescribed in all areas.[99] This study will assist policymakers in improving the use of antimicrobials. Alkhuzaei et al. (2015) show that the physicians and pharmacists of the Primary Health Care Corporation (PHCC) in Qatar provide satisfactory antibiotic use consultation.[100]

Babiker et al. (2014) concluded that the pharmacists in Qatar have adequate information about medicines use, though there are some areas that need further improvement.[101] El-Hajj et al. (2018) report that the pharmacists in Qatar provide primary care for diabetic patients and provide limited advanced diabetes services.[102] However, they need more training and education for better provision of these services. The common challenges in this respect are identified to be time and availability of private counselling areas.[101-103] Bain et al. (2019) describe how pharmacists could help to improve insulin ordering in hospitals by reviewing prescriptions and using decision-support resources, for example, algorithms and prescribing charts, electronic prescribing software and evidence-based guidelines, all of which would help improve patient safety.[115] Sonallah et al. (2017) suggest that medication reconciliation by pharmacists reduces medication errors, as most medication discrepancies happen on hospital admission.[105]

2.1.3.2 Challenges regarding the use of medicines

Aljayyousi et al. (2019) reports that while some study participants in Qatar thought physicians and pharmacists were giving sufficient patient education about proper antibiotic use, half of the participants stated that physicians and pharmacists did not give enough time to explain the

proper use of antibiotics.[41] Hamid and Ibrahim (2017) emphasise the need for a digitized/electronic interconnected transparent regulatory structure and pharmacovigilance (PV) programmes to improve medicines safety.[106] They argue that data could be missed when using paper-based documentation. Al-Essa et al. (2015) explain that the regulators require the pharmaceutical sector to comply with regulatory obligations before and after medicines are made available for patients and consumers. Also, in order to monitor medicines' safety and efficacy, continuous follow up with the pharmaceutical industry is needed.[107]

Qatar's healthcare reforms could improve pharmacovigilance practices with greater accountability and transparency, and through the useful implementation of policies and regulations.[106, 108] Alshammari et al. (2019) describe how the Pharmacy and Drug Control Department (PDCD) is regulating medicines and working to develop the pharmacovigilance programme in the State of Qatar.[109] There is an Adverse Drug Reaction (ADR) programme organized by the Medication Safety and Quality Center (MSQC) at the Hamad Medical Corporation (HMC).[109, 110] Abdelrahman et al.'s (2015) study also shows that the most common paediatric accidental poisoning cases reported were through the use of analgesics and antipyretics among children one to five years old.[111] This also highlights the need for a systematic and structured training programme covering the fundamental aspects of Medicines Use Review (MUR) services in Qatar.[101]

Ibrahim et al. (2016) concludes that community pharmacists provide sub-optimal medicines dispensing services, including insufficient time spent on patient counselling, providing limited knowledge about the use of medicines, and dispensing too many antidiarrheals and antimicrobials. [96] Their general practices were also found to be lower than expected. Furthermore Rouf et al. (2018) state that in Qatar, a pharmacist has only an average knowledge about the use of medicines in pregnancy, and there is a need to introduce continuous education programmes about this. [112]

Additionally, El-Hajj et al. (2014) reports that pharmaceutical care service providers identified the obstacles as lack of access to medical records, availability of time and a poor image of pharmacists in society. [113] Furthermore, Stewart et al. (2018) describe issues with Qatar's patient safety

culture.[114] This indicates that there is a need for improvement. This should be done at the organizational policy level and not focused only at the level of individual practitioners. The goal should be to improve the patient safety culture.

Aljayyousi et al. (2019) suggests that in Qatar, health educators should develop focused awareness promotions to educate the public about the proper use of antibiotics, the effects of antibiotics misuse and the difference between bacterial and viral infections.[41] Awareness should be raised and there should be a focus on changing attitudes and behaviours through various behavioural interventions. Additionally, the healthcare organizations in Qatar should offer advanced education for healthcare providers. These are the ones who have the authority to prescribe antibiotics, to improve antibiotic prescribing and to improve health professionals' communication methods. The government should emphasise the regulations and guidelines to improve prescribing and dispensing of antibiotics.[41]

2.2 Future Overall Health

In 2007, the World Health Assembly (WHA) identified that health technologies are essential instruments for preventing, diagnosing, treating, rehabilitating and agreeing on health-related development goals.[115] The WHA report said that health technologies are both a technical and financial challenge to health systems worldwide.[115] Babar et al. (2020) point out that in the pharmacy profession, researchers consider there is a need to have better emphasis on professional competency, improved leadership skills and a move towards organizational change.[52] The health system in Qatar has excelled in the last decade; however, there is a need for additional medical workers in primary health care.[116]

2.2.1 Future Access and Use of Medicines

Antibiotic resistance could be managed by identifying thresholds for all antibiotics used in the country; therefore, an antibiotic policy to decrease the thresholds for each antibiotic and to control antibiotic resistance should be mandatory. [98] This study concluded that there are issues around belief systems and about the use of antibiotics for viral infections in Qatar. Also, the inappropriate use of antibiotics increases antimicrobial resistance, increased adverse medicines

reactions and extra cost. Another study suggests that community pharmacists can play a vital role in improving knowledge, views and antibiotics practices.[117]

Diabetes is challenging Qatar's health care system due to its high burden. Therefore there is a need to reduce incidence by using surveillance and monitoring mechanisms.[118] Baines et al. (2018) argue that the pharmacy system should recognize advances in technology and develop the procedure and competencies to improve pharmacy dispensing and pharmaceutical care services.[119]

Babar and Scahill (2020) explain that in the developed world, pharmacists work under a remunerated system, which does not depend on retail sales subsidizing professional activities. [120] However, in the developing world, there are challenges due to poor government regulation and utilizing less qualified staff rather than fully trained pharmacists. The use of generic medicines policies and their implementation are inconsistent among developed and developing countries. In those countries where there is a higher rate of generic medicines use, market structure supports healthy competition producing substantial savings; thus, considerable price variation exists between generic drugs and brand-name ones.[121] Therefore, extended community pharmacy services and use of generic medicines can improve aspects related to access and use of medicines in Qatar.

2.2.2 Future Medicines and Pharmaceutical Policy Research

In future medicines and pharmaceutical policy, researchers have suggested that the vital drivers are four main areas, including population demographics, technology, pharmacy as an institution of professionals and consumers of healthcare services, and new research skills developing from technological changes.[52] Eljilany et al. (2018) show that the number of economic evaluation studies is low, and this can be improved by the inclusion of health economics expertise to assist. Similarly, if the research focus is on the quality and quantity of health outcomes, pharmacoeconomic analysis and using the health economics expertise for making policies in the GCC countries can be helpful.[122]

Nagaria et al. (2020) suggests that pharmacy practice research should investigate vital questions on the growing relationships among pharmacy, pharmaceutical and economic efficiency,

healthcare and public policy, which can be solved by managing barriers to change and developing a future model for pharmacy practice.[123] This model will help policymakers to make decisions on healthcare systems and therefore improve health outcomes.

Babar et al. (2014) argue that future pharmacy practice research should include different researchers, such as sociologists, economists and epidemiologists, so the research is broadly acknowledged and received.[124] The future of healthcare needs a link among different professional practitioners to create a joint vision, and the same applies to medicines policy and research. Babar et al. (2018) also suggests that community pharmacy researchers should study community pharmacy practice issues about patient-centric services and pharmacy business challenges.[125] Bigdeli et al. (2018) commented that healthcare policymakers should participate in future collective decision making, which would give a chance to the policymakers to utilize extensive available information on medications, health policy and systems.[126]

2.3 Summary of the Literature Review

A medicines policy is a national framework that focuses on and explains the challenges associated with medicines access and use. In the last 10 years there are a number of studies covering overall health issues in Qatar however now there is an increasing focus on medicines and pharmacy. Medicines policy covers issues related to medicines marketing, access, distribution, pricing and reimbursement, formulary management, pharmacovigilance, and prescribing. In Qatar, The Ministry of Public Health (MoPH) is responsible for many issues including medicines pricing and access. Very few original studies in Qatar are being conducted on pricing, access, and generics necessitating doing more work on the topic. The community pharmacy services include dispensing, however, there is a potential for advanced pharmacy services in the country. For this, pharmacists need advanced training and education. The challenges for pharmacists include patient counseling and remuneration. A number of studies conducted in Qatar's healthcare system also show the overall benefits of pharmacy services for patients and consumers.

There were very few studies pertaining to medicines policy in Qatar. Though individual studies cover issues including pricing, antibiotics use, health promotion, and suboptimal use of

medicines, a study covering the overarching direction of policy was lacking. It is in this context that this study was planned.

CHAPTER 3

This chapter provides an overview of the methodology used in this study. It is crucial to select the right methodology for the research. The four philosophical areas in research ontology include epistemology, axiology, and logic of inquiry. Ontology is the study of the nature of reality and it describes a researcher's views. Epistemology involves the knowledge of reality. Axiology looks into personal values. The logic of inquiry shows the research reasoning.[127] "There are also four paradigms involved including positivism, postpositivism (or realism), interpretivism (or constructivism) and pragmatism. These are relevant to pharmacy practice research." Positivism and postpositivism are used in quantitative studies, interpretivism is used in qualitative studies and pragmatism is used in mixed methods research.[127]

3 Research Methods and Qualitative Research

Qualitative research is related to the interpretative perspective, whereas quantitative research informs about the empirical perspective. The qualitative research method is mostly used in pharmacy practice research to explore a topic.[128] The qualitative research method answers "why" questions. It also emphasizes in-depth study of people's words, actions, local situations, conditions, attitudes, values, opinions and stakeholders' needs. It can provide essential healthcare facts, reasons, opinions and personal experiences of participants.[128] Qualitative research methods include interviews, observation, document analysis and netnography.[70]

While quantitative research is about numbers, qualitative research goes beyond numbers.[129] As quantitative research is built on "numbers", the research methods will not be adequate to comprehend the feelings of individuals involved in a particular phenomenon.[130] On the other hand, qualitative research provides the opportunity to explore details and could enhance our understanding of medicines policy research.[131] It also answers questions about "why" and "how" various participants act in response to circumstances by revealing their beliefs and thoughts.[132, 133]

Qualitative research can provide important understanding of health-related experiences by gaining insight into fundamental explanations, views and reasons from participants, providing precious details about the study objectives.[130] The phases in qualitative research include the

conceptual design and planning stage, empirical data-generation phase, analytical phase and dissemination.[72] The main techniques used in qualitative research are one-to-one interviews and focus group discussions. Supplementary methods consist of participant-observer research, action research, grounded theory, case studies and the Delphi method.[134] The researcher should be certain that the carefully chosen design is suitable for the research's main aim and objectives, as the validity of the illustrated conclusion in qualitative research is dependent on the chosen design.[135]

In this qualitative study, a general inductive method was used and semi-structured exploratory interviews were conducted to carry out the research. The approach involved recorded interviews from stakeholders and transcriptions were done followed by thematic analysis. The interviews were designed to explore participants' opinions regarding priority medicines policy issues in Qatar.

3.1 Why Qualitative Research was Chosen for this Study

This study explored priority medicines policy issues for Qatar and identified the challenges and opportunities involved. The key healthcare stakeholders' opinions and perceptions needed to be gathered in the form of interviews to explore their views on medicines policy-related issues in Qatar's healthcare system. For this reason, the qualitative research method was the right approach to adopt.[128]

The qualitative research method was used as it can provide an exploratory view related to study objectives and the topic. As there was no existent medicines policy in Qatar, hence this was considered the best method to unearth the details on knowledge, information, and understanding related to various dimensions of medicines policy.

A general inductive method was adopted. A general inductive method is a systematic method for analysing qualitative data in which the analysis is directed by specific evaluation objectives.[136] Also, the general inductive method is comparative method of data analysis and so has been commonly used during qualitative research to generate results.[137]

3.2 Ethics Approval

This study was approved by the University of Huddersfield Ethics Research Committee, Reference Number SAS-SREIC 14.5.19-2. Ethics approval was also obtained from Sidra Medicine, Qatar, Reference Number IRB-A-SIDRA 2019-0029, and ABHATH Research Center of Hamad Medical Corporation, Qatar. The ethics approval documents are available in Appendices 3, 4 and 5.

3.3 Participants Selection

The researcher contacted 55 stakeholders in Qatar by face-to-face meetup, email, WhatsApp and phone calls. The recruitment method involved meeting with key stakeholders and using a snowball sampling procedure. There were 21 participants selected for exploratory, semi-structured individual interviews throughout Qatar using the selection criteria. The participants had been living in Qatar or the Middle East for more than five years.

The inclusion criteria included: (a) participants working or involved in Qatar's healthcare system; (b) participants having experience or working knowledge of medicine policy documents, different facets of medicines policy, use of medicines and access to medicines; and (c) participants well versed in the English language. The selection was intended to cover stakeholders from a broad range of healthcare and policy institutions in Qatar.

The respondents were mainly from healthcare practices, pharmacists, and academia. All respondents have more than 5 years of working experience in Qatar as healthcare professionals, healthcare management, or in academia. They have the relevant background and knowledge to respond and answer queries on health policy and medicines use in Qatar.

SN	Healthcare sector	Stakeholders invited (55)	Stakeholders accepted (21)	Area(s) of practice and professions	Designated in the thesis
1	Academic physician and	8	4	Academic Physician	AcPhy1
	pharmacists			Academic Pharmacists	AP1, AP2, AP3
2	Private and public hospitals	25	13	Physicians	Phy1, Phy2
					Phy3, Phy4
					Phy5,
				Senior Nurse Manager	SNM1
				Pharmacists	P1, P2, P3
					P4, P5
				Drug Supply Manager	DSM1
				Drug Supply Supervisor	DSS1
3	Community pharmacies	3	2	Pharmacy Managers	PM1, PM2
4	Distributors	3	1	Pharmaceutical Distributor	PD1
5	Regulatory – MoPH, Qatar	5	1	Registration & Drug Pricing Manager	RDPM1
6	Pharmaceutical Industry	4	0		
7	Consumer groups	3	0		
	Total stakeholders	55	21		

Table 2. Outline of the participants' areas of practice and profession.

3.4 Development of Semi-Structured Interview Guide

The semi-structured interview guides were adapted from the study by Babar and Francis (2014).[67] Also, from the literature synthesis and informal meetings with the key stakeholders, changes, adaptations and amendments were made to this guide.

In the interview guide, new questions were asked about the medicines policy in Qatar. The questions include "Where can someone find medicine policy in Qatar?" and "What are your views about the medicines policy issues and priority medicines in Qatar?" The interview guide also asked questions related to the process for marketing authorization of medicines. The specific questions also include the import/export of medicines. For example, "Are you aware of procedures to enhance support for the development or import of medicines that target an unmet medical need?" and, the question about "What kind of assessment does the newly developed or imported medicine go through before or at the time of application for marketing authorization." There were specific questions about the future of overall health and medicine use in Qatar in the next 3 to 5 years. All these questions fit in with the overall aims and objectives of the study. The guide is available in Appendix 2. This was to cater for the Qatar healthcare system's local needs.

The amended guide was tested on 10 participants, and their views and perceptions were taken into account. The pilot interviews also provided the opportunity to estimate the time required for an interview. The logistics learned from the interview included (a) interviews should be conducted in a quiet area to avoid background noise; (b) it is necessary to maintain an interview bag or kit to keep all items and documents secure that are needed during the interview and for management of records; and (c) an Interview Guide check list was needed. This was to ensure that the ethics were followed.

Amendments were also made as a result of the pilot interviews. The initial questions describing medicines policy, access and medicines policy issues were included. These questions were asked at the start to enable focus on more in-depth questions. It was explained that the study would be conducted from a healthcare system perspective. A new question about the use of medicines was also included before asking other questions. Two additional questions on future research

were also included. Some terminologies in the interview guide were further explained; for example, the term "marketing authorisation" (registration) was added.

The final interview guide has four key themes as illustrated below:

3.4.1 Priority Medicines Policy Issues

All participants were questioned about their understanding and definition of "medicines policy" and where to find documents pertaining to medicines policy in Qatar, and their views on medicines policy, procurement and the development of medicines policies nationally. Their views about how the State of Qatar or health institutions deal with priority medicines policy issues were also explored.

3.4.2 Access to Medicines in Qatar

Access to medicines is a vital component of medicine policy and crucial for the State of Qatar because of geopolitical issues and pharmaceutical imports from around the world. The questions revolved around perceptions about access to medicines in Qatar, and issues related to access for Qataris and expatriates.

3.4.3 Use of Medicines in Qatar

The use of medicines is another key component of medicine policy; therefore, this section in the questionnaire guide included questions exploring the participants' understanding of the use of medicines, antibiotics used, compliance, concordance and prescribing guidelines, and as well as exploring these issues in the future.

3.4.4 Future of Overall Health and Medicines Use in Qatar

One of the objectives of this study was to find out participants' opinions on future issues which may impact Qatar over the coming years. The questions included participants' opinions on overall future of health, future issues related to access and use of medicines, and the challenges associated with these. There was also a section with an open-ended question for if they would like to add any further comments on the study.

3.5 Interviews

3.5.1 Participant Recruitment

A snowball sampling procedure was used to recruit participants. In snowball sampling, participants identify further participants.[138] The recruitment of the stakeholders was carried out by an email invitation, through follow up emails or calls, or through WhatsApp messages. When the stakeholders were contacted, an initial briefing was done on the research project for the introduction and seeking consent. If they showed interest and provided consent, then the invitation letter was sent by email. Fifty-five stakeholders were approached, of whom twenty-four did not reply, three referred to their colleagues and two replied that they were not confident about participating in the research study. Twenty-one contacts agreed to participate.

3.5.2 Conducting Interviews

All interviews were done by face-to-face meeting, one-on-one with privacy, except for one interview which was held on Zoom Meetings because of the COVID-19 pandemic situation in Qatar. The interviews were conducted between September 2019 and March 2020. Before the interviews, an email was sent to all participants, which included an invitation letter and an interview guide. There was no financial compensation offered to participants. All interviews were conducted in the English Language. Each interview lasted for about 40 minutes. All participants have a full-time job and busy schedules; therefore, preference was given to participants' availability and, to reduce the participant engagement time for this project, the researcher drove to the participants' locations in Doha, Qatar, to conduct the interviews.

During the interviews, only the questions relevant to the study were asked. Formal consent was asked from the participants before starting the interview questions. All interviews started with a summary of the study, a meeting agenda, confidentiality statement and an inquiry whether the study participants needed to share any questions or concerns.

All interview audio recordings were made on a SONY ICDPX470 Stereo Digital Voice Recorder and saved in the password-protected computer, and all files were named using a code number for further protection of confidential information. The Alpha numeric coding format was used and the details are shown in Table 2.

3.6 Data Analysis

All interviews were transcribed verbatim. The coding was performed after reading the transcribed document, followed by the identification of themes and sub-themes for the thematic analysis. The analysis was performed by using the NVivo 12 software application.[67] The semi-structured interviews provided spontaneous and natural conversation between participants and researcher.[132, 139]

The thematic analysis method is the most generally adopted method within qualitative research. [140] This method includes six steps. Clarke and Braun suggested thematic analysis is to be recursive rather than linear. In thematic analysis, the process may provoke the researcher to look back to previous steps if new data or newly emerging themes needs additional review. There are six steps that were followed for thematic analysis in this research. [140] (1) The data consists of interviews (2) The second step is to generate codes and the connections between data were explored (3) In the third step, the codes were examined and were subsequently organized to find possible themes. (4) The themes were reviewed by a two-step analytical process and a thematic map was developed. (5) In this step, the themes were defined and named (6) The last step is the write-up.

CHAPTER 4

4 Results

This chapter provides details on the research findings.

4.1 Demographics

This study aimed to understand priority medicines policy issues for Qatar and to identify the related opportunities and challenges. For this research, we were invited 55 stakeholders from all healthcare sectors. Table 2 shows the participants' healthcare sector and the areas of practice.

4.2 Themes

The following themes appeared after the analysis of the transcriptions. The main outcome of the research include a series of themes and subthemes related to medicines access, medicines use and a series of exploratory priority medicines policy issues. These are all described below and they fit very well with the main aim of the research. The figure 1 is entitled as "Themes and subthemes related to priority medicines policy issues for Qatar".

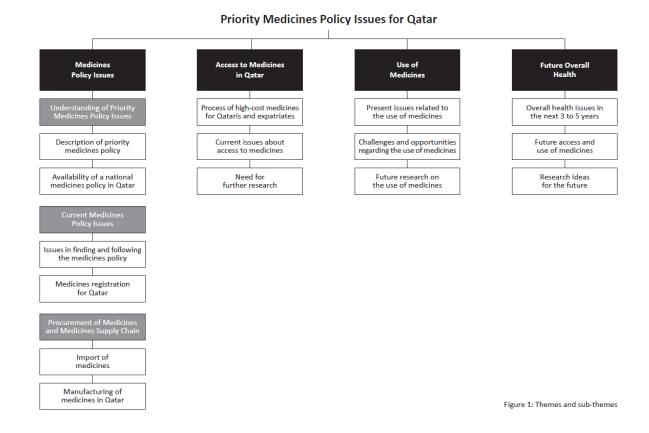


Fig 1. Themes and sub-themes related to priority medicines policy issues for Qatar

4.3 Priority Medicines Policy Issues for Qatar

There were three subthemes around the understanding of medicines policy issues, current medicines policy issues, and medicines procurement.

4.3.1 Understanding of Priority Medicines Policy Issues

Our results showed that most participants have some form of understanding regarding medicines policy.

4.3.1.1 Description of medicines policy

There were different opinions regarding medicines policy among the participants. The drug supply supervisor described medicines the policy issue as:

In general, so it starts by, I think, by procuring medication, how medication is procured, how the

medication is prescribed, adverse events regarding medications, how to report these adverse events. That is it. (DSS1).

However, an academic pharmacist described medicines policy as follows:

I can describe 'medicine policy'. Medicine policy, in my opinion, are all regulations and guidelines on procurement, distribution cell and use of medications and other pharmaceuticals in a certain country; medicine policy has to be something that is written and documented guideline on how medicines are procured, how medicines are distributed, how they are used and how they are even disposed, within a certain country. (AP2)

Whereas a physician explained a medicines policy as:

Medicine policy is the one that is governed by the state, which represents society and the whole purpose of those policies are to govern the safe use of medications for the general population but also to ensure that safety is balanced with the access around that and those are typically stipulated by the governing body for the country that is the jurisdiction where you live, and for this particular be...this would be the State of Qatar. (Phy3)

One of the senior nurse managers of a hospital stated:

I assume this is the use of medicines within State of Qatar to include national formulary. (SNM1)

A pharmacy manager of a chain community pharmacy described medicines policy as:

Medicine policy is the rules that regulate them, that flow of medicine from outside Qatar to the in user the patient, how that govern and control the process; what are the rules for access for medicines, for the prices and the availability and the expiry (in case of expiry) or...these the rules that govern medicine flow in Qatar. (PM1)

Additionally, an academic pharmacist described the policy in the following words:

I think it like a document written by experts, whether hospital level or national level or ministry level. It could include, it could start from like the basic level of developing the medicine, testing the medicine, approving the medicine and then basically approving the medicines for use, and

then we could have policies on procurement like how to get the medicine into a specific country, what requirements, what qualifications, what practices like the medicine, like what are the GMP practices; for example, for adopting or entering or procuring a specific medication to the country. (AP3)

The following is the opinion of a registration and drug pricing manager in a public office on medicines policy:

This is like big word medicine policy because it has different angles and different views. Here in the country, they are following the international standard for having the medications in the country, apart of that following GCC policies. GCC is one which is taken all the policies from WHO and international guideline for having a medicine in the country. (RDPM1)

A physician in a hospital described medicines policy in the following words:

My understanding of 'medicine policy' is that it is a set of regulations which governs the provision of medicine at different levels, including the community level, in the hospitals and to the patients at various healthcare facilities. (Phy4)

4.3.1.2 Availability of a national medicines policy in Qatar

Here is the statement of a registration and drug pricing manager related to medicines policy in Qatar:

We do not have like such one bundle of documents, which is called medicine policy but to have it in different documents. Yeah, but it is not like a one booklet, which is known as medicine policy to be available in one document. (RDPM1)

A drug supply manager believed that medicines policy and all policies were available on the MoPH portal; he stated:

In the ministry of public health portal, all the policies related to...starting from the license of pharmacy professionals up to the level of registration of a new medication, we will find the rest of medicines registered. We find what are the restrictions, anything related to the policy of usage or access to medicines in Qatar. We will find it in the portal, very transparent. (DSM1)

On the other hand, other participants believed that the medicines policy was not available. Here is the opinion of an academic pharmacist on Qatar's medicine policy:

The State of Qatar does not have any written medicine policy. This is to the best of my knowledge. There is lack of national medicine policy in the State of Qatar, but in place, of course, there are some unwritten regulations and rules related to access to medicine. So issues to access, availability, affordability, there are some written documents, even with the pharmacy and drug control, but there is no consolidated national medicine policy that covers all this aspect as well as aspects related to generic medicines, which are also part and parcel on national medicine policy. (AP2)

The drug supply supervisor's views about the availability of a medicines policy in Qatar were as follows:

Well, if there is a published national medicine policy, I don't know. I am not sure, but I know that there are some regulations for importing medication in Qatar and based on this, we submit for import permit approvals unless the item is registered other than that registered medications. But about a policy or a national policy I did not, I have not seen. (DSS1)

One of the physicians referred to the MoPH website, and he outlined this in the following statement:

In order to get information for medicine policy in Qatar I think the best source for it is the QCHP documents and they are available online to the general public as well as to the healthcare providers. (Phy4)

4.3.2 Current Medicines Policy Issues

The participants had differing opinions on medicines policy issues. However, the two most common issues were where to find the policy, as well as issues regarding medicines registration processes in Qatar.

4.3.2.1 Issues in finding and following the medicines policy

Most participants felt it was a challenge to find, understand and follow the medicines policy in Qatar. A pharmacy manager replied about the medicines policy in the following manner:

I think there is no strict policy for medicine in Qatar. So, maybe this makes it like not much clear for every health care provider; you know, there are some issues that I am not clear, maybe regarding some of the rules for some medicines. Just some issues, prescribing issues, I am not sure about; not everything is clear, maybe this is because it is not stated. Because I think reason for that, it is not created. There is no medicine policy clear for everyone. (PM1)

Also, a drug supply manager said about the medicine policy in Qatar:

It would be better to have one policy that covers everything. (DSM1)

Additionally, a hospital pharmacist said it was a challenge to find policies on modern healthcare technology to reflect and guide current healthcare practice:

My views on the policy itself, I think It's quite dated, and also there are some aspects of it that need modernizing, particularly now that we are dealing a lot more with electronic prescribing, with automated dispensing tablets. Things have moved on so we no longer keep in paperwork for many, many things and I think the medicines policy should take time to reflect and review what change is necessary, and where the country that is full of ex-pats, it is important that the document is translated in English. A lot of the time, it is in Arabic and Arabic only, so finding a reliable translation is quite difficult. (P1)

An academic pharmacist emphasized the importance of the medicines policy, and regulators were aware that there is a need for a written national medicines policy:

Priority medicine policy issues are very, extremely, incredibly important and definitely this comes as part of medicine policy in the country under the umbrella of national medicine policy. Unfortunately, we do not have the national medicine policy, that does not mean in the State of Qatar. We do not have issues from the regulatory authorities and other healthcare institutions related to the priority medicines. I think the policymakers are fully aware about the priority medicine issues, but a written policy because of the lack of national medicine policy. So also, there is no any kind of priority medicine policy that is written. (AP2)

A physician shared a different view and pointed out that Qatar is a multicultural society. There are challenges in communication and understanding of medicines policy.

Like every healthcare setting throughout the world, there are some issues, and especially in Qatar, we can see that the...my personal understanding is that it's a multicultural society. So overall awareness of the public is a major issue, especially people coming from abroad or especially people coming from third world. They have a poor understanding of the 'medicine policy', and that is in my understanding is that this is one of the major issues to be addressed. (Phy4)

The pharmaceutical distributor pointed out that medicines policies should be self-explanatory, and the regulator should help healthcare providers and stakeholders to understand the medicines policy. The pharmaceutical distributor stated this in the following manner:

Priority medicine policy issues, actually, there are many discussions. Everywhere there is people speaking about policy, medicine policy, medicine rule, how to deal with policy, how to deal with medicine, but I think it still needs a lot of efforts. It needs a lot of, to teach people or to read to make the message more simpler for the healthcare provider, so as they can digest the word 'priority medicine' and they can put it as part of their daily activism with whatever, whether it is service or it's medicine. I mean to provide the medicine or manufacture the medicine or distribute or dispense the medicine. (PD1)

4.3.2.2 Medicines registration for Qatar

Every participant had an opinion about a different aspect of Qatar's medicines registration, and there are a few quoted here. There was a general concern that medicines registration takes a long time, an average of nine months. However, there is a fast track registration process for some medicines, which may take four to six months by the MoPH.

The participants (DSS1 and PM1) reported that registration of medicines takes a long time, which resulted in the reduced availability of medicines. This is also being identified by participants (DSS1 and PM1) and this fits very well within the main theme regarding access to medicines.

Here is the opinion of a drug supply supervisor about the medicines registration process in Qatar:

Well, frankly speaking, when we talk about Qatar and the MOPH and the drug control, there are no...I cannot find like a written policy, or there is a scheme for registration if we want to talk regulatory from the regulatory aspect. There is a scheme for the regulatory requirements for registration of all this, but for the policy, no. Nowadays, they are really accelerating the process because of all that is happening here. So before it used to take at least nine months but nowadays, maybe more than four to six months. (DSS1).

Also, the pharmacy manager stated, regarding the time consumed with regards to medicines registration in Qatar:

Registration for the medicines is taking a long time. They have some...there is something called fast track for some medications to be fast track registration. So registration usually take a long time, but they have some fast track medication registration in the Ministry of health. As I know, there are some examples of medicines, especially after the embargo, there are some medicines that quickly enter to the Qatar, and they have some temporary solution like they will make temporary parallel important approval. They will not give the approval for certain distributors here to make medicines available until they finish the registration process. They have some solutions here. (PM1)

The hospital pharmacist at Hamad Medical Corporation (HMC) explained the process for different medicines registration processes for approval, direct purchasing and bringing medicines to HMC for all patients. The following was stated by the hospital pharmacist:

See, we have our own process in HMC. Usually, what we do is the ones which are prioritized, essential, which sometimes, which is lifesaving at times, so, we have very accelerated process. So that is been there because we have our own process in HMC, where we directly contacted the authorities in other countries and embassies, and they would contact the manufacturers, and it comes through the embassy when it is urgently needed. So, there is a process in place until unless the product is not available. (P2)

All other healthcare sectors must get approval from MoPH for any medicines, including private sector pharmacies, distributors, hospitals, clinics, national and international manufacturers, and suppliers. The following is a statement by a pharmacist from the hospital:

They go through the Ministry of Public Health, request with does not go through HMC as such. So use of health, you look into all the certificates' quality, etc., etc., see if all the requirements are fulfilled even if FDA product is introduced here. It's easier than uploading, which is not FDA approved or EMEA approved, but that goes at the Ministry of Public Health level. (P3)

4.3.3 Procurement of Medicines and Medicines Supply Chain

Two points were noted within this subtheme, one was on the import of medicines, and the other was the manufacturing of medicines in Qatar.

4.3.3.1 Import of medicines

For the import of medicines in Qatar, the registration application must be submitted to MoPH. If the FDA, Health Canada and EMEA have approved the medicines, then only MoPH will review the application for medicines registration. A pharmacist in the hospital explained this in the following manner:

They go through the Ministry of Public Health, request with does not go through HMC as such. So use of health you look into all the certificates' quality, etc., etc., see if all the requirements are fulfilled, even if the FDA product is introduced here. It's easier than uploading which is not FDA approved or EMEA approved, but that goes at the Ministry of Health level. (P3)

Also, the drug supply manager described the import of medicines in the following manner:

Ok, what I am aware about is that certificate of origin, certificate of analysis, certificate of materials kind of like the same files that are submitted to the FDA with all the research database that have to approve. One mandatory thing [is] that you cannot register in Qatar unless you are just registered either in FDA or EMA. So that is mandatory that you cannot start by Qatar. (DSM1)

The drug supply supervisor added that the MoPH has a special import process for some medicines:

Well, sometimes they provide like a special import for this medication, until it is registered. They usually do so. If the medication is needed and still some documentation is still missing, they provide a special import approval based on, of course, the need and the justification. (DSS1)

4.3.3.2 Manufacturing of medicines in Qatar

There are a few national pharmaceutical manufacturing companies in Qatar. After the embargo placed on Qatar by other GCC countries in 2017, some pharmaceutical manufacturing started in the country. The following was explained by a drug supply manager regarding the local manufacture of medicines in Qatar:

Yes, local manufacturing has started before the embargo, mainly Qatar Pharma. They were producing only intravenous fluids but now, after the embargo, in Qatar feels that the availability of medication is part of the national security. We have now kind of like four-five factories inside the country. They focus on the essential medicines. Still country is importing most of the medications from outside, especially the new medicines and the generic medication. (DSM1)

One of the things that they are to secure is to kind of like buy the shares of the main manufacturers. So if I can't manufacture internally, I will secure the essential medications on the supply chain through buying shares in Byer, Pfizer, so nobody can stop the supply to the country. So that's what I am aware about. (DSM1)

4.4 Access to Medicines in Qatar

He also stated the following on contract manufacturing:

4.4.1 Process for High-Cost Medicines for Qataris and Expatriates

All medicines are paid for by MoPH in all public sector hospitals and primary care clinics. This payment is in full for Qatari nationals and up to 80% for non-Qatari residents. The 20% medicines cost for residents is paid by either employer insurance or private insurance, including for high-cost medicines. In the private sector, all medicines cost is paid by MoPH for Qatari nationals, but all residents have to pay the full cost of medicines. Here is what an academic pharmacist had to say about access to medicines in Qatar:

Well, as far as I know, there is no differentiation. If an expat needs like an expensive chemotherapy

medicine, they are not denied access to it. So, if that particular drug is needed and it's in stock and available in this country, the patient will receive it, and you know this is the big benefit about living in this country is that the Expats are not denied medical care. (AP1)

The following is a statement from a registration and drug pricing manager about the cost of medicines:

For Qatari, no problem as they are not paying. But the good thing also for the expats. Government always paying 80% of the bill. They only pay the 20% and even for the chronic diseases such as cancer and diabetic patients and cardiac patients, paying only 10%. (RDPM1)

Additionally, a pharmacist in the hospital stated the following on high-cost medicines:

So our organization, there is a high-cost committee, so that reports to the pharmacy and therapeutics committee. They provide some conceptual structure around a high-cost medicines and some clinical governance on when and how they should be used. So we do have some, you don't have to be national. Whether it is national or the expat in terms of the patients, there is no beyond distinction between the two. Some of the organizations do. We don't. (P1)

For Qatar's residents, the high-cost medicine prices or co-payment can also be financially managed by their insurance and/or other societies in Qatar. Here is what the pharmacist at the public hospital stated about the insurance:

The insurance has not been there, so I would emphasize insurance. The country looked at the insurance before, and they're still working on the insurance now. So once the insurance comes, then probably it should not be a problem with a higher cost, even at this point. It's not a problem at all. But for private sectors, there are many issuance companies which is covering that cost, but in HMC, the price is not a problem. (P2)

Also, the pharmacist of a public hospital explained the availability of a medicines support system:

There are impressive support systems available. So there are societies as such like for expensive medication. Multiple sclerosis society, they will recruit funds and support addition. Red Crescent is a very big source of funding as well. There are all kinds of charity organizations which will help the patients who need the financial help, also for the expensive medications as such, yeah. (P2)

4.4.2 Current Issues about Access to Medicines

Transportation from the manufacturing country to Qatar is a concern because sometimes this could delay the medicines. The manager of registration and drug pricing stated this as follows:

We are trying to encourage local manufacturing plants to manufacture this kind of product locally. Because other issue is waiting for the transportation issue, you know, have the medication timely. It takes time. Yeah, it takes time. Sometimes you are not receiving at the time we need. (RDPM1)

Also, the senior nurse manager talked about medication supply issues:

We have good and easy access for the drugs that are available in the country. You know, again, I know that limits are what the prescribers can offer to some patients based on, you know, what is available in-country and this goes down even both to the type of the drugs and the formulation. So I know those are the same challenges, and we don't have a consistent access to drugs supply. (SNM1)

Additionally, a physician in the hospital stated the following regarding availability:

One thing I noticed over the last couple of years of working here in Qatar is that range of medicine availability, range of medicine is an issue. Again, there is a limited range of available medicine in some areas, so that is...and especially the narcotic, analgesic and their prescription of the patient and availability of patient for taking home is an issue. (Phy4)

The pharmacist in acute care highlighted issues including access to medicines without a prescription, repeat supplies of narcotic medicines and holding medicines in stock, as availability is uncertain.

A lot of things are built, or they are made for sale without a prescription, which means that people can access them but we are not sure if they are using them properly. Because you can just buy it without a much control. (P1)

Other access issues are narcotics and psychotropics because of the prescription length. That can cause a bit of a problem because patients have to return to the pharmacies quite often to pick up the medications. Yeah, it's a five day supply. So as per the policy, it is a limited number of days.

Also, medications that need more than that you have to return again. So it's quite strict laws on narcotics mainly but also on psychotropics. (P1)

The availability of medicines was also discussed by the acute care pharmacist:

The other access issue could be whether to stock or not because we are relying heavily on imports we all been holding within a country so, you know, it's not something that's available now. That can cause an access issue. (P1)

Qatar's pharmaceutical market size may also affect medicines availability, as a drug supply supervisor in a hospital explained:

The issues are mainly by being a small market. Not all registered medications are available. The high cost, let me say the essential medications, most of them, they are not registered and the companies, they are not keen to register because it's easy to put a...to have it here available in the market through Hammad. They [MoPH] are trying to like formalize a unified national formulary for all Qatar and to...and to just to force all companies to register their medications to be able to have like a fair like availability for a medication. (DSS1)

The availability of a national medicines policy, private medical insurance coverage, and the use of generic medicines were also some of the issues described by an academic pharmacist:

The issues surrounding around access to medicine...the issue of the national medicine policy, because when there is national medicine policy, national medicine policy was clearly state all that is needed in terms of giving access to the medicine and so on, and when it does not exist, it creates a kind of disparities or differences or inconsistencies in terms of how different organizations operate in terms of giving access to the medicine. (AP2)

There is differentiation, and that is linked to when they are employed, the employees, the level of health insurance that they are given. It's not the same. So there are issues of safety there. There has to be some kind of creating safety name for the disadvantaged population. I think this is an issue in terms of, not completely they do not have access, but it is the restricted kind of access and if there is a policy in place as well as users' organizations that are employing them, will improve

the insurance coverage. That will bring the uniformity in terms of how people are getting access to medicines in the State of Qatar. (AP2)

They are barriers in terms of access to medicines, and those who will understand when you talk about most of the institution, there is kind of misconception, for example, about the use of generic medicines. So because of these misconceptions, the clinicians don't trust, and the patients also they don't trust if you give them anything. This is a huge expenditure on health and therefore, there are...there could be also barriers from that perspective. (AP2)

On the other hand, access to medicines without prescription emphasizes the pharmacist's role at community pharmacies. This should be to educate and optimize medicines use. The following was stated by the academic pharmacist.

We have too much access actually, and with that in any one of the public can now go to the pharmacy and buy antihypertensive that you know, without any prescription. So we have too much access that has to be restricted honestly on some drugs, yes. (AP3)

The pharmacist is not really offering a good advice to the patient. Since the majority of the medications are available over the counter, pharmacist should have a role in that more in educating the public about the optimal use of medications. (AP3)

4.4.3 Need for Further Research

The following section elaborates thoughts on areas for future research. For example, a pharmacy manager at the community pharmacy stated that research is needed on leftover medicines at patients' homes:

Yeah, probably, what people do with the incomplete medications or unused medicines. One of my concerns. I would love to have a research done on that so that there is no left-over medicines at home which can harm another person. (PM2)

A registration and drug pricing manager stated that there is a need to develop a comprehensive national medicines policy:

Like further research and to compile these [medicines policy] documents in one document together... Because most of the practitioners are coming from abroad expect the same thing from the home country but this country is very unique for the medicine access. (RDPM1)

This view was echoed by a hospital pharmacist:

I would be interested to know about over the counter sales and the clinical effectiveness of doing that, so where you are frequently selling products without having much guidance from the physician or the prescriber and then a pharmacist too. What is the impact of that and how does it compare to some of the standards around the world? (P1)

Academic physicians have an interest in developing policy, regulation and improved patient safety:

But clinical choice is a big problem that is not...now we established whole clause of medical education, and it has no access to clinical choice because the legal aspects are not clarified. So, no drug companies, they have to start; no doctors, they have to start; because there is no justification and there is no monitoring if side effects that may identified. There is no unit to say "No, no" this is now to stop, and also, the legal implications of making mistakes in relation to research are too tough. You can go to jail if you make a mistake, and they are working on that. (AcPhy1)

More research is needed on clinical practice guidelines, as a physician in a public hospital suggested:

Actually, the most research I think should be, for each problem, or medical problem, should be matched it by guidelines; and because it's still doubt, the practice at the level of institute. It's not, again, with the policies or guidelines. That means it is very open to each physician to use whatever he thinks is best for the patient unless this utilize or done. (Phy2)

Antibiotic resistance is another area where physicians would like to see some work:

I think the issue of resistance of different organisms to antibiotics and people come from a different part of the world. They already have access to the even very high potency antibiotic,

which they take inappropriately, and they come here with different set of resistance of microorganisms. While at the same time, the good majority of the people, who come from a part of the world where there is very controlled access to these antibiotics, and they have a different actually resistant status. This area needs a bit more exploration, attention or work need to be done. (Phy4)

It was also suggested by a physician that a sociological study about patients' expectations on medicines is needed:

I think it will be an intriguing sociologic study to understand why every patient that walks in wants to talk over the medication. If I don't give a medication, I am considered a bad doctor, and it will be an interesting to understand the why of the population because it puts an automatic conflict and the distrust in the system if you don't get a medication. And one of the reasons why antibiotic overuse here is because they just won't go away without any and think you are a bad doctor and all those things. (Phy3)

Similarly, pharmaceutical distributors would also like to see more research on antibiotic policies and guidelines:

If I think about the research, I will think about the type of antibiotics available in the country. I think it need to be looked in term of suitability of this medicine to the situations in Qatar, whether it is really effective, or it needs to be. I mean antibiotic policy. (PD1)

An academic pharmacist also emphasized the need to do research on medicines availability, affordability and cost:

So like I describe, that depth of literature or the scarcity of literature, inability to issues of medicine accessibility, availability, affordability and cost. I think this is a niche area of research; wherever there is a need of researchers that are working in the area over a medicine policy to do more in terms of understanding these issues. (AP2)

Similarly, a hospital pharmacist also talked about research on generic medicines and the barriers related to the use of these medicines:

The first thing is I will talk about generics and brands, so that will be the best thing to look at in which people have looked at it before, but there are some barriers which need to be overcome initially. (P2)

4.5 Use of Medicines for Qatar

As shown earlier in Table 3, four sub-themes were observed within this theme. These include "general description on the use of medicines", "present issues with regards to use of medicines", "challenges and opportunities with regards to use of medicines", and "future research on the topic".

4.5.1 Use of Medicines

There were differences of opinion regarding the use of medicines. One physician reported as follows:

Use of medicine is in Qatar is similar or same as every anywhere else where modern healthcare facilities available that over the counter medicine available to the people. (Phy4)

A drug supply supervisor described the use of medicines in the following manner:

Use of medicines is mainly medication prescribed by the physician for a specific indication. This indication has to be mentioned in the...mainly from the regulatory perspective the...in the insert leaflet, or it has to be registered for this indication. (DSS1)

An academic pharmacist made an interesting point:

This seems to be a very broad question, and I don't know where to start, in fact. So, the use of medicine from the perspective of utilization, from the perspective of healthcare institutions or from the perspective of regulatory authority or from the consumer perspective; I think if you talk about use of medicine, you should look at it in different perspective. (AP2)

An academic pharmacist described this from a patient's point of view:

If I will say from the patient's perspective, it's how the patient is using the, basically, the medication, so proper or not proper according to the direction or not direction. Is it the right drug dose, not a right dose, for there is good duration or not a good duration? Yes. (AP3)

The hospital pharmacist explained the use of medicines in the following manner.

For HMC, we have JCI accredited. We have something called a chapter medication use...utilization medication advisor that clearly tells us how things have to run around, right from the start if you talk about how do you select a medication; how it goes into the P&T committee, then how it is approved, then how it has to be dispensed, how it has to be prescribed, how it has to be stored, then how it has to be monitored. (P2)

4.5.2 Present Issues Related to the Use of Medicines

The study participants stated concerns about a number of issues related to patients using medicines; these also include prescriber issues and broader medicines policy issues. An academic pharmacist emphasized the need to educate patients regarding the appropriate use of medicines:

Well, I think the biggest thing has to be that the general public has to know more about how they should be using the medicines properly. They get the prescription, they don't get much of the information from doctor, and they go to the pharmacist at the pharmacy, and the pharmacist tells a bit of an information, but still, they don't know much that much, and that leads to a big problem. (AP1)

The registration and drug pricing manager at MoPH described this in the following manner:

We realized that patients are misusing this medication. For this, we added it to one of the controlled drugs, which is done once in a month only in order to avoid this kind of misuse. (RDPM1)

Because medicines are free or subsidized, patients have more medicines, which increases misuse

Issue is that the medicines, although is coming from abroad very expensive, and registry is free and being dispensed to patients, some of them are free and some are highly subsidized. This affects the use of medication. (RDPM1)

Another participant, a drug supply supervisor reported:

and harmful effects of the medicines. He explained that.

For me also is the adverse event reporting system for me. It is...it is...we lack this here in Qatar. (DSS1)

A physician mentioned the issue of expired medicines at patients' homes:

The only thing is that a lot of people might have a...might have lots of medication which have not used, maybe hanging in somewhere in the house. So maybe from time to time, there would be like a collection of this expired medication and...and the medication which are not used, so they can be disposed. (Phy5)

A few participants stated their concerns regarding medicines use policy issues; for example, a pharmacist stated:

So I don't know about any medication-related national policy being available on Qatar. The only thing is I know is that they have the programme for the vaccines that Ministry of Health is executing and monitoring. The only advice that I would have is that the policy [should be] nationwide. It's good to have one nationwide that covers all the stages of medication management and how the institutions have to follow that. (P5)

An academic pharmacist stated the following regarding a specific policy for the use of medicines:

I think when we have national medicine policy, it is a big umbrella that encompasses all these issues, including the issue of use and supply and procurement of medicine. It talks about medicine misuse and abuse and regulations that are governing all of this, and when there is lack of one, we will continue to record the issues related to all these branches that come under the big umbrella. (AP2)

A pharmacist from a public hospital talked about the medicines policy and use of medicines in the following manner:

I think we need to have like a more standard medication policy or more public awareness about the optimal use of medications and this, because now...initially it was like Hammad corporation, now another corporation like Primary Healthcare, Sidra, the Army, all of them. They have like now hospitals, polyclinics and standard policy will be beneficial. (P4)

Antibiotic prescribing and the prescribing policy were also discussed by a few participants. An academic physician explained this in the following manner:

As I say, the restrictions and training of the staff not to prescribe antibiotics as widely as it is done, this is the major issue, and I think this is deep major as many others are not like that. (AcPhy1)

A physician in a public hospital stated the following on prescribing and the use of antibiotics, as well as narcotics:

What to my understand mainly is now currently towards the antibiotics and towards a narcotic; others general clear policies is not there actually. And even for the narcotics, as I mentions, it solves now only ICU doctors and anaesthesia and neurology only were supposed to write such a medicine. (Phy2)

A pharmaceutical distributor opined that different stakeholders need to adhere to regulations to achieve optimal use of medicines:

I think the main issue [is] that we need to teach the people that the adherence to the regulations. It doesn't mean we don't want to give you the drug. We want to choose that when you use the drug. It should be used in the right way, and it should achieve the target of using the drug. (PD1)

4.5.3 Challenges and Opportunities Regarding the Use of Medicines

The participants suggested that a computerized patient's health record system for all healthcare providers would resolve prescribing and medication management issues. The pharmacy manager in community pharmacy indicated that:

There are no patients file and this will lead to misuse for a patient medication. (PM1)

A pharmacist would like to have a national health record database system in place:

A unified health record system, national health record system for the whole country, should be implemented in this country, so that every health care provider knows what medications are being used by each one. (P1)

Healthcare providers face challenges including patient education and awareness. This is the view of a physician working in a private hospital:

Challenges for the physicians are that they face because they have to restrict the excessive medication usage. In this regard, physicians face challenges. So it just needs some sort of education and proper continuous education, public awareness. (Phy1)

A pharmacy manager suggested that there is a need to educate society on the proper use of medicines:

Probably the need to educate more the society about the importance of the right usage of medication and honest medical fraternity, physicians, pharmacists to ensure that this education reaches the society. Probably there can be outreach methods, joining the universities and the community pharmacies, community medical facilities, where the patient medical personal interaction is more. (PM2)

Additionally, an academic pharmacist emphasized that public education is needed with regards to the role of pharmacist in the healthcare system:

So that the public understands that the pharmacist is not like a business dealer, but the pharmacy there is for education and actually doing medical treatment with the drugs when they go to see the pharmacist. (AP1)

An academic pharmacist also emphasized the role of the pharmacist and public perception:

I think the main challenge is basically is about the role of pharmacists. You know, the public here is not really aware of, or they don't really expect the pharmacist to give them good education about optimal use of medication. So you may find some patients not really accepting the idea of having a pharmacist counselling. They only look at the pharmacist who dispense the medicine. (AP3)

A few participants also mentioned about the challenges of not having national antibiotic guidelines for Qatar's private and public sectors. The drug supply supervisor from a hospital pointed this out in the following manner:

So the challenges are the issues in the system. The opportunities that you have here is to create our national guidelines. Hammad (HMC) has the guidelines. Sidra (Sidra Medicine) has guidelines. Some of our private hospitals which are in the primary stage, but we need national guidelines. If

you need national health insurance and national health codes, why not to have national guidelines also? (DSS1)

A senior nurse manager commented on the issue of guidelines as follows:

I think publicizing the guidelines better around these antibiotics, and holding the institutions accountable of antibiotics use, and meeting those recommendations and guidelines...it is a big opportunity that we can do fairly compact country to kind of hold providers accountable to the published guidelines. (SNM1)

The senior nurse manager also stated the need to have a robust primary care model in the country:

You know the primary care model is still building in this country, and I can go to seven different places and I get the same medication for my child from seven different people. You know, without a clear good primary healthcare model that was...I could take inside the system and outside of the system, and without that constant kind of reminder of the primary care model we can overprescribe and get into some pretty dangerous situations. (SNM1)

A drug supply supervisor in a hospital pointed out the lack of a pharmacovigilance system in Qatar:

Well, Qatar lacks pharmacovigilance system, and if pharmacovigilance system is available, everything regarding medicine will be documented. Specifying the indications, following up on adverse events, adverse event reporting, I think this is mainly what is missing. (DSS1)

An academic pharmacist also mentioned the need to focus on quality use of medicines:

I see an opportunity for the academia to take the lead in terms of more research related to medicine use and quality use of medicine, whereby you can have a centre for quality use of medicine that decides the whole area and produce more information on how you can advance in your country in terms of medicine use and supply in the country. And that comes back to also medicine safety issues in a country. (AP2)

4.5.4 Future Research on the Use of Medicines

A number of participants suggested more research should be done on various issues. An academic pharmacist stated this in the following manner:

They should do more research on what are the barriers that are preventing the advancement of pharmacy practice in community pharmacies. What is it that causing the barriers, and how those barriers can be overcome, because this is got to be one of the biggest areas where it can be improved in community pharmacy practice. (AP1)

Another hospital pharmacist also stated the need to research areas such as patient counselling and the use of medicines:

I would like to understand better on what the information is given to the patients on the use and how is that information is given in quality of that; so we talked little about the things like labelling and counselling and advice, like how do we capture some data or not to understand how about the work and what can be done differently. (P1)

Some participants suggested topics such as narcotics and control of medicines, supply and procurement issues. The following was suggested by a physician.

Prescription medicine for patient to take home and some of the strong analgesic medicine and antipsychotic medicine, which patients definitely need, and system here puts a little bit restriction of these medicines like in terms of provision to the patient. I think this area need an immediate and urgent and very focused attention. So availability are of these medicine to the patient from the institution or at the community pharmacy level is very limited. (Phy4)

An academic pharmacist also emphasized the need to look at supply, demand and consumer satisfaction issues:

The regulatory agencies are looking at policy-related issues, looking at supply and demand and procurement related issues from different aspects. And as well as I think it is important also to look at the patients and consumer satisfaction in terms of use of medicine, in terms of how the system operates. (AP2)

A hospital pharmacist also suggested the need for research on pharmacoeconomics and on drug use evaluation:

The first thing would be the drug use evaluation. So you need to evaluate how well the drug is working; a lot of pharmacoeconomics research that can be done and we are doing a couple of researchers in for pharmacoeconomics, which is been booming now, and we are really there looking at the cost [and] how effective the medication is. (P2)

An academic pharmacist suggested research should be done on disposal of medicines by patients:

Like there is no really clear system on how to dispose medications. That is, just many people are just throwing it in the garbage or in the toilet. (AP3)

4.6 Future Overall Health and Use of Medicines for Qatar

There were three sub-themes within this theme (see Table 3): overall health issues in the next three to five years, future access and use of medicines, and research ideas for the future.

4.6.1 Overall Health Issues in the Next Three to Five Years

Most participants were of the view that overall health in the next three to five years will be better because Qatar has started Qatar National Vision 2030 and National Health Strategy 2018-2022, and the focus is on better health outcomes. A pharmacy manager explained this in the following manner:

With the new standards of education or new standards of practice which is being envisioned by the Qatar by the vision for every five year, there is going to be a definite change which will actually reflect upon better health practice, better health outcome and better health reports in very next three to four years. I am very hopeful. (PM2)

The senior nurse manager was also hopeful about future overall health and investment in the primary healthcare model:

It is such a great health care system. Its number five in the world so it doesn't...there are so many opportunities and they have done just massive investment in it, and I think that the primary care model is just really is good, but just making sure it gets embedded and not the kind when people

get into the system, they stay into the system and they don't jump providers to go to private physicians; because that's really what's gonna make this country fantastic, that investment in the primary health care model. (SNM1)

A hospital pharmacist mentioned this in the following manner:

The overall health, I think, with the current direction of Qatar, one aspect is that I hope they will continue with promoting sports and physical exercise and preventive measures to prevent diseases and so on, and you can see a very good progress in this. (P5)

An α cademic physician expressed optimism on the future of overall health:

I think it's a very good public health strategy they have made, and it's very operational and to the point, and I have seen that they have made cancer solidarity and they have made the heart hospital. When you are focused on things like now, they want a focused public health strategy. They take things, and they implement, so I think it will improve. I am quite optimistic. (AcPhy1)

The following was stated by the drug supply supervisor on the future of overall health:

Well, although all these issues and obstacles, but I see that it is promising because I lived in the different GCC countries and I experienced here the best health systems, really, for I am talking about me and my kids and everyone. Their main concern is health, either you are a Qatari or an expatriate. So from...I lived in three other countries in the GCC and I can tell you for sure that this is my best experience. (DSS1)

The drug supply manager also emphasized the need for having national health insurance in the future:

So I see, once the national insurance is already launched, more and more investors will come and invest in healthcare market in Qatar. We will find decent polyclinics and private hospitals, and that's how I see the market, and that's based on the fact that it started already when they piloted the programme for a while, and it will recap again once restarted. (DSM1)

A physician linked the future of overall health with obesity and life style:

I think that in Qatar, maybe like in everywhere else, we heading to more obesity and less...and

more proper diseases which are related to obesity. However, from what I see, the health organization of the government is trying to encourage people to...for healthy diet, for active treatment, for having a lot of voluntary work and a lot of sports activities where people actually can participate, makes it looks, I would say, pretty good or better than maybe in another country. (Phv5)

An academic pharmacist linked the future with the blockade and the need to have a comprehensive national medicines policy:

I think more and more, especially after the blockade, the political issues related to the medicine sector the way I see the future, because more and more the State of Qatar understand the implications and now there are in place emergency preparedness strategies. I am also anticipating the realization of the lack of national medicine policy, which is apparent will result now in the emergence of one in the State of Qatar. It looks like it is going to be imminent. (AP2)

A hospital pharmacist also emphasized the need to focus on local manufacturing of medicines to secure the future:

So the future should be good in terms...but we require real experts to work on this. So what I could say is they have to be self-sufficient. In Qatar, we have, I think, after a couple of pharmaceutical companies. Okay, so first thing is being self-sufficient; you need to manufacture medications. Once you have this, 90% of the problem is resolved. (P2)

A pharmacist in the hospital linked the future to an emphasis on mental health and elderly people:

I will refer here to the Qatar national health strategy, which is covering the next five years. This is like the second launch after the one finished before the five years, and now we are more focusing on a specific area and the strategy like a mental health, elderly people's...so overall, I think we are moving in the right direction in terms of health and medication utilization in Qatar. (P4)

However, a pharmacy manager at a community pharmacy did not share much optimism for the future:

I am from sixteen years here. I did not see like significant improvement, and so I did not expect in this coming three-four years. I think that we are copying the previous years and we are working in the same way. (PM1)

4.6.2 Future Access and Use of Medicines

A number of participants believed that in the future, use and access to medicines would improve, though an academic pharmacist stated that cost would be a hurdle for improvement in community pharmacies:

It will have to see if government wants to see and force the changes in community pharmacies they need to do, not just force but to give them incentives, because I think this is the major issue, the cost. Lot of pharmacies don't wanna make improvements because it's gonna cost them money, and if there is some sort of incentive that government can work on to help to make that process of change happen, we could see the practice of pharmacy advance. (AP1)

A manager at a community pharmacy expressed his view in the following manner.

I wish by these increased standards of practice the incidents of wrong medication, the incidents of incomplete medications or compliance, will improve very much through proper pharmacy counselling. Yeah, just like in the Canadian health sector and as well as US health sector found that the community pharmacists can play a pivotal role in changing the health outcome as well as health practice in a nation. Yes, I see even with the Qatar National Vision, the health vision, they have included the community pharmacies with a great importance and hope they will rise to this vision. (PM2)

A registration and drug pricing manager referred to the importance of national manufacturing:

Having more plants locally is very important because, you know, the development of the country and increase in the population. For this, we need to by developing and amending the policies, you know, to cope with this development of the country. (RDPM1)

An academic pharmacist at the university stated that the Qatar healthcare system has improved in terms of efficiency:

I think the State of Qatar has taken so many strategies and initiatives in terms of expanding and improving the health sector, and that comes also with a lot of the national health policies and strategies or plans or health care plans for the country. We have seen the Qatar National Health Policy 2016, which has passed and now we have the new one that started in 2018, I think until 2022, the National Health Strategy. The statistics of Qatar clearly articulated the direction of the healthcare system for the country and I do strongly believe, because the government take this issue seriously, therefore, I expect to see a lot of changes in the healthcare system in terms of improving efficiency, in terms of improving quality in the healthcare sector. (AP2)

A hospital pharmacist pointed out that medicines use will increase in the future in Qatar and hence, policies and regulations need transformation. He stated this in the following manner:

Medication use will, I mean, as the population grows more, there will be more use of medications. However, I think how we use them, what we use, needs a change. There needs some modernization in terms of policies, procedures and regulations in the next three to five years on how we use those medications. (P1)

A hospital pharmacist also expected improvement in medicines regulation and regarding the overall use of medicines:

Depends on the initiatives, to be honest, that are going to be taken by the ministry and the government and so on. I think it will improve from one side. I think nationally, there might be developments on vaccine use, controlling antibiotics use, promoting certain lifestyles. I think, on that perspective, the medicine use hopefully will be better and also because of the budget constraint, e.g. that might lead organization institutions to, you know, think about the medication use and the financial aspect as well. So I think hopefully it will further improve in the coming years. (P5)

A drug supply Manager emphasized the need for research on genetic diseases and rare disorders:

I think Qatar will be one of the countries that will be a research target from the manufacturers, because in Gulf in general, the rate of rare disease might be more prevalent due to a marriage

between the families and those kinds of things. So the genetic diseases might be of interest for some manufacturers to come here and test the medicines. (DSM1)

A hospital pharmacist mentioned more pharmacy involvement in clinical areas:

I think also things are moving in the right direction. We see more and more pharmacy involvement in clinical areas. Initially, like our in-patient area now, we are expanding to, like an ambulatory service. Also our rules and policy guidelines has also expanded, which is I'm sure that will all reflect on medication use in Qatar. (P4)

A few participants thought that the government should invest more in drug development. A physician in a hospital stated this in the following manner:

So I mean, an idea I had is, well, let government get into the drug business; let them be willing to assume the risk, is essential. At the end of the day, research grant may not see any return on their investment. (Phy3)

This is what a drug supply supervisor said regarding the national health insurance and the use of medicines:

Well, I'm not sure because we have been hearing about some changes in the insurance and regarding Qataris and expatriates, and this definitely will affect medication use; and nowadays, some hospitals are going to generics and alternatives because some patients definitely will not if insurance is minimized or affected by the changes. There will definitely be a change in medicine use. (DSS1)

A hospital pharmacist also emphasized the need for implementation of a generic medicines policy:

The future depends upon, as I told you, they need to introduce generics, so if once they introduce generics, the cost wise it will be quite good. And in the same time, it has to be linked to the research activities to see whether there is a benefit of introducing generics or not. (P2)

The following is the opinion of an academic pharmacist regarding frameworks and strategies in relation to access to and use of medicines:

I would expect more restriction and more control, and I hope for that. Yeah, in terms of medicine, there's still more work that has to be done, but I'm sure that Ministry of Public Health is really working on strategies and frameworks. I am sure they are working on frameworks and strategies in relation to access to medicine and ensuring optimal use of medicines. (AP3)

4.6.3 Research Ideas for the Future

A physician stated the need to emphasize policies related to import and export of medicines:

I see we need to more work about organizing policies for importing and exporting some medicines and hopefully, this will be much...with some, all health services and health institute, academics or service...do much together and came with one plan and one policy. (Phy2)

A physician at the university emphasized the need to implement quality control on medicines guidelines, as well as on publications:

Future research, I think what needs to be done before that is maybe just to implement the quality control system regarding how the current clinical guidelines are followed. I think this would be the most important development for me. Yes, this has to be done. Maybe you can say research on quality control, not only the publications because others have done that before, but it can have a huge impact on society. (AcPhy1)

A number of participants suggested more research should be done on community pharmacy. An academic pharmacist stated this in the following manner:

One is they need to do more research on advancing community pharmacy practice. So I think it's gonna be a must, and the other thing is that they need to have more focus on educating the public about proper use of medicines. (AP1)

A senior nurse manager at the hospital indicated a need to conduct research on public engagement of pharmacies in their local areas:

I think it would be interesting to see, and this isn't like hardcore research, but on average, how

many pharmacies the families use because I go to the same pharmacy all the time, but how many pharmacies do people generally go to. Do they have a consistent pharmacy? Do they have relationship with their community pharmacist? Do they see it in that way that they have a community pharmacist? (SNM1)

A physician also suggested research should be conducted on issues related to "use of medicine at community level" and "over the counter medicines":

So again, it's a very wide area; every area needs exploration and research and various levels of research are ongoing, but my suggestion would be that the area which needs more attention and where generally little work is done [is] the use of medicine at community level and review the list of over the counter medicine. (Phy4)

Additionally, a pharmacist at the hospital pointed out the need to do research on pharmacists' education and counselling:

I like to assess the quality of pharmacist education and link to patient in terms of counselling, directions that they give them and reassess some standards; I think it could be quite variable right now. (P1)

A few participants showed interest in research on health outcomes and the use of medicines. A pharmacist working in the hospital emphasized the need for medicines outcome research in the following manner:

I think the outcome research will be nice to see about more research in terms of outcome. What outcomes are being achieved with certain use of medications? Whether there is positive outcomes or negative outcomes. I think that will be interesting to see, specifically, you know, specifically for the national population. (P5)

An academic pharmacist indicated the need to work on the "socio-behavioural aspect of health and the use of medicines":

There is more research that needs to be done related to the socio-behavioural aspect of health and medicine, the area of health economics, as well as outcome-based research, whereby...because at the end of the day, no matter how efficient your healthcare system is, no

matter how good you are in terms of accessibility and availability of medicine, it has to stem down to what are the outcomes. (AP2)

Our patients doing better, our quality of life of patients or individuals living in Qatar is better with this better healthcare system, so more research needs to be done even at that level in terms of health outcomes, health economics and outcome-based research. (AP2)

Drug development in Qatar was another topic which was raised. A drug supply manager stated this in the following manner:

...that is to see the research on the opportunity of national drug development, maybe not for the Qatar only but in the region. What is the future of the drug development in the region here, especially in the Gulf specifically, because the Ministry of Public Health can fund this and they have some fund for this. Like we can research that for future development of drugs from scratch, patent medication to be initiated for the whole world. (DSM1)

An academic pharmacist mentioned that more research is needed on healthcare and medicines policy overall:

Yes, one is focusing on medicines use, but to me, it's all about surrounding the same issue. I think there is more research needs to be done in terms of, in all areas, in terms of policy. Ok, there is need for more research in terms of policy, policy of medicine and policy of healthcare policy because there is limited literature in that aspect. (AP2)

The academic pharmacist also suggested the need to have a large database to conduct robust research:

We do not have large databases for doing research in the State of Qatar. So when you want to do research, you have to do research at micro level instead of doing research at macro level and national level because there are no existing databases, large databases, whereby the whole country is connected, where you can collect data and look at issues in a broad context for the country. So maybe that's an area also where government can look into establishing those kind of, I would say, infrastructure for doing research. (AP2)

In summary, these results show that there are issues in relation to non-availability of a comprehensive national medicines policy for Qatar, medicines registration, import and availability of medicines, high-cost medicines, extended community pharmacy services, antibiotic use, medicines compliance, patient counselling and centralized health data in Qatar. The results in this chapter have explored myriad and detailed policy issues in Qatar. It is hoped that the resolution of these issues could improve medicines use and access indicators in the country.

Themes	Subthemes	Details
Priority Medicines Policy Issues for Qatar	Understanding of Priority Medicines Policy Issues	Description of priority medicines policy
		Availability of a national medicines policy in Qatar
	Current Medicines Policy Issues	Issues in finding and following the medicines policy
		Medicines registration for Qatar
	Procurement of Medicines and Medicines Supply Chain	Import of medicines
		Manufacturing of medicines in Qatar
Access to Medicines in Qatar	Process of high-cost medicines for Qataris and expatriates	
	Current issues about access to medicines	
	Need for further research	
Use of Medicines for Qatar	Use of medicines	
	Present issues related to the use of medicines	
	Challenges and opportunities regarding the use of medicines	
	Future research on the use of medicines	
Future Overall Health and Use of Medicines for Qatar	Overall health issues in the next 3 to 5 years	
	Future access and use of medicines	
	Research ideas for the future	

Table 3. Themes and sub-themes

CHAPTER 5

5 Discussion

The objectives of the study were to identify priority medicines policy issues for Qatar. The specific objectives were to explore and identify key challenges affecting Qatar in terms of priority medicines policy issues, including medicines use and access, and to explore what the future approach should be in terms of overall health and medicines use in Qatar. In this section, the results outlined in Chapter 4 will be discussed in relation to the literature.

Literature review encompasses large portions of access and medicines use policy components. This includes imports and use of medicines, pharmaceutical system issues, and the broader medicines policy components. As there is no "definitive medicines policy in Qatar", these different components form into a "medicines policy framework". The issues identified in the literature review have informed the research aim "identifying priority medicines policy issues for Qatar". The literature review themes identified have also been the basis of key questions in the semi-structured interview guide.

The literature covered the various facets of national medicines policy globally. It includes examples from both public and private healthcare sectors and the use of medicines. The topics include medicine development, manufacturing, marketing, distribution, pricing and reimbursement, formulary management, patient eligibility, prescribing practices, and access and affordability of medicines. The literature on the use of medicines includes pharmaceutical services, pharmacovigilance, and patient counseling, and medicines adherence. There are also several articles on the development of national standard treatment guidelines, selection of essential medicines pricing policies, allowing price competition, supporting bulk procurement, implementing generic medicines policies, negotiating fair pricing, and promoting local production.

The literature also includes sustainable financing, out-of-pocket expenditures, increased public funding, expansion of health insurance schemes, and exploration of external funding and financing mechanisms.

Also, there is a growing number of articles on Qatar's healthcare system and various dimensions of pharmacy services and medicines policies. The literature reveals the community pharmacy services are more "traditional" in Qatar, most involved dispensing and pharmacists spend less time on counselling patients. It also explores vital issues related to medications nonadherence and its impact on health outcomes in Qatar. The literature also outlines challenges faced by pharmacists including access to medical records, and pharmacist's overall image in society. The literature highlighted the need to emphasize pharmacists growing role to reduce morbidity, mortality and to improve patients' safety in Qatar. Several articles also reported the need to have increased pharmacy staffing, and to promote education and training for pharmacists.

The participants in this study emphasized that the national medicines policy is instrumental to develop the health system. They described the various components of the policy and this is in line with the findings from the literature. These components include regulations, guidelines, governance, access, and rational use of medicines. As no comprehensive national medicines policy is available in Qatar, the work needs to be done in this direction. Some specific components with difficulties include medicines registration; however, there is fast track medicines registration process, and a special import process for some medicines in MoPH. There were also interesting results coming up with regards to the funding of medicines as in Qatar, health services are free for Qataris. For non-Qatari residents, the services are subsidized.

The participants identified issues with regards to the use of medicines and the challenges related to community pharmacists providing optimal patient counselling for medicines. These factors may contribute to nonadherence and misuse of medicines. There could be issues with regards to the rational use of medicines as patients have several prescribed medicines and have access to over counter medicines at home. There are also because some classes of therapeutic medicines are available without a physician's prescription. On the other hand, some participants also suggested that because there is no national computerized healthcare database, community

pharmacists and other healthcare providers do not have access to vital patients' health status and electronic health records. This could lead to prescribing errors and "medication management issues". From the literature, it was also noted that these medicines use issues are very similar in the countries with developing health systems.

5.1 What is Medicines Policy?

The study showed that the participants' understanding of medicine policy is dependent upon the area in which they practice. One participant believed that medicines policy is about procuring medicines, medicines prescribing and adverse events related to medicines. Though this may be correct, medicines policy covers more than medicines prescribing. Caijun et al. (2020) maintains that a medicines policy should work as a legislative framework to control medicine development, manufacture, pricing, medicine supply systems, medicine financing, quality assurance, use of medicines, research, human resources, monitoring and evaluation.[32, 50, 141] However, Morrow (2015) explains the utilization of a healthcare system simply as a means to achieve improved health outcomes.[79]

5.1.1 Access to Medicines Policy

The research also showed that most participants were not aware of Qatar's medicines policy and suggested that a medicines policy may be available from the Ministry of Public Health. However, the literature shows that Qatar's national medicines policy is neither available nor published. However, there is a National Health Strategy 2018.[6] It was observed that Qatar's national medicines policy is not available as one single document, but is an amalgamation of a set of regulations, procedures, rules, strategies, control processes and standard operating procedures (SOPs) regarding the use of and access to medicines.[23]

5.1.2 Issues Related to Finding a National Medicines Policy

Most participants pointed out the lack of a comprehensive national medicines policy in Qatar. There are rules and regulations, but they are not clear, do not provide details and are not updated. Some of the regulatory documents are not translated into English, which is challenging for non-Arabic participants. Other participants added that in Qatar, being a multicultural society, there are people from different backgrounds. Therefore, it is imperative to have a medicines

policy that includes rules and regulations so that healthcare professionals can understand and benefit from it. In Australia, McLachlan and Aslani (2020) also suggested that a national medicines policy should include issues related to biologicals and biosimilars, precision medicines, health services insurance and issues related to the pharmaceutical industry.[142]

5.1.3 Medicines Registration in Qatar

The findings showed that some participants could not find a written policy for the registration of medicines. Another issue is that due to the blockade, it took some pharmaceutical companies at least nine months to register a medicine. Moreover, even post-Qatar blockade, it may take four to six months, although there is fast-track registration for specialized medicines, including blood products and any medicines required urgently. The research also revealed that a pharmaceutical product must be registered in Qatar every time someone decides to bring the product into Qatar, and the detailed registration procedure and requirements are available on Qatar's MoPH website. All pharmaceutical product registration is under the Ministry of Public Health in Qatar. The registration process includes the registration of a company and the manufacture of pharmaceutical products.[35] Hamad Medical Corporation (HMC) also has a particular procedure to procure needed medicines. This is done by directly contacting the authorities in other countries, including embassies and manufacturers, to purchase these medicines.

5.1.4 Import of Medicines for Qatar

The import of medicines in Qatar depends upon product prices, market size and competition. All medicines registered by MoPH, and medicines pricing, are regulated by Ministry of Public Health (MoPH). The literature shows that Qatar's pharmaceuticals sector is very much reliant on imports of pharmaceutical products. The government is trying to eliminate price controls that have affected consumer affordability. [10] After the blockage in 2017, Qatar developed new alternative suppliers for medicines and successfully overcame the medicines supply challenge. [7] Overall, the import of medicines has challenges, including the fact that the registration process is time-consuming and complicated.

Manufacturing of Medicines in Qatar

Qatar Pharma was the first company to start local manufacturing. After Qatar's 2017 blockade, more local pharmaceutical companies began planning to start operations. Some companies are still in the planning stage, including Qatar Al-Hayat, Q-Med, Al-Mutamayyiz pharmaceuticals and Doha factory for pharmaceutical products. There was a need to reduce dependence on imported pharmaceuticals.[38] Qatar Life Pharma is another domestic pharmaceutical manufacturing company. It was started in 2014 and is working to get FDA USA approval.[32] Another company starting local manufacturing is the Qatar Pharmaceutical Industries Company.[39]

Understanding Access to Medicines

5.1.5 Process of High-Cost Medicines for Qataris and Expatriates

The research reveals that both Qataris and expatriates have access to the healthcare system and medicines. Qatari citizens do not pay for their medicines, while expatriates pay only 20% of the medicine's price in the public sector and Qatar's government pays 80% of it. For cancer medicines, expatriates pay only 10% of the price of medicine. The expatriates pay for medicines from their health insurance coverage or from their own pocket. There is a National Health Insurance Scheme for all Qataris, which pays for all their healthcare services and medicines in the public and private sector. The government of Qatar is planning to offer the National Health Insurance Scheme to expatriates too.

Additionally, there are support systems available for expatriates to pay for medicines, including expensive medicines; non-profit organizations, for example, the Multiple Sclerosis Society, Red Crescent and other charity organizations support expatriates. The medicines pricing method in the public sector is not publicly available, but medicine prices in the public sector are noted to be considerably lower than in the private sector.[23] The Ministry of Public Health (MoPH) controls medicine pricing. The Pharmacy and Drug Control Department (PDCD) negotiate with pharmaceutical companies and other stakeholders to propose prices for medicines, and the MoPH has the authority to fix the prices.[10] Overall, Qatari nationals and expatriates have access to high-cost medicines in Qatar. Challenges with high-cost medicines are a global phenomenon,

and they present health and economic challenges for healthcare organizations. These include affordability, decision-making, reimbursement and coverage of these medicines.[92]

5.1.6 Issues with Access to Medicines in Qatar

The participants have the opinion that overall, consumers and patients have access to a large number of medicines in Qatar, though there are issues with a few medicines. Specifically, the public sector in Qatar has a satisfactory level of availability of medicines,[143] but the issues mentioned included inconsistency of the medicines supply, limited range of some classes of medicines, and the fact that not all registered medicines are available. The research revealed that many companies are not registering their medicines due to the small market size. However, the Ministry of Public Health (MoPH) is working to formalize the National Formulary. Additionally, the participants revealed during interviews that labourers have a different level of access to medicines in the private sector because of the different co-payment method for health insurance plans.

The majority of medicines are available over the counter at pharmacies in Qatar for the public. This increases the pharmacist's role in improving the optimal use of medicines.[9] However, the research shows that there are misconceptions about the use of generic medicines, both among clinicians and among the public.[31] Therefore, the clinicians are reluctant to prescribe, and patients do not trust, generic medicines and prefer the branded products which are more expensive options.

The findings revealed that patients must return to the pharmacy quite often to pick up narcotic and psychotropic medicines due to stringent regulations which result in dispensing of smaller quantities medicines. Due to the absence of a standard national medicine policy, there are discrepancies and inconsistencies in how different organizations work to provide access to medicines.

The results also revealed that there are medicine affordability issues, especially in Qatar's private sector. This is specifically the case in the area of high-cost medicines for expatriate patients. Furthermore, in the context where some of them have employer's health insurance, patients may not be able to pay the co-payment for medicines. [143, 144]

5.1.7 Need for Further Research

The participants stated that they would like to see more research on medicines that are frequently being sold without guidance from physicians and pharmacists. Patients may have adverse effects from medicines and compare them with other countries. Other participants would like to see research on the outcome of guidelines, policy and use of medicines issues.

The participants would like there to be more research into antibiotic resistance because in Qatar, people come from different parts of the world where they have more access, or more controlled access, to antibiotics and they have different resistance status.

During the interviews, the participants identified a need for research on barriers to access, availability, affordability and cost of medicines from all perspectives, such as from policymakers, clinicians, consumers and others. They also said there were issues around the cost of generics and branded medicines, what happened to patients' unused medicines, and why most patients expect to receive a medicine prescription at every physician's appointment.

5.2 Use of Medicines

The participants revealed how they would describe the use of medicines, whether looked at from the perspective of medicines utilization in healthcare institutions, regulatory authority or the consumer perspective. "Use of medicines" includes selection and approval of the prescribing, dispensing, monitoring and storage of medicines. [97] The participants also discussed medicines from the patient's perspective, in terms of whether patients are using medicines as prescribed or directed with the right dose. [107]

Present Issues Related to the Use of Medicines

This study states that a national medicines policy should cover all aspects of policies and procedures for medicines. This includes all phases of medication management, including antibiotics policy, medication prescribing, adverse drug monitoring, use of medicines, drug supply chain, and policy governance in the public and private sectors.

The participants in the study opined that for most patients receiving medicines, there were patient compliance issues such as misuse of medicines or expired medicines at home. Literature

from Qatar also confirmed these findings, one study indicating that about 82% of patients were using antibiotics without prescription, in 45% of cases the antibiotic course was not completed and 23% had purchased antibiotics from the community pharmacy without a prescription.[41] Another study concluded that medicine use is impacted by factors involving adherence to drug therapy, the duration of chronic disease, diagnosis and control of the disease, as well as patients being employed or receiving support from family.[145] Hence it is recommended that a standardised national medicines use policy should be formed to improve patient health outcomes.

5.2.1 Challenges and Opportunities for the Use of Medicines

The results suggest that there are policies and guidance with regards to the use of medicines in Qatar public sector institutions, including Hammad Medical Corporation (HMC), Sidra Medicine, and others; however, not all private institutions have clinical guidelines. Also, there is no national health record database for all patients' health information which can be accessed by healthcare providers, public and private institutions, hospitals, clinics and pharmacies. A national medical database would help to improve the use of medicines. It would also help to improve and build prescribing policies for medicines. Awaisu et al. (2014) concluded that a nationally organised project should be started to develop a generic medicines policy, guidelines, and a comprehensive national medicines policy in Qatar.[31] Regarding generic medicines use and prescribing, a study by Awaisu et al. (2014) found that 89% of Qatar's pharmacists agreed that bioequivalence data should be available before marketing a generic medicine. Most also agreed that community pharmacists should be authorised to dispense generic substitution of medicines in Qatar.[31]

This study's findings show that multidisciplinary team collaboration is another challenge that needs resolution. There are also challenges with regard to other issues, including prescribing of antibiotics, pharmacovigilance system implementation, and generic medicine availability and prescribing. This is supported by a study in Qatar which revealed that 75% of pharmacists and 50% of physicians do not provide sufficient patient education on antibiotics use in the country.[41] Aljayyousi et al. (2019) concluded that there is a need to increase public education about appropriate antibiotic use and to emphasize behavioural interventions.[41] The study

further concluded that health institutions should educate healthcare practitioners about antibiotic prescribing, guidelines and better communication methods.[41]

5.2.2 Pharmacoeconomics Research

The results of this study showed that there is a need for pharmacoeconomic research to evaluate the cost-effectiveness of use of medicines. More research is also needed on procurement and availability of medicines. Furthermore, the participants suggested that studies are also needed on wastage of medicines.

Overall Health in Next Few Years

The participants believed that health indicators will improve in Qatar in the next few years. This is because the State of Qatar has implemented emergency preparedness strategies, including strengthening of regulatory agencies, as well as the strengthening of ministries including the Ministry of Commerce and Ministry of Public Health, and the focus is now on the medicines sector. In addition, the study's results revealed that Qatar is starting national pharmaceutical manufacturing; hence there is a chance that the country is on the road to self-sufficiency in medicines supply in the next few years. Qatar's primary care services model is effective. It appears that in the next few years, the Qatar healthcare system will continue to improve because of the National Health Strategy 2018-2022 and Qatar National Vision 2030.[6]

However, Qatar still needs improvement in antibiotics prescribing, access, patient education and public awareness. Aldeyab's (2020) research shows that antibiotic resistance could be controlled by understanding the thresholds for all antibiotics used in a country and forming an antibiotic policy.[98] A study conducted in Qatar also showed that the public believes antibiotics can be used for viral infections. This could lead to inappropriate use of antibiotics and increased cost; therefore, community pharmacists should play an active role in improving knowledge and public views about antibiotics.[117]

5.2.3 Community Pharmacy in Qatar

The community pharmacy services provided are mostly "traditional" with no extended pharmacist roles or cognitive services in Qatar. Community pharmacy has not developed the essential steps to be recognized as an essential source for public health and primary health

care.[9] Babiker et al. (2014) also concluded that pharmacists need more education and training for medicine use reviews in Qatar.[101] Babar (2021) explains that to improve community pharmacy, training in clinical skills and patient-oriented pharmacy services is needed.[146] Private community pharmacies in Qatar also need to be involved in the government health coverage system to improve the affordability and access of medicines.[146] In developed countries, most pharmacists are remunerated for pharmacy services they provide; however, this is not the case in many countries including Qatar.[109] More research is needed in Qatar to identify challenges in developing community pharmacy and how to overcome those difficulties, as well as how to improve communication with patients.

5.2.4 Future Use of Medicines and Community Pharmacy

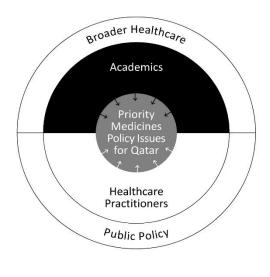
This study indicates that community pharmacy has the potential for improvement and practice change, and more research is needed in this context. The Qatar National Vision 2030 and National Health Strategy 2018-2022 both include the community pharmacy's importance; hence community pharmacy services could be improved in the coming years.[6] The participants in this study suggested that there is a need to have modern policies, procedures and regulations related to community pharmacy in the next few years.[21] The cost of medicines is increasing, putting pressure on the healthcare budget. This needs more scrutiny of medicines to use, as the use of generic medicines would reduce the total cost of medicines in Qatar. The literature illustrates that there is inconsistency in executing generic medicines policies between developed and developing countries, and where generic medicines are used there are considerable savings on medicines.[121].

5.2.5 Future Research Ideas

The suggested future research areas include the quality of clinical consultations, pharmacists providing counselling and advice to patients, and reassessing clinical guidelines. Other research areas could be outcome research, use of medicines among nationals and expatriates, and the availability of over-the-counter medicines at community pharmacies in Qatar. One of the participants also suggested creating large medicines databases for research. This could help in

looking at critical areas including population demographics, medicines utilisation, disease burden and consumer use with regards to medicines [52]

A conceptual model has been built to identify and synthesise priority medicines issues arising from this work (Diagram 1). "Healthcare practitioners" and "academics" are feeding into this model and their thoughts, ideas and knowledge are shaping the model. As shown below, the outer circle of the model represent "broader healthcare" and "public policy". The main issues arising from this model include (a) extended community pharmacy services; (b) antibiotics use, medicines compliance and counselling; (c) access to high-cost medicines for Qataris and expatriates; (d) issues related to medicines registration, import and availability of medicines; (e) forming a comprehensive national medicines policy for Qatar; and (f) centralised health data for patients, pharmacists and healthcare professionals.





Issues:

- i- Extended community pharmacy services
- ii- Antibiotic use, medicines compliance and counselling
- iii- Access to High-Cost Medicines for Qataris and Expatriates
- iv- Medicines registration, import and availability of medicines
- v- Forming a comprehensive national medicines policy for Qatar
- vi- Centralized health data for patients, pharmacists and healthcare professionals

Diagram 1. A conceptual model deriving priority medicines issues for Qatar.

CHAPTER 6

6 Conclusion

The research concludes that though there is no comprehensive national medicines policy in Qatar, there are a number of rules, regulations, policies and procedures in place. There are challenges in following and understanding these policies, as they are not available as a single document. The access issues identified include availability of medicines, inconsistency of medicines supply, limited range of some classes of medicines, and the fact that not all registered medicines are available. There are misconceptions about the use of generic medicines among clinicians and the public. There are instances when clinicians are reluctant to prescribe and patients do not trust generic medicines, resulting in increased cost for patients. The challenges with regard to medicines use include prescribing of antibiotics, pharmacovigilance system implementation, and generic medicines availability and prescribing. The community pharmacy services provided are mostly "traditional", with no extended pharmacist roles or cognitive services. There is a need to extend the role of the pharmacist and this can be done by providing financial incentives, education and training for pharmacists, as well as improvement in policies, procedures and regulations. This also includes authorisation to dispense generic substitution of medicines. There is also a need to have a national health record database for all patients' health information, which can be linked to healthcare providers, public and private institutions, hospitals, clinics and pharmacies.

Future research areas to focus on include quality of clinical consultations, pharmacists providing counselling and advice to patients, and reassessing clinical and therapeutic guidelines. Other research areas could be outcome research, use of medicines among nationals and expatriates, and availability of over-the-counter medicines at community pharmacies in Qatar.

The main aim of this research was to identify and explore priority medicines policy issues impacting Qatar. These objectives were explored and achieved through a series of semi-structured qualitative interviews. A thematic analysis was performed and main themes were identified. An overarching theme was also identified that though respondents know components of national medicines policy, however, they were not aware of an existing medicines policy

document. From literature, it is observed that over 100 countries in the world have developed a national medicines policy which has led to improve medicine use in respective countries.

Medicines are an essential component of a health system and from the findings of this thesis, it is believed that the formation of such a policy would also benefit Qatar and would improve healthcare in the country.

Implications for policy and practice

This study has achieved its objective by identifying vital issues related to medicines policy, access and use of medicines, future overall health and use of medicines. The study has identified empirical data points, which have formed and fed into a conceptual model. Vital research points are coming from medicines use and access, if implemented these can improve patient health outcomes and can improve the use of medicines in the country.

6.1 Limitations and Strengths of the Study

For many of the participants, English was not their first language. In addition, of the 55 stakeholders who were contacted and invited, only 21 participated in the interviews. This may have limited the range of stakeholders by not including patient support groups or the pharmaceutical manufacturing sector, who did not participate in this study. However, despite these limitations, the study provides enough data to portray an overall picture in terms of medicines use and access. These data add to our understanding of the medicines policy issues, and future health challenges and opportunities for Qatar.

The strength of the study is that it is the first such study on the topic. It emphasizes the various facets of medicines policy and provides a comprehensive analysis of policy issues in detail. The major themes are covered on medicines use and access situation in Qatar, including community pharmacy practice, medicine registration, patients counselling, medicines access, and medicines adherence issues.

6.2 Recommendations

The findings suggest that in the last 20 years Qatar has moved towards advancing healthcare, however, there are gaps and opportunities. These are quite pertinent with regards to improving medicine use, access, and developing a medicines policy in Qatar.

A national medicines policy should be developed through a consultative broad-based process in which prescribers, physicians, pharmacists, and healthcare professionals be given a chance to contribute. A framework should also be developed regarding the implementation, monitoring, and evaluation of this medicines policy.

Based on these study findings strategies need to be developed to resolved access to medicines issues, the priority being medicines registration, import etc

With the rise of chronic diseases and a growing population, there is also a need to work to improve medicines adherence among patients. The strategies need to be developed on patient counseling. There is also a need to improve professional training and continuing education for pharmacists to advance pharmacy practice. This would help to improve medicine use among patients and consumers.

CHAPTER 7

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7 Appendices

7.1 Appendix 1

Invitation Letter: MSc Research - Priority Medicines Policy Issues for Qatar: Challenges and

Opportunities

Dear Respected,

Invitation Letter: MSc Research - Priority Medicines Policy Issues for Qatar: Challenges and

Opportunities.

My name is Nadeem Zia, and I am serving as a Clinical Pharmacist, Pharmacy Department

Educator, Department of Pharmacy, Sidra Medicine, Doha, Qatar. As a health care professional,

my research team and I am very much interested in the priority medicines policy issues for Qatar:

challenges and opportunities.

Therefore, in collaboration with the Centre of Pharmaceutical Policy and Practice Research,

University of Huddersfield, UK, and Qatar University College of Pharmacy, a qualitative study is

planned to explore the priority medicines policy issues for Qatar: challenges and opportunities.

For that purpose, our team identified you as an important and influential stakeholder with

interests and experienced relevant to the aim of this study and would like to humbly request you

for a 60-minute interview session personally. The benefit of participating in the study is that we

will have documented the opinions and views of influential stakeholders about the priority

medicines policy issues for Qatar.

Please let us know by replying to this email as soon as possible if you agree to participate. The

interview will be in English. An interview guide will be sent to you by email prior to the mutually

agreed date and time of the interview session.

Confidentiality: All the information we receive from you, including your name and any other identifying information (if applicable), will be strictly confidential and will be on a password-protected server. We will not use any information that would make it possible for anyone to identify the opinions you contributed to the interview session. The interview will be recorded so that a comprehensive transcript can be produced. Digital files of the recordings will be destroyed upon completion of the transcript approximately 7-10 days after the call, and names and other identifying information will be deleted from all electronic and paper copies of transcripts.

If you have questions about this project, you may "reply" to this email, and we will respond to your questions as soon as possible. You may also call us at +974-7479-8399.

Thanks

Madeem The

Nadeem Zia, B Pharm, PEBC, RPh,

Pharmaceutical Sciences MSc (Research) Candidate,

University of Huddersfield, UK

Clinical Pharmacist - Pharmacy Department Educator, Sidra Medicine, Qatar

Supervisors:

Professor. Mohamed Izham Mohamed Ibrahim, Head of Research and Graduate Studies - Pharmacy, Medical & Health Sciences Office Professor of Social & Administrative Pharmacy College of Pharmacy, Qatar University, PO Box 2713, Doha, Qatar.

Professor. Zaheer-Ud-Din Babar, Professor in Medicines and Healthcare

Department of Pharmacy, University of Huddersfield, Queens Gate, HD1 3DH, Huddersfield, United Kingdom

7.2 Appendix 2

Interview Guide – Semi-Structured Interview Guide

Research Title: Priority medicines policy issues for Qatar: Challenges and opportunities

1. Priority medicines policy issues

- 1.1 Can you please describe the "medicine policy"?
- 1.2 Where can someone refer to the medicine policy in Qatar?
- 1.3 What are your views about the priority of medicines policy issues in Qatar?
- 1.4 Are you aware of any scheme or procedure to enhance support for the development or import of medicines that target an unmet medical need?
- 1.5 Is there any support available to medicine developers or importers in Qatar?
 - 1.5.1 To optimize the generation of robust data on medicine's benefits and risks.
 - 1.5.2 To enable accelerated assessment of medicine applications.
- 1.6 What kind of assessment does a newly developed or imported medicine (on the priority list) go through before, or at the time of, application for marketing authorization (registration)?
- 1.7 Are there any regulatory frameworks or tools already available for accelerated assessment (for medicines on the priority list)?
- 1.8 Is there any national policy on the use of medicines and access to medicines in Qatar?
- 1.9 How does the Qatari government or health authority deal with priority medicines policy issues?

2. Access to medicines in Qatar

- 2.1. What is your general perception of access to medicines in Qatar?
- 2.2. How do Qatari nationals and expatriates get access to (high cost) medicines?
- 2.3. What are the issues surrounding access to medicines in Qatar?
- 2.4. Is there enough evidence (literature or data) on these issues to make decisions in Qatar?
- 2.5. Is there any other issue or question which you think should be researched?

3. Use of medicines in Qatar

- 3.1 Can you please describe the use of medicines?
- 3.2 What are some issues related to the use of medicines in Qatar?
- 3.3 What are the challenges and opportunities in the use of medicines in Qatar?
- 3.4 What are the medicine policy issues on the use of medicines in Qatar?
- 3.5 What type of research would you like to see on issues related to the use of medicines in Qatar?

4. Future of overall health and medicines use in Qatar

- 4.1 How do you see the future in terms of overall health in Qatar in the next 3 to 5 years?
- 4.2 How do you see the future in terms of medicines use in Qatar in the next 3 to 5 years?
- 4.3 What are the issues related to access to medicines in the next 3 to 5 years?
- 4.4 What type of research would you like to see on issues related to future overall health and medicine use in Qatar?

Nadeem Zia, B Pharm, PEBC, RPh

Pharmaceutical Sciences MSc (Research) Candidate

University of Huddersfield, UK

Clinical Pharmacist - Pharmacy Department Educator, Sidra Medicine, Qatar

7.3 Appendix 3

Ethics approval letter form, University of Huddersfield, UK.



School of Applied
Sciences University of
Huddersfield
Queensgate
Huddersfield

14th May 2019

HD13DH

Dr Syed Shahzad Hasan School of Applied Sciences University of Huddersfield

Dear Syed,

Re: Priority medicines policy issues for Qatar: challenges and opportunities (Nadeem Zia)

Thank you for submitting your proposals to the School Research Integrity and Ethics Committee (SRIEC). I am happy to confirm that the project has been approved from the date of this letter up to and including the 7th January 2021 as indicated on the documents submitted.

We note that the study will be conducted in Qatar and whilst we have given approval for the project based on the project specific details as presented here, there maybe specific

requirements that need to be met by your partners in Qatar. It is therefore incumbent upon you to ensure that appropriate permissions are obtained prior to the start of the project in Qatar. Based on the study design however, we are happy that this does not raise any significant ethical concerns regarding the questions being asked or the handling of any data.

Please quote this reference number in any future correspondence: SAS-SREIC 14.5.19-2

Yours sincerely

R.m. Phinips.



Chair – School of Applied Sciences Research Integrity and Ethics Committee



Queensgate Huddersfield HD1 3DH UK Telephone +44 (0) 1484 422288 Fax +44 (0) 1484 516151

Vice-Chancellor: Professor Bob Cryan BSc MBA PhD DSc

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7.4 Appendix 4

Ethics approval letter form Sidra Medicine, Doha Qatar.



Tel: +974-4003-7747 Email: <u>irb@sidra.org</u> Sidra IRB MOPH Assurance: IRB-A-SIDR-2019-0020 Sidra IRB MOPH Registration: MOPH -Sidra-IRB-099

Sidra IRB DHHS Assurance: FWA00022378 Sidra IRB DHHS Registration: IRB00009930

EXEMPT DETERMINATION

Dear Dr. Masud,

On 20 November 2019 the IRB reviewed the following and determined that it fits the exempt criteria.

Type of review:	Initial Review
Protocol Title:	Priority medicines policy issues for Qatar: challenges and
	opportunities
Principal investigator:	Faraz Masud
IRB number:	2019-0029
Sponsor/ Funding Agency:	None
Grant title and ID, if any:	N/A
Documents reviewed:	IRB-406 Initial Review Form (version 1.1, December 2018) IRB-400 Informed Consent Form (version 1.1 October 2018) Sidra Research Protocol (received 19 November 2019) Information Sheet (dated 01 May 2019) Interview Guide (received 26 May 2019) IRB-409 Research Personnel Form (version 1.1, December 2018) Training and Credential
Exempt categories:	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, unless the information is obtained and recorded in such a manner that human subjects can be identified, directly or through identifiers linked to subjects; and any disclosure of the human subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

PO Box 26999 Doha - Qatar Sidra.org



Tel: +974-4003-7747 Sidra IRB MOPH Assurance: IRB-A-SIDR-2019-0020 Email: <u>irb@sidra.org</u> Sidra IRB MOPH Registration: MOPH -Sidra-IRB-099

Sidra IRB DHHS Assurance: FWA00022378 Sidra IRB DHHS Registration: IRB00009930

Continuing review by Sidra Medicine IRB is not required.

COMO)

This determination applies only to the activities described in your submission and does not apply should any changes be made. If changes are made please be aware that the research may not qualify for IRB exemption anymore. Please submit a new request to the IRB for a determination prior to implementing the changes.

If you have questions or concerns, please call the IRB office at 4003-7747 or send an email to irb@sidra.org.

Sincerely yours,

Catherine Cole, MD

Chair Institutional review Board Sidra Medicine +97440036567

7.5 Appendix 5

Ethics approval email from Saad Abdullah, Abhath IRB, Hamad Medical Corporation (HMC), Doha Qatar.

